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

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

DATE: July 15 and 16, 2009

LOCATION: Radisson Hotel at Los Angeles Airport
6225 West Century Boulevard
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
Stanley C. Weisser, RPh, Treasurer
Ramón Castellblanch, PhD, Public Member
Randy Kajioka, PharmD
Greg Lippe, Public Member
Robert Swart, PharmD
Shirley Wheat, Public Member

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Susan L. Ravnan, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joan Coyne, Supervising Inspector (7/16)
Judi Nurse, Supervising Inspector (7/15)
Joshua Room, Deputy Attorney General (7/15)
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager

Call to Order

President Schell called the meeting to order at 9:10 a.m.

General Announcements

President Schell recognized former board president, Stanley Goldenberg, and chairperson of the National Association of the Boards of Pharmacy (NABP), Rich Palombo. He also recognized Merv Culman representing the California Department of Public Health, and Lorie Rice representing the University of California, San Francisco School of Pharmacy.

I. Approval of the Full Board Meeting Minutes of April 30, 2009 and May 1, 2009:

Board Discussion

Kristy Schieldge, DCA Staff Counsel, requested a correction on page 15 to change the word “baring” to “barring.”

There was no additional board or public comment.

MOTION: To approve the minutes of the April 30, 2009 and May 1, 2009 Board Meeting with the requested change.

M/S: Weisser/Swart

Approve: 6 Oppose: 0 Abstain: 1

II. Enforcement Committee Report and Action

A. Mail Back Program for Unwanted Prescription Drugs

Robert Swart provided that over the past year, the board has been working with other state and local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. He stated that in February, the California Integrated Waste Management Board finalized these guidelines. Dr. Swart indicated that the guidelines were developed pursuant to SB 966 (Simitian, Statutes of 2007), and provide components for three primary types of take back programs: 1. in pharmacies or sometimes other locations, 2. at one-time or ongoing community events, and 3. return via mail back.

Dr. Swart provided that according to data collected late in 2008 by the California Integrated Waste Management Board, fewer than 100 California pharmacies report they are participating in take back programs. He stated that this is probably lower than the actual number of pharmacies in California operating such programs; however, staff is aware that many pharmacies will not participate in any take back program until the board supports the programs. (There are over 6,100 community pharmacies and over 500 hospital pharmacies in California.)

Dr. Swart provided that staff from the Integrated Waste Management Board has been invited to provide a presentation to the board on the baseline survey of pharmaceutical waste returned in 2008 in California but were unable to attend due to state budget restrictions.

Presentation by Sharps Compliance, Inc.

Claude Dance and Mark Stechschulte, representing Sharps Compliance, Inc., provided an overview of the mail back program for prescription drugs and sharps.

Mr. Dance provided that, on an annual basis, over 200 million pounds of patient medication in the U.S. are unused and can adversely affect the environment if disposed of improperly. He reviewed relevant regulations, pending legislation, and pharmaceutical disposal legislation being introduced nationwide.

Mr. Dance provided an overview of Sharps Compliance, Inc. including that they are fully compliant with Occupational Safety and Health Administration (OSHA), Department of Transportation (DOT), and United States Postal Service (USPS) Federal Regulations. He discussed two products, the "TakeAway Envelope" and the 10 Gallon "TakeAway Community Environmental Return System", that have been developed for improving safety and patient solutions for the disposal of unwanted prescription drugs and sharps. Mr. Dance reviewed and demonstrated the capabilities of both products. He also discussed the "Sharps Drug Tracer," a secure, proprietary online data warehouse that provides unique information for each client. Mr. Dance reviewed the advantages to this program including the environmental benefits and security and risk reductions, the benefits to pharmacy personnel, and indicated that the program is HIPPA compliant.

Board Discussion

Stan Weisser sought clarification regarding what solution is inside of the box and the cost of each box.

Mr. Dance responded that an absorbent is provided in the box in the event that there is any liquid leakage and advised that to date, there has not been any package failure with the system. He indicated that the 10 gallon box costs $69 and the 20 gallon box costs $99. Mr. Dance provided that the cost for each box includes the packaging and the data regarding the return freight, the receipt by law enforcement, and the destruction of the inventory.

Greg Lippe asked where the incinerator is located and whether there was any potential for radioactivity in that area.

Mr. Dance responded that the incinerator is located in Carthage, Texas. He explained that the product is not put into a commercial setting and is only used for patient use.

Ramón Castellblanch asked where the waste goes after it has been incinerated.

Mr. Dance responded that the ash is sent to an approved landfill.

Dr. Castellblanch sought clarification regarding whether any medication is recycled.

Mr. Dance reviewed the security controls in place and provided that inventory is not opened and the facility is constantly monitored.

Dr. Swart asked if an “honor system” is used to assume that control drugs are not in the packages.

Mr. Dance provided that the mail back system will be a key solution and added that it is strongly publicized that control substances should not be returned. He indicated that an infrastructure is in place in the event that a controlled substance is included.

Executive Officer Virginia Herold referred to the five components of a mail back program that are provided in the current model guidelines. She reviewed each of these five components and whether Sharps Compliance Inc. is in compliance with these guidelines.

Mr. Dance provided an overview of their compliance with the five components.

Randy Kajioka sought clarification regarding the serialization of the mail backs and asked if pharmacies should be tracking the distribution of these mail backs.

Mr. Dance provided that this is an option and that pharmacies have this capability with the serialization information provided. He added that an online tracking system could be created.

Dr. Castellblanch sought clarification on the funding of Sharps Compliance Inc.

Mr. Dance responded that funding is currently coming from private sources. He added that various California cities have received grant money to purchase the supplies.

President Schell asked where the packaging is manufactured. He also sought clarification regarding serialization and the potential for counterfeit products.

Mr. Dance responded that a contractor in Texas manufactures and fully assembles the packaging. He provided that each package has a unique serialization. Mr. Dance discussed that, although there is the potential for counterfeit boxes, these products would not have the unique serialization. He

also highlighted the internal controls to secure the boxes before they are provided to the pharmacies, etc.

Public Comment

Lorie Rice, representing the UCSF School of Pharmacy, asked for clarification on the activity of the consumer who would be utilizing the 10 gallon box and the inventory control and the security of the box.

Mr. Dance provided that the consumer places the unused drugs in the box under the supervision of the pharmacist.

Mr. Stechschulte clarified that the inventory control is on the box, not on the items within the box.

Discussion continued regarding inventory control and security measures.

Ms. Herold provided that the box does not meet the board's guidelines or the guidelines established by the Integrated Waste Management Board for a collection device in a pharmacy and highlighted the parameters of an acceptable collection device.

Mr. Dance provided that the box is a significant advancement over the "fishbowl" option that some are currently employing.

Dr. Swart highlighted some of the board's efforts to secure the pharmacy supply and expressed some of his concerns regarding the box.

John Cronin, representing the California Pharmacists Association (CPhA), expressed concern regarding the security of the packages in transit and avoiding any indicators of the contents in the box. He highlighted the competing interests with this issue. Dr. Cronin encouraged the board to balance the issues so that a solution can be implemented.

Mr. Dance provided that the packaging was designed to be nondescript. He added that changes can be made if needed.

Dr. Castellblanch expressed concern regarding functionality and the security of the sample envelope.

Mr. Dance provided that the samples have been improved and offered to provide new samples to the board.
Mr. Lippe asked why the box needs to open.

Mr. Dance explained that the box was designed to lock and seal for shipment.

There was no additional board or public comment.

B. Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies

Dr. Swart provided that SB 26 (Simitian) would have required this board to develop policies and programs for pharmaceutical waste. He stated that the board would have been required to develop regulations for such programs. Dr. Swart advised that SB 26 has been stalled in the Senate Appropriations Committee due to fiscal issues and is now a two-year bill.

Dr. Swart provided that the board needs to discuss how it will proceed in the future with respect to take-back programs for pharmaceutical waste and sharps.

Dr. Swart provided that the public is demanding the creation and widespread availability of such programs, and pharmacies are one of the primary locations favored for such returns. He advised that safeguards are needed to protect the drug supply so that drugs are not diverted from take back channels into the primary pharmaceutical supply chain to patients.

Dr. Swart provided that there are also proposed amendments that were never incorporated into SB 26 regarding regulation of reverse distributors. He stated that reverse distributors are board-licensed wholesalers who return drugs from pharmacies to manufacturers. Dr. Swart advised that they are not authorized to handle pharmaceutical waste, which is the purview of integrated waste haulers, who are licensed by the California Department of Public Health.

Dr. Swart provided that the Department of Consumer Affairs recommends that the board develop regulations in this area, either duplicating or strengthening the regulatory parameters for drug take back programs.

Dr. Swart highlighted some of the concerns of take back programs and spoke in support of safeguards in current guidelines.

Board Discussion

Ms. Herold provided that the public wants to take back drugs to pharmacies. She highlighted some of the problems with the current programs. She requested that the board consider several issues including whether the current model guidelines should be published in *The Script*, whether the board should educate around the guidelines, and whether the board should enforce against the guidelines. Ms. Herold clarified that the return of sharps is a separate issue but is considered in the more global “take back” program.

Joshua Room, Deputy Attorney General, suggested that the board initiate the mail back program as a “threshold” to start with. He provided that the collection bin issue can be addressed separately.

Dr. Swart expressed concern regarding the cost. He provided that the board has consistently expressed support for mail back programs.

Shirley Wheat asked whether the board has provided a statement regarding the sharps mail back program.

Ms. Herold responded that the board has released a statement. She advised that the board does not endorse any particular product and explained that the purpose of the presentation was to demonstrate how a mail back program might work.

Mr. Lippe sought clarification regarding whether there is any significant diversion that takes place with non controlled substances.

Dr. Swart provided that this tends to occur with more expensive drugs and referred to a relevant case in Washington.

President Schell expressed concern about being too restrictive and cautioned against precluding against the aggregate if a safe and secure option is developed.

Discussion continued regarding take back receptacles and the appropriate course of action for this issue. Concern was expressed regarding the security of take back receptacles.

Public Comment

It was clarified that action taken regarding this issue would impact the envelope mailers, and not the boxes or other receptacles that were discussed.

Mel Snedman sought clarification on whether a consumer could purchase the mail back directly from the vendor.

Mr. Dance responded that consumers can purchase a single envelope on the Sharps Compliance Inc. web site.

Discussion continued regarding the tracking of an envelope that has been purchased and utilized by a consumer.

Stan Goldenberg recommended that the board inform pharmacies about proper disposal as some may be following outdated information.

Dr. Castellblanch expressed concern regarding consumers being able to purchase the mail back receptacles on a web site.

There was no additional board or public comment.

MOTION: Without prejudice to subsequent consideration of other forms of take backs including collection bins programs that will be subsequently considered by the board, the board will allow pharmacies to participate in drug individual patient specific mailer programs as long as such programs have adequate levels of security from tampering and diverting.

M/S: Weisser/Wheat

Approve: 6 Oppose: 0 Abstain: 1

Ms. Herold provided that the board is emphasizing the utilization of public mail backs. She stressed that the board needs to determine how it would like to advertise or inform the public about other options if available. Ms. Herold advised that CIWMB guidelines have established a bin that can be located near the licensed area, but not within the licensed area.

Discussion continued regarding take-back alternatives. It was determined that the board will endorse the mail back program and refer those who choose to use alternative programs to the CIWMB guidelines for take-back requirements.

Public Comment

Lorie Rice, representing the UCSF School of Pharmacy, sought clarification regarding whether a medication needs to be emptied from its bottle before it is deposited into the receptacle and if the medication would immediately be pulverized.

Ms. Herold confirmed that the medication would be emptied from the bottle and that it is preferred that the medication is immediately pulverized.

John Cronin, representing the California Pharmacists Association (CPhA), discussed need for the board's enforcement policy on this issue. He sought clarification regarding whether a pharmacy would be disciplined for using a program that is not compliant with the CIWMB guidelines.
Dr. Swart provided that the board will focus on educating pharmacies about the guidelines in order to promote compliance.

Ms. Herold confirmed that it is the preference of the board to educate. She provided that severe violations will be fined.

Dr. Cronin asked if discipline would apply to county-approved programs. He expressed concern regarding the impact this would have for pharmacies and pharmacists.

Ms. Herold confirmed that the guidelines would apply to county-approved programs.

Mr. Room provided that the board is seeking good-faith compliance.

Dr. Cronin encouraged the board to discuss this policy in *The Script.*

Ms. Schieldge emphasized that current pharmacy law includes a paramount requirement for the safety and integrity of the drugs and ensuring that members of the public do not have unlawful access to controlled substances or dangerous drugs. She provided that these enforcement “benchmarks“ should be used as the governing standard.

Dr. Cronin discussed that the take-back boxes and containers are not located in the pharmacy and consequently, are not under the board’s jurisdiction.

The board discussed the scope and applicability of possible action for this issue.

There was no additional board or public comment.

MOTION: To direct board staff to educate and encourage compliance with existing guidelines established by the California Integrated Waste Management Board to support consistent standards for take back programs.

M/S: Schell/Weisser

Approve: 6 Oppose: 0 Abstain: 1

C. Summary and Discussion of June 9, 2009 Meeting of the Enforcement Committee

1. Overview of the Board of Pharmacy’s Complaint Investigation Processes

Dr. Swart stated that Executive Officer Herold provided an overview of the board’s investigation program.

No board or public comment was provided.

2. Discussion of the Board of Pharmacy's Citation and Fine Program Involving Medication Errors

Dr. Swart stated that Executive Officer Herold provided an overview of the citations and fines issued for medication errors in 2008 through May 2009.

No board or public comment was provided.

3. Discussion of the Board of Pharmacy's Pharmacists Recovery Program

Dr. Swart provided that the committee heard a presentation on the Pharmacists Recovery Program by Anne Mierles of Maximus, the program's contracted provider. He suggested that the presentation be given to the full board at a future board meeting.

No board or public comment was provided.

4. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Dr. Swart provided that the committee heard a presentation on SB 1441. He stated that Senate Bill1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. He advised that this committee is subject to Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus. Dr. Swart indicated that the Board of Pharmacy is one of these participating boards.

Dr. Swart provided that a Uniform Standards Meeting was held on May 5, 2009 to discuss standards 1 - 6. Future meetings are scheduled for:

- July 15, 2009
- September 22, 2009
- November 10, 2009

Dr. Swart provided that an SACC meeting was held on May 18, 2009 to consider uniform standards 1 – 6. Additional SACC meetings to continue evaluation of all standards are scheduled for:

- July 27, 2009
- September 30, 2009
- November 16, 2009
- December 15, 2009

No board or public comment was provided.

5. Presentations and Discussion on E-Prescribing Pilot Programs Underway in California by the California HealthCare Foundation and CalPERS

Dr. Swart provided that the committee heard presentations about various e-prescribing efforts underway in California. He discussed some of the information provided in the presentations including that California is not one of the highest users/adopters of e-prescribing at this time (Massachusetts is, routing 20 percent of all prescriptions this way), while California only routes 3.28 percent. Dr. Swart indicated that 74 percent of California pharmacies had the connectivity needed to accept e-prescribing in 2008 (up from 72 percent in 2007). He recommended that similar presentations should be given to the medical board to help facilitate e-prescribing efforts.

No board or public comment was provided.

6. Discussion Regarding AB 718 (Emmerson), E-Prescribing Pilot Project

Dr. Swart stated that the Enforcement Committee heard a presentation on Assembly Bill 718. He stated that Assemblymember Emmerson introduced AB 718 which would establish a pilot project in the Inland Empire until January 1, 2013, to demonstrate the value and benefits of e-prescribing. Dr. Swart indicated that this project would be called the Inland Empire Health Plan E-Prescribing Pilot Program.

Dr. Swart stated that the board took no position on this bill during its April 2009 Board Meeting being aware that future amendments were coming. He indicated that on May 27, 2009, the bill was substantially amended to specify the components of the pilot program. Dr. Swart advised that the board's Legislation and Regulation Committee will be discussing the bill in its current form and may provide the board with a recommended position.

No board or public comment was provided.

7. Demonstration of Technology Proposed for Future Pharmacy Use in California

Dr. Swart provided that during the committee meeting, Jiwon Kim, PharmD., representing the USC University Hospital, provided an overview of "i.v.STATION," an automated, robotic-like device for compounding injectable drug. He stated that USC is seeking permission to proceed with the testing of the i.v.STATION system. Dr. Swart stated that Dr. Kim was advised that the board

will require a written request and that the board will likely wish to have an opportunity for the board to see the system in operation.

Presentation to the Board

Jiwon Kim, PharmD., representing the USC University Hospital, provided an overview of the i.v.STATION system. She stated that this system will enhance patient safety by preparing compounded drugs with decreased contamination, shorter wait times for patients, and increased accuracy. Dr. Kim indicated that the i.v.STATION would be implemented as a pilot program for validation testing at several universities around the country. She demonstrated the i.v.STATION dispensing process to the board.

Board Discussion

The board posed several questions regarding program procedures, accuracy controls that will be used, and the timeline for the pilot.

Dr. Kim provided that accuracy data is available and discussed the photo capability to ensure security and accuracy when loading the device. She indicated that the USC University Hospital will conduct a 1-month run-in period before the program will be fully initiated for a 3-month run, hopefully by September 2009.

Public Comment

Mel Snedman asked who manufactures the device.

Dr. Kim provided that the name of the manufacturer is Health Robotics.

Mark Salas expressed concern regarding the handling of antibiotics and similar products that tend to dissolve quickly.

Dr. Kim stated that most of the drugs will be in the solution form. She described the process for shaking and reconstituting drugs that are in powder form.

Merv Culman sought clarification regarding the labeling process.

Dr. Kim provided that the product is labeled inside of the device before it is dispensed. She explained the accuracy controls for ensuring that each drug is correctly labeled.

Joan Jones asked if a technician would be involved in the process.

Dr. Kim responded the there will be no technician involvement. She explained that orders will be double-checked by two pharmacists.

Ms. Jones sought clarification regarding who would provide maintenance to the device.

Dr. Kim responded that this detail will be released soon after all details have been finalized.

Ms. Jones asked if other agencies would be able to see a demonstration of the device.

Dr. Kim provided that this is possible.

The board discussed the need for more information before taking action on this issue. It was suggested that the matter be referred back to the enforcement committee for additional information.

There was no additional board or public comment.

D. Strategic Plan Update for the Enforcement Committee for 2009/10 and Discussion of Future Activities of the Committee.

Dr. Swart referenced to the strategic plan update for the Enforcement Committee contained within the board packet.

Ms. Herold requested that the board review and consider approval of the strategic plan.

There was no additional board discussion. No public comment was provided.

MOTION: To adopt the Enforcement Committee's recommendation to approve the Enforcement Committee's strategic plan update for 2009/10 with the following additions:

- Objective 1.5, Task 11: Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.
- Objective 1.5, Task 12: Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.

Approve: 6 Oppose: 0 Abstain: 1

E. Fourth Quarterly Report on Enforcement Committee Goals for 2008/09

Dr. Swart referenced to the fourth quarterly report on the Enforcement Committee's goals contained within the board packet.

No board or public comment was provided.

F. Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), referred to information regarding the board's complaint investigation processes provided in the board packet. He expressed concern that the citation and fine program is not consistent with a "traffic ticket". Dr. Cronin suggested that the board establish some type of "traffic school" to remediate the citation and fine.

There was no additional public comment.

Recognition of Pharmacists Licensed with the Board for 50 Years

President Schell provided that the recognition of pharmacists in service for 50 years was a program initiated by former board member Stan Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition, as will be done today.

President Schell recognized Vernon Mah. Mr. Mah has been a pharmacist with VMRx for over 40 years and was licensed in 1959. Mr. Mah shared that he comes from a family of pharmacists. He highlighted some of the changes in pharmacy and stated that overall; the changes that have been made are good. Mr. Mah encouraged the board to decrease regulations to allow pharmacists to work more with the public. Randy Kajioka presented Mr. Mah with a pin.

President Schell recognized Nelly Nigro. Ms. Nigro was licensed in 1948 and has worked at a variety of hospitals. She was the president of the Southern California Hospital Pharmacists in 1962. Ms. Nigro stated that the profession has been quite a journey and shared that she was one of three women from her graduating class. Shirley Wheat presented Ms. Nigro with a pin.

III. Licensing Committee Report and Action

A. Subcommittee to Evaluate Drug Distribution within Hospitals

President Schell provided an overview of the subcommittee. He indicated that the subcommittee was established to work with various agencies to develop ways to

improve recalls and other changes needed to provide for improved drug distribution control within a hospital. He stated that the first meeting of this subcommittee was March 2, 2009, at the Crowne Plaza Hotel in Irvine, California, and was well attended. Dr. Schell provided that during this first meeting, the FDA and Department of Public Health discussed recall requirements at both the state and federal level and participants discussed best practices related to drug recall process within hospitals.

President Schell provided that the second meeting was held June 2, 2009, at University of California San Francisco. He stated that attendance was good, although not as many attended as had attended the March meeting. President Schell indicated that this meeting focused on recall best practices and the needs of hospitals to change practices to provide patient care.

President Schell provided that the subcommittee will proceed with future meetings and is seeking more input from pharmacists.

No board or public comment was provided.

B. Summary and Discussion of June 18, 2009 Meeting of the Licensing Committee

1. Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)

   Mr. Weisser provided that disasters create the need for emergency care, and those not injured in the event often are relocated from their homes without their medicines. He advised that in both cases, board licensees are called upon to aid these people in ways law may not specifically provide for. Mr. Weisser stated that in the early to mid 2000s, the board sponsored legislation to ensure the public would not be deprived of necessary medicines when disasters occur and emergency response teams are making efforts to care for the public. Mr. Weisser referenced to Section 4062 (Furnishing Dangerous Drugs During Emergency) and Section 4064 (Emergency Refill of Prescriber without prescriber authorization).of the California Business and Professions Code.

   Mr. Weisser provided that by late 2006 (following Hurricane Katrina), the board developed an emergency response policy to aid pharmacies with knowledge about what the board expected pharmacies, pharmacists, wholesalers and other licensees to do in the event of a declared disaster. He stated that the emergency response indicates that once an emergency is declared, use sound judgment, but “take care of patients.”

Mr. Weisser provided that during the committee meeting, attendees heard a presentation from Dr. Dana Grau, the Department of Public Health Emergency Response Unit, who oversaw California's H1N1 response earlier this year. He indicated that Dr. Grau provided an overview of the Interim Guidance on Distribution and Dispensing of State and Federal Antiviral medications and the Interim Guidance on Antiviral Recommendations for Novel Influenza A (H1N1) Virus Infection. Mr. Weisser stated that Dr. Grau shared the department's response as well as deficiencies identified in the disaster response plan that need correction before the next declared disaster.

Mr. Weisser provided that one problem discussed during the meeting is the delivery of flu medicines from the national stockpile did not contain sufficient quantities of oral dosage forms of Tamiflu and Relenza to provide to infants and young children.

No board or public comment was provided.

2. Becoming Licensed as a Pharmacy Technician in California: An Overview of Application Processing and Frequent Deficiencies

Mr. Weisser provided that as defined in pharmacy law, a pharmacy technician is an individual who assists a pharmacist in a pharmacy in the performance of nondiscretionary tasks as specified.

Mr. Weisser stated that during the committee meeting the Board's Licensing Manager, Debbie Anderson, provided an overview of the application process as well as information on how to avoid common deficiencies.

Mr. Weisser stated that over the last five fiscal years, the board has realized an increase of more than 25 percent in the number of pharmacy technician applications, and that the number of pharmacy technicians continues to increase. Mr. Weisser stated that as the numbers of applications continue to grow, board staff remain dedicated to processing applications in a timely manner; however, that task is becoming increasingly more difficult as workload increases, but staffing remains unchanged.

No board or public comment was provided.

3. Release of the National Association of Boards of Pharmacy's Report of the Task Force on Standardized Pharmacy Technician Education and Training

   Chair Weisser provided that in September 2008, the National Association of Boards of Pharmacy (NABP) convened a task force meeting to evaluate standardized pharmacy technician education and training. He stated that the task force established a resolution which was approved by the NABP membership at the Association's 104th Annual Meeting. Mr. Weisser advised that the resolution contained seven recommendations, including changes to the Model Rules for the Practice of Pharmacy.

   Chair Weisser provided that at the committee meeting, Executive Officer Herold advised that it is at the board's discretion as to whether it will adhere to the resolution.

Board Discussion

Dr. Castellblanch asked if a test is required for pharmacy technician licensure.

The board clarified that this is not a requirement; but it is recommended by the NABP.

Assistant Executive Officer Anne Sodergren clarified licensure requirements for pharmacy technicians.

There was no additional board discussion. No public comment was provided.

4. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams

   Mr. Weisser stated that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that board staff initiated the process; however, because of a recent Executive Order signed by the Governor, the process has been halted.
   Mr. Weisser added that the PTCB and the ExCPT can be used to satisfy requirements for pharmacy technician licensure.

Board Discussion

Mr. Room provided a historical overview of how the PTCB was grandfathered in.

Dr. Swart asked if ExCPT could pay for its own psychometric assessment.

Ms. Herold responded that this could be done under contract; but, advised that the department is not accepting zero dollar contracts.

There was no additional board discussion. No public comment was provided.

5. Discussion of the Reporting and Accounting of Intern Hours for California Pharmacy School Students

Mr. Weisser stated that under current law, an intern must complete 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California. He explained that under current board regulations, a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy, and that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically earned within a pharmacy. He stated that California pharmacy students typically earn the 600 “discretionary” hours for school-related experiential training (clinical clerkship).

Mr. Weisser provided that at various Licensing Committee Meetings over the last few years, various proposals have been suggested by different proponents to amend the intern hour requirements. He reviewed several proposals.

Mr. Weisser advised that the committee has discussed the need for students to thoroughly understand the workings of a pharmacy, and why such experience is important to a pharmacist’s future as a supervisor of pharmacy functions and personnel and that, without a solid understanding and actual experience in such environments, pharmacists will have a difficult time because core experience in a newly licensed pharmacist is lacking.

Mr. Weisser provided that coupled with this discussion is the major change to intern experience requirements established by the Accreditation Council for Pharmacy Education in the last few years. He advised that these new requirements added hours to the educational requirements students need as part of their intern training. Mr. Weisser indicated that as these new requirements were being put in place nationally, California pharmacy schools were undertaking an initiative to establish core competency assessment (via an exam) of pharmacy intern skills. He stated that it is the understanding of the board that this examination is no longer being proposed as a model.

Mr. Weisser provided that the committee considered several questions, including if clarification was need on the definition of “obtained in a pharmacy” in section 1728(a)(1)(A) of the California Code of Regulations. He indicated that staff counsel advised that clarification was not required.

Mr. Weisser provided that the committee suggested that the board seek input from community pharmacists regarding the adequate preparation and training of new graduates and heard testimony that the practice of pharmacy has changed substantially since the establishment of the intern hours required.

No additional board or public comment was provided.

6. Private/Public Partnerships to Add Health Care Practitioners to California's Work Force

   Chair Weisser provided that in May 2009, the California Hospital Association (CHA) and The California Endowment sponsored a one-day conference focused on promising practices in partnerships that address the need for qualified, diverse allied health professionals. He stated that the purpose of the event was to share promising practices in public-private partnerships in allied health workforce education and training.

   Chair Weisser referenced to a press release from the Office of the Governor, announcing a $32 million public-private partnership to add health care professions to California's Work Force.

   No board or public comment was provided.

7. Obtaining a Pharmacy License in California: An Overview of the Process

   Chair Weisser stated that during the committee meeting, the Board's Licensing Manager, Debbie Anderson, made a presentation on the application process for obtaining a community pharmacy license. He indicated that Ms. Anderson discussed pharmacy ownership structures and associated application requirements, and reviewed the process for receiving a temporary pharmacy license in the event of a change of location for a pharmacy or a change of ownership.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), asked if the board would be able to implement on-line status checks.

Ms. Herold indicated that the board would like to provide this option. She reviewed the i-Licensing program, BreEZe, which is a department-wide system that will offer online application and renewal of licenses. Ms. Herold explained that this process cannot move forward until the Department of Consumer Affairs fully implements the program. She also discussed the use of an in-house tracking system.

There was no additional board or public comment.

8. Impact of State Furloughs on Processing Timelines and Work Flow of the Board

Ms. Herold provided an overview of prior and current processing times. She explained that processing times have been delayed by the implementation of the furlough days from 30 days to 45 days.

Ms. Sodergren clarified the processing times for each of the application types. She stated that board staff is evaluating areas to be streamlined to increase efficiency. Ms. Herold advised that board staff have been asked to update their outgoing messages to inform callers about current processing times.

Ms. Herold provided that the board receptionists have been advised to transfer callers who have been waiting for notification regarding an application for more than 60 days to a manager. She stated that board staff is not allowed to work overtime.

Board Discussion

President Schell referenced to the Board of Registered Nursing (BRN) and questioned how the furloughs have affected enforcement activities.

Ms. Herold identified certain priority areas that require immediate action. She reviewed factors that have been delaying case processing times including an increase in the number and severity of complaints received and the loss of two inspectors.

President Schell suggested that a presentation be made at a future meeting to review the enforcement processing times.

Mr. Room highlighted that unlike the BRN, the board has an advantage with its own enforcement inspection staff. He provided that many of the boards within the department use the Division of Investigation to perform their investigations.

Ms. Herold highlighted how complaints are monitored to ensure appropriate handling and timely investigations

There was no additional board discussion. No public comment was provided.

9. Pharmacies Refilling Orders for Other Pharmacies with Prescription Drugs Owned by Neither Pharmacy

Mr. Weisser stated that for many years, chain store pharmacies and entities such as Kaiser Permanente have established specialized, centralized refill pharmacies to refill medications for delivery to patients of their multiple pharmacies in an efficient manner. He explained that, typically, these medications are maintenance medications that are telephoned in, filled at the refill pharmacy and then delivered to the patient's neighborhood pharmacy overnight. Mr. Weisser indicated that, in turn, this process allows the neighborhood pharmacy to focus on filling first-time or immediate need patients' medications, and allow the others to be delivered in.

Mr. Weisser stated that board regulations authorizing such practices are contained in Title 16 CCR §1707.4.

Mr. Weisser provided that the board was recently asked about deviations of the model described above, as indicated below:

1. A refill pharmacy prepares medications for other community pharmacies not owned by the same owners as the refill pharmacy. Each neighborhood pharmacy is owned by a different owner. The drugs are not owned by either pharmacy, but a third-party who will bill the dispensing pharmacy once the patient-specific drugs are delivered to the neighborhood pharmacy. The drugs in the refill pharmacy are not owned by the pharmacy, but by another entity.

2. A refill pharmacy is owned by a pharmacy chain, but the drugs are owned by another party until they are delivered to the neighborhood chain store. The billing is from the owner of the drugs to the neighborhood pharmacy. The staff of the refill pharmacy is employed by the chain store, but the technicians are employed by the owner of the drugs.

Mr. Weisser stated that during the Licensing Committee meeting held in June, the committee heard a presentation from representatives from McKesson. He stated that McKesson filed an application to open a refill pharmacy located in southern California. Mr. Weisser explained that this refill pharmacy would offer refill pharmacy services to independent pharmacies in southern California and would operate in compliance with Title 16 CCR § 1707.4. He indicated that according to the presentation, the refill pharmacy will not take title to any drug; rather, the title would remain with McKesson Wholesale until transferred to the dispensing pharmacy when a prescription is filled. Mr. Weisser advised that the refill pharmacy will be responsible for the safety, effectiveness, and integrity of all drugs in its possession until such drugs are received by the dispensing pharmacy.

Mr. Weisser provided that the committee voted to direct board staff to further evaluate this issue and to report back to the full board.

Board Discussion

Ms. Wheat questioned if this process was similar to drop shipment.

Mr. Weisser explained that it was not.

Mr. Room provided that, within this model, the title of the drugs is not changing until the drugs are dispensed and delivered to the community pharmacy.

Discussion continued regarding the specifications of this model.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), sought clarification regarding what concerns the board has with regard to this model.

Ms. Herold responded that the board is uncertain if there is an issue with a refill pharmacy maintaining drugs that it does not own.

Mr. Room provided additional clarification. He discussed that the refill pharmacy may have less concern over diversion issues because they don't have any financial ownership.

Ms. Schieldge clarified that the standard in pharmacy law is "possession." She explained that the entity in possession of the drugs is legally responsible to the board for their conduct in relation to the drugs.

Mr. Weisser provided that the committee wants staff to more fully vet this issue to insure that the board is comfortable with the model.

Ms. Herold provided the history of the request. She stated the board needs to ensure that there is adequate security in the refill center.

Mr. Cronin stated that this issue needs to be resolved. He advised that it would be beneficial to identify and remedy any legal hurdles.

There was no additional board or public comment.

10. Accreditation of Internet Pharmacies by the National Association of Boards of Pharmacy

Mr. Weisser explained that internet pharmacies often operate in violation of state and federal pharmacy laws. He stated that consumers, often unaware of the dangers of internet purchase of drugs, will make purchases from Web sites which may not be pharmacies at all. Mr. Weisser indicated that, as a result, consumers may not be getting the medication they intend. He added that they may also seek to obtain medication without the supervision of a prescriber.

Mr. Weisser provided that in the early 2000s, the National Association of Boards of Pharmacy (NABP) initiated a program to certify and accredit internet web sites that are licensed as pharmacies and comply with guidelines of the NABP. He stated that this created a "Good Housekeeping Seal" of approval. Mr. Weisser indicated that the certification is called VIPPS (Verified Internet Pharmacy Practice Sites). He explained that NABP also recently established a similar accreditation and approval process for veterinary pharmacies (Vet-VIPPS).

Mr. Weisser provided that recently the NABP researched whether a number of web sites met or did not meet these criteria.

Mr. Weisser referenced the information regarding the VIPPS program provided in the board packet and encouraged those in attendance to review this information.

Public Comment

A member of the public, Mostav Iser, explained that he frequently receives unsolicited emails from companies who are selling prescription drugs. He asked who he would report this to and how he would determine if these companies are legitimate.

Mr. Room responded that these emails typically come from out-of-state and out-of-country facilities that are not under the jurisdiction of the board. He recommended verifying that the company is licensed in California via the board's web site.

Stanley Goldenberg reviewed the certification of internet pharmacies. He discussed that the VIPPS seal of approval ensures a company's validity. Mr. Goldenberg also explained that the NABP has implemented a process to help identify rogue pharmacies.

Mel Snedman asked whether the board has control of drugs coming from other states.

Ms. Herold responded yes – the board does have regulations and statutes in place. She provided that legitimate pharmacies licensed in other states are

required to be licensed by the board to ship drugs into California. Ms. Herold discussed control issues and stated that consumers who are able to receive the drugs they want, without a prescription, are not likely to file a complaint.

Mr. Room stated that the federal Drug Enforcement Administration (DEA) is taking a more direct approach towards the regulation of internet pharmacies.

Dr. Castellblanch sought clarification regarding whether the board is seeking to regulate internet pharmacies. He also sought clarification regarding the NABP.

It was confirmed that the board is seeking to regulate Internet pharmacies.

President Schell provided that the NABP, the National Association of Boards of Pharmacy, is an organization that represents and coordinates each state board of pharmacy. He stated that California Board of Pharmacy became a member of the NABP in 2004.

Ms. Herold highlighted some of the obstacles the board realizes when attempting to investigate internet pharmacies.

Ms. Wheat also highlighted that the board also has consumer materials available relating to this issue.

There was no additional board or public comment.

11. Competency Committee Report

(a) Pharmacist Exam Performance Statistics for October 2008 – April 2009 CPJE and NAPLEX Exam Administrations

Mr. Weisser explained that the overall pass rate during the specified time frame for the CPJE is 75.2% and 96.9% for the NAPLEX.

No board or public comment was provided.

(b) Comparison of Licensing Statistics with California's Pharmacist Licensure Examination Administered Prior to January 2004

Mr. Weisser explained that, in general, the overall pass rate on the previous pharmacist licensure exam (administered through June 2003) ranged from 41.1% to 59.8%.

Mr. Weisser provided that beginning in 2004, when the exam changed to the CPJE and NAPLEX, the overall pass rates are higher. He stated that the pass

rate for the CPJE ranges from 69.9% to 81.6% and the pass rate for the NAPLEX ranges from 90.7% to 97.6%.

No board or public comment was provided.

(c) Job Analysis for the CPJE to Be Undertaken at the End of 2009

Mr. Weisser stated that the Competency Committee will develop a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm during its annual meeting scheduled for the end of July 2009. He stated that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. Mr. Weisser advised the board anticipates releasing this survey to a random sample of pharmacists before the end of year. He indicated that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Mr. Weisser provided that in response to the Executive Order, the board has been granted an exemption to move forward with the analysis.

No board or public comment was provided.

12. Meeting Summary of the Licensing Committee Meeting Held June 18, 2009

Mr. Weisser provided that the minutes of the Licensing Committee Meeting are contained within the board packet.

C. Strategic Plan Update for the Licensing Committee for 2009/10 and Discussion of Future Activities of the Committee.

Mr. Weisser reviewed the recommended additions to the strategic plan.

Public Comment

Lorie Rice, representing the UCSF School of Pharmacy, asked for clarification regarding the intern hours.

Mr. Weisser responded that concern has been raised about the use of discretionary hours. He explained that the committee would like to continue to review this issue.

There was no additional board or public comment.

MOTION: To adopt the Licensing Committee's recommendation to approve the Licensing Committee's strategic plan update for 2009/10 with the following additions:

- Objective 2.4, Task 14: Improve reporting of and accounting for intern hours.
- Objective 2.4, Task 15: Participate in initiatives to increase the number or pharmacists in California to meet demand.
- Objective 2.4, Task 16: Assess the operations of specialty pharmacy services.

Approve: 6 Oppose: 0 Abstain: 1

D. Fourth Quarterly Report on Licensing Committee Goals for 2008/09

Mr. Weisser referenced the fourth quarterly report on the Licensing Committee's goals contained within the board packet.

E. Public Comment

No public comment was provided.

IV. Legislation and Regulation Committee Report and Action

Part 1: Regulation Report and Action

A. Action to Repeal Title 16 CCR §§1716.1 and 1716.2, Amend and Adopt §§1751 through 1751.8, and Adopt §§1735 through 1735.8 – Pharmacies that Compound Medicine

Mr. Lippe stated that current pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. He added that pursuant to Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. Mr. Lippe indicated that there are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. He stated that this proposal would establish guidelines to provide uniformity in compounding for California consumers.

Mr. Lippe stated that the 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. He indicated that at the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

Mr. Lippe explained that during the January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt some of the record keeping requirements detailed in proposed section 1735.3 for sterile products that are compounded on a one-time basis for administration within 2 hours, as specified. A 15-day Notice of Modified Text was issued in February 2009, and the board received a significant number of comments. Mr. Lippe indicated that at the April 2009 Board Meeting, staff provided the board with the comments received during the 45-day and 15-day comment periods, as well as a draft response to these comments for board consideration.

Mr. Lippe stated that based on comments received during the 15-day comment period, executive staff of the board suggested three options to further modify proposed section 1735.3(a)(6). He said the board then voted to pursue a second 15-day comment period to exempt some of the record keeping requirements in proposed section 1735.3(a)(6) for sterile injectable drug products compounded on a one-time basis for administration within *24 hours*, as specified, and that the board received comments during this 2nd 15-day comment period.

Mr. Lippe provided that the recommendation before the board is to adopt the regulation as noticed on May 4, 2009. He advised that the board will specify that the requirements will not go into effect for six months following approval by the Office of Administrative Law to allow for implementation. Mr. Lippe indicated that board staff will exercise its enforcement discretion for an additional six months to allow for education and transition. He explained that, at this time, the board can take action to either (1) continue to pursue the regulation as currently proposed, or (2) withdraw the rulemaking and start over.

Public Comment

Stanley Goldenberg sought clarification regarding the implementation timeline.

Ms. Herold responded that the typical timeline for adoption of a regulation is about one year. She provided an overview of the regulatory approval process. Ms. Herold stated that board staff will likely submit the rulemaking to the Department by August 1, 2009, and she does not expect that it will be returned from Agency before November 2009. She estimated that the process may be finalized by June 2010.

There was no additional public comment.

MOTION: To adopt the regulation as noticed May 4, 2009, and to specify that the requirements will not go into effect for six months following approval by the Office of Administrative Law.

M/S: Schell/Lippe

Approve: 6 Oppose: 0 Abstain: 1

MOTION: To direct board staff to take all steps necessary to finalize the rulemaking package and to delegate to the executive officer the authority to make non-substantive changes to the rulemaking and sign the Order of Adoption.

M/S: Schell/ Lippe

Approve: 6 Oppose: 0 Abstain: 1

B. For Information – Approved Regulations

1. Amend 16 CCR §1760 – Disciplinary Guidelines

Mr. Lippe provided that changes to the Disciplinary Guidelines have been approved.

C. Board Approved Regulations – Currently Undergoing Administrative Review

1. Proposed Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course

Ms. Sodergren provided that this rulemaking is currently undergoing review at the Office of the Administrative Law.

D. Board Approved Regulations – Currently Awaiting Notice

1. Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Ms. Sodergren provided that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. She advised that board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

2. Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality

   Ms. Sodergren provided that this regulation would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as strengthen the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

   Ms. Sodergren provided that board staff will notice this rule making prior to the October 2009 Board Meeting.

E. Regulations Under Development

1. Title 16 CCR §1780 – Update the USP Standards Reference Material

   Mr. Lippe provided that CCR §1780 sets minimum standards for drug wholesalers. He stated that Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. Mr. Lippe indicated that the USP Standards is updated and published annually. He advised that consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

   Mr. Lippe provided that because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

   President Schell provided that due to a recent vacancy, the subcommittee is not able to make a recommendation at this time.

2. Title 16 CCR §1732.2 – Continuing Education for Competency Committee Members

   Mr. Lippe provided that at the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

   Mr. Lippe provided that the Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. He stated that a committee member's term is generally about eight years.

Mr. Lippe provided that annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. He stated that each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Mr. Lippe stated that committee members also participate in 2-4 writing assignments based on the examination development need. He advised that committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

Mr. Lippe provided that one of the core functions of this committee is to complete an on-line review of all test questions prior to administration. He stated that as the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Mr. Lippe explained that given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. He indicated that typically, committee members are not compensated for their time to complete this function. Mr. Lippe stated that if a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.

Mr. Lippe provided that current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. He stated that currently, pharmacists can earn CE

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Mr. Lippe provided that, additionally, the board will award CE for

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Mr. Lippe provided that board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.

Public Comment

No public comment was provided.

Part 2. Legislative Report: Discussion and Action on Pending Legislation

A. Board-Sponsored Legislation:

1. SB 819 (Senate Business, Professions & Economic Development Committee) – Omnibus Provisions (formerly contained in the enrolled version of SB 1779 [2008], vetoed).

   At the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business, Professions and Economic Development Committee) which was vetoed by the Governor (prior session).

   The omnibus provisions included in SB 819 are categorized into four types of changes:

   a. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.
   b. General omnibus provisions.
   c. Use of mobile pharmacies.
   d. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.

   Status: Staff reported at the July 8, 2009, Legislation and Regulation Committee that the measure passed Assembly policy committee and was referred to Assembly Appropriations.

   No board or public comment was provided.

2. SB 820 (Senate Business, Professions & Economic Development Committee) New Omnibus Provisions

   Status: Staff reported that recent amendments to SB 820 moved the Board of Pharmacy's omnibus provisions related to the renaming of the Department of Consumer Affairs Office of Professional Examination Resources (4200.3 and 4200.4) into SB 821.

   No board or public comment was provided.

3. SB 821 (Senate Business, Professions & Economic Development Committee) New Omnibus Provisions Specific to PIC and DRC Requirements

At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions.

Status: Staff reported that the measure was amended on July 6, 2009 to incorporate the Board of Pharmacy's omnibus provisions (previously found in SB 820) related to the renaming of the Office of Professional Examination Resources. SB 821 now makes conforming changes throughout the Business and Professions Code to reflect this name change.

Board Discussion

Mr. Lippe provided that SB 819 and SB 821 are scheduled to be heard in the State Assembly Committee on Appropriations today, July 15, 2009. He indicated that SB 820 has been amended and no longer affects Pharmacy Law.

Public Comment

Lorie Rice requested that the status of the bills be provided.

Ms. Herold indicated that the bills are moving and that the board is comfortable with the provisions.

There was no additional board or public comment.

4. SB 470 (Corbett) Prescription Labeling to Add "Purpose" -- Proposal to Amend B&PC §§4040 and 4076

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where many consumers suggested that the purpose of the medicine be included on the label.

Senator Corbett is authoring this bill for the board. This bill will amend Business and Professions Code sections 4040 and 4076 to include the "condition or purpose" for which a medicine is prescribed. (Senator Corbett authored SB 472,

Chapter 470, and Statutes of 2007, requiring the board to standardize the prescription label to make them patient-centered.)

Board staff has been working to establish a broad base of support for this proposal. The California Medical Association submitted a letter advising the author's office that it has taken a Support If Amended position and offered amendments. Senator Corbett's Office has advised CMA that they accepted the amendments offered. Additionally, Senator Corbett's office is also working with the California Retailers Association and National Association of Chain Drug Stores who submitted an Oppose Unless Amended position.

Status: Staff reported that the measure was scheduled to be heard July 8, 2009, in Assembly Appropriations.

Board Discussion

Ms. Sodergren provided that SB 470 has passed out of the house of origin and both the policy and the fiscal committees in the second house. She indicated that the bill is scheduled for its third reading in the Assembly.

There was no additional board discussion. No public comment was provided.

5. AB 977 (Skinner) Pharmacists: Immunization Administration -- Proposal to Amend B&PC §§4052 and 4052.8

At the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Assembly Member Skinner authored this bill for the board. This bill will amend Business and Professions Code section 4052 and add 4052.8 to allow a pharmacist to administer immunizations as specified. As stated above, as introduced, this bill would have allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP); however, with the approval of the board president, this proposal will be amended to allow a pharmacist to administer influenza and pneumococcal vaccinations or any other immunization pursuant to a prescriber protocol. The National Vital Statistics Report published by the U.S. Department of Health and Human Services reports that combined, influenza and pneumonia are the eighth leading cause of death in people of all ages, and the sixth leading cause of death in people over 65.

Board staff has been working with stakeholders to establish a broad base of support. Unfortunately the California Medical Association (CMA) continues to oppose the bill, even with the proposed amendments.

Status: This bill failed passage in the Assembly Business and Professions Committee and did not meet the deadline to be passed out of the house of origin.

No board or public comment was provided.

6. AB 1071 (Emmerson) Pharmacy Fees -- Proposal to Amend B&PC §§4110, 4127.8, 4160, 4400, and 4127.5

At the January 2009 Board Meeting, the board voted to pursue a statutory change increase to its fees.

Assembly Member Emmerson is authoring this proposal for the board. AB 1071 adjusts application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. This bill also builds in a cap to increase future fees by no more than 30 percent.

During the January 2009 Board Meeting, significant discussion occurred regarding the best way to determine fees. The board voted to pursue the statutory fee increase, but did not reach consensus on the fees themselves. With approval of the board president, board staff drafted language that begins to reduce the current subsidy that exists between individual and site licenses, resulting in the (2/27/09) introduction of AB 1071.

Status: Staff reported that AB 1071, as introduced, passed policy and fiscal committees in the Assembly, and recently passed both policy and fiscal committees in the Senate.

No board or public comment was provided.

B. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. AB 583 (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours

   Existing law (BPC 680) requires a health care practitioner to disclose his or her name, license on a name tag in 18-point type. AB 583 as amended 7/8/09 further requires a health care practitioner to provide their license type and the highest level of academic degree he or she holds on either a name tag, in writing to a patient as specified, or on a prominent display in his or her office. The measure provides specified exceptions for those licensed under BPC 2700 and makes additional requirements to those licensed under Chapter 5 or under the Osteopathic Act, and makes further requirements of physicians and surgeons who supervise locations outside of their primary office. The measure excepts from some of the requirements those who work in a facility licensed under HSC 1250 or in a clinical laboratory licensed under HSC 1265.

Board Discussion

Mr. Lippe provided that this measure was not discussed at the Legislation and Regulation Committee meeting.

Carolyn Klein, Legislation and Regulation Manager, provided that the Department of Consumer Affairs has an oppose position. She indicated that DCA provided an analysis in which it was explained that the bill was found to be "unnecessary." Ms. Klein advised that the bill is still moving.

Discussion continued regarding the impact and intent of this bill.

Ms. Wheat recommended that board staff continue to watch this bill.

Public Comment

Lorie Rice, representing the UCSF School of Pharmacy, provided input regarding the impact of this bill. She stated that a PharmD designation would be indicated on a pharmacist's name tag.

President Schell provided that board staff will be directed to informally watch this bill.

There was no additional board or public comment.

2. AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012

As amended 6/30/09, AB 718 removed amendments to Pharmacy Law and, instead, in the Welfare and Institutions Code, creates the Inland Empire Health Plan E-Prescribing Pilot, which is to be funded with funds made available by the Federal American Recovery and Reinvestment Act of 2009.

Following discussion of the bill and the board's stated support in general of e-prescribing, the committee voted to recommend that the Board "Support" of AB 718 as Amended 7/7/09.

Committee Recommendation: "Support" AB 718 as Amended 7/7/09
Bill Status: Amended (7/7) and passed out of Senate Business, Professions and Economic Development. Referred to Senate Appropriations.

Board Discussion

Mr. Lippe highlighted the intent of the bill.

Ms. Sodergren provided that the bill has been amended and is now under the Welfare and Institutions Code. She clarified that prescribers who are in the Inland Empire Health Plan are not required to participate in the pilot program.

Dr. Castellblanch expressed concern regarding the provisions of the bill. He provided apprehension about the support of this bill.

Mr. Lippe clarified that committee recommended support of this bill. He provided a brief summary on the current status of the July 7, 2009 amendment.

Mr. Weisser commented with regard to formulary drugs and provided that the context of the bill could be described as a formulary.

Discussion continued regarding formulary drugs and the provisions of this bill.

President Schell expressed support for the bill.

There was no additional board discussion. No public comment was provided.

MOTION: To establish a position of support on AB 718.

M/S: Weisser/Swart

Approve: 5 Oppose: 1 Abstain: 1

3. AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid

This bill replaces various drug compendia references with compendia approved by the federal Centers for Medicare and Medicaid Services.

During the Legislation and Regulation Committee Meeting, Ms. Herold provided an overview of the measure and discussed recent amendments that remove amendments to Pharmacy Law which addressed previous concerns regarding this bill. The committee voted to recommend that the Board "Support" AB 830 as Amended 7/6/09.

Committee Recommendation: "Support" AB 830 as Amended 7/6/09
Bill Status: Referred to Senate Committee on Health.

Board Discussion

Mr. Lippe highlighted the scope of the bill.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), expressed concern regarding the drafting of the bill.

Mr. Weisser provided that the author has been receptive to the changes in the bill.

Ms. Herold explained that the board originally took a position of "oppose" on this bill. She discussed that the author was able to address for the board's concerns in the amendments.

Discussion continued regarding the language of the bill. It was clarified that the bill no longer affects the board's jurisdiction.

MOTION: To establish a position of support on AB 830.

Approve: 6 Oppose: 0 Abstain: 1

4. AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container

This bill would increase the number of oral dosage form and suppository dosage forms of drugs for storage within the SNF emergency container to 48. The current limit is 24. The committee discussed the proposed expanded size of the e-kits, the time in which prescriptions are filled, and the use of the e-kits in STAT situations. Physicians determine what constitutes an "emergency" in a skilled nursing facility. Ms. Herold clarified that these e-kits are within the jurisdiction of the California Department of Public Health (CDPH). The committee requested more information on the intent of the bill. The committee did not recommend a position on this measure.

Bill Status: In Senate Committee on Health. The committee has postponed hearings on this bill.

Board Discussion

Mr. Lippe provided an overview of the bill. He clarified that the dosage for each drug would be increased to 16. He stated that the committee referred the bill to the board for any action.

Dr. Kajioka expressed concern regarding the use of the e-kits as satellite pharmacies. He questioned whether the intent is for convenience or for the safety of the patient.

President Schell provided that from a clinical perspective, he has concern regarding the use of these particular drugs in an emergency setting.
Ms. Herold sought clarification that the California Pharmacists Association (CPhA) is the sponsor of the bill and was confirmed.

Public Comments

Stan Goldenberg provided that he has a background in long-term care. He stated that the kit should be referred to as a "first dose kit." Mr. Goldenberg discussed the frequent use of these kits within a nursing home. He explained that the goal is to enable a pharmacy to get the drugs to the patients in a skilled nursing facility in a timely manner. Mr. Goldenberg highlighted the regulation and inspection of the kits.

Mr. Lippe asked how many e-kits are provided to each facility.

Mr. Goldenberg responded that usually one kit is provided per nursing station. He explained the procedures for obtaining a new kit and discussed the use of electronic kits such as a "Pyxis Machine."

Ms. Wheat asked if there have been incidents where an e-kit was not sufficiently supplied in order to meet the patient's needs.

Mr. Goldenberg responded yes and offered examples of multiple patients, dosage shortages, pharmacies closed for long weekends, and rural communities. He provided that the electronic kits may be a possible alternative. Mr. Goldenberg provided that common medications include antibiotics, nausea management and pain relief drugs. He advised that the regulations mandate that the drugs available in a facility must be patient specific.

Discussion continued regarding the use of e-kits and a concern regarding the dramatic increase in doses. It was encouraged upon the board that ultimate benefit of the e-kits goes to the patient inside of a nursing home

Dr. Swart expressed concern regarding the drastic increase in doses.

Discussion continued regarding timeframes and the expiration and sealing of drugs provided in the e-kits.

Dr. Jones, representing the California Department of Public Health (CDPH), addressed some concerns. She explained that the county would provide drugs in the event of an outbreak. Ms. Jones stated that an e-kit will be replaced within 72 hours. She expressed concern regarding the security of controlled drugs within certain kits. With regard to the administration time of an antibiotic to a patient, and in reference to general acute care hospital settings, Ms. Jones stated that there is no reason that a patient within a skilled nursing facility would need the antibiotic before 4 hours. She indicated that nursing home inspections are done every 12-15 months. Ms. Jones advised that CDPH will need to further discuss the issue of increasing the dosage from 24 to 48.

A motion was offered to oppose AB 931.

Dr. Swart explained that he feels that the proposed increase in dosage is unnecessary.

Dr. Cronin provided that the increased dosage will allow for a larger variety of drugs to be provided.

Merv Culman, representing CDPH, provided that from his perspective, he believes the bill aims to allow for sufficient amounts of medication to be accessed by personnel without the prior review by a pharmacist. He encouraged pharmacies to have contractual relationships with skilled nursing facilities to ensure that medications are delivered in a timely manner.

Mel Snedman provided that based on his experience in long-term care facilities, the e-kit was never used until the pharmacy was called. He added that it was at the pharmacist's discretion as to whether the e-kit was used.

President Schell provided that with respect to the provided comments, he would prefer to take a position of neutral or refrain from taking a position at this time.

There was no additional board or public comment.

MOTION: To establish a position of oppose on AB 931.

M/S: Swart/Kajioka

Approve: 2 Oppose: 3 Abstain: 2

5. SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus

The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, who petition for reinstatement of a revoked, surrendered or canceled license, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

The committee discussed how the agency receives fingerprint data, and Ms. Herold clarified how that data is secured. The committee voted to recommend that the board take a "Neutral" position on the bill.

Committee Recommendation: "Neutral" position on SB 389 as Amended 6/1/09
Bill Status: (7/7) Failed passage in ASM Public Safety. Reconsideration granted.

Board Discussion

Ms. Sodergren reviewed the status of the bill. She provided that reconsideration has been granted but the bill has not yet been scheduled for hearing.

Mr. Lippe provided an overview of the bill. He indicated that the committee chose to change the support position to a neutral position.

Ms. Wheat sought clarification regarding whether the board needs to change its position if an amendment has not been made to the bill.

Mr. Room clarified that the board's position does not stand if the bill has changed. He explained that the board's position applies to the specific version of the bill that was voted upon.

Ms. Herold provided that there is a staff obligation to scan bills. She explained that significant amendments are discussed with the board president.

There was no additional board discussion. No public comment was provided.

MOTION: To change the current position of support and establish a position of neutral on SB 389.

Approve: 0 Oppose: 6 Abstain: 1

6. SB 484 (Wright) Ephedrine Products to Schedule V

The current version of this bill (5/12/09) provides that transactions of specified ephedrine substances are to be reported to the Department of Justice. The bill also provides that any person obtaining a substance specified in H&S §11375.5(b) shall be guilty of a crime. At the committee meeting, Ms. Herold discussed that some drug manufacturers are offering a tracking system that would be funded by the manufacturers. The committee discussed inconsistencies in the language of this version. The committee did not establish a recommended position on this bill.

Bill Status: (6/30) Failed passage in ASM Public Safety. Reconsideration granted.

Board Discussion

Mr. Lippe provided an overview of the bill and its inconsistencies. He explained that the amendment to the bill does not classify ephedrine products as Schedule V drugs but maintains that anyone who obtains these products without a prescription is guilty of an infraction or a misdemeanor.

Discussion continued regarding the status of the bill. It was clarified that this bill will likely be a 2-year bill.

There was no additional board discussion. No public comment was provided.

C. Legislation that Failed Passage and May Become a 2-Year Bill

1. SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews

This bill would redefine the sunset review process. The bill was held in Senate Rules and did not meet the deadline for bills to be passed out of the house of origin. Ms. Herold indicated that she has been working with the Senate Business, Professions and Economic Development committee to identify options to secure an extension of the board's sunset date. Following discussion, the committee voted to recommend that the board authorize the Executive Officer to have the Board of Pharmacy's sunset provisions addressed through a different legislative measure in order to extend the board's sunset date.

Committee Recommendation: Authorize the Executive Officer to take steps to have the Board of Pharmacy's sunset provision extended through another legislative measure.

Board Discussion

Mr. Lippe provided an overview of the bill.

Ms. Herold provided that the board is one of ten boards that are set to sunset on July 1, 2010. She explained that the bill would extend the board's sunset date and protect the board from merging into the Department of Consumer Affairs. Ms. Herold indicated that the board's sunset review is being delayed due to the reevaluation of the sunset review procedural process by the Senate Rules.

Ms. Herold suggested that if no other legislative vehicle can be identified, the board may wish to consider placing the board's sunset date extension into one of the board's current bills. She discussed the use of preemptive clause.
There was no additional board discussion. No public comment was provided.

MOTION: To authorize the executive officer to take the necessary steps to have the Board of Pharmacy's sunset provision extended through another legislative measure.

Approve: 6 Oppose: 0 Abstain: 1

D. Strategic Plan Update for the Legislation and Regulation Committee for 2009/10 and Discussion of Future Activities of the Committee.

Mr. Lippe provided that the committee discussed the Strategic Plan Update for the Legislation and Regulation Committee and voted to approve the plan as submitted.

No board or public comment was provided.

MOTION: To adopt the committee's recommendation to approve the Strategic Plan Update for the Legislation and Regulation Committee for 2009/10.

Approve: 6 Oppose: 0 Abstain: 1

E. Summary of the Legislation and Regulation Committee Meeting Held on July 8, 2009

Mr. Lippe provided that the minutes of the Legislation and Regulation Committee will be provided on the board's web site.

No board or public comment was provided.

G. Fourth Quarterly Report on Legislation/Regulation Committee Goals for 2008/09

Mr. Lippe referenced to the fourth quarterly report on the Legislation/Regulation Committee's goals contained within the board packet provided.

No board or public comment was provided.

H. Public Comment

No public comment was provided.

President Schell recognized former board member Tim Dazé.

V. <u>Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings</u>

No public comment was provided.

President Schell announced that there will be a Communication and Public Education Meeting following the recess of this board meeting.

Recess for Day

The board meeting was recessed at 3:15 p.m.

The board reconvened at 8:34 a.m. on July 16, 2009.

President Schell provided that no quorum was present. He stated that the board would proceed without any action until a quorum was established.

VI. Communication and Public Education Committee Report and Action

A. Update Report on *The Script*

Ms. Herold provided an update on the status of the board's newsletter *The Script.* She stated that work on the July 2009 issue of *The Script* is completed and the text is undergoing legal review. Ms. Herold indicated that the next issue will be released no later than August 2009.

Ms. Herold provided that future publications of *The Script* may be done electronically, rather than in print due to publication and mailing expenses. She stated that several hundred copies can be produced to be distributed at educational and community events and a subscriber alert will notify pharmacies when a new issue is available.

Board Discussion

President Schell suggested that CDs could be produced to allow organizations and institutions to print out *The Script* themselves.

Ms. Herold discussed the cost savings of implementing the use of CDs. She explained that the board is seeking to reduce costs in other budgetary areas.

There was no additional board discussion. No public comment was provided.

B. Update on Public Outreach Activities

Ms. Herold provided an update on the public and licensee outreach activities performed during the fourth quarter of Fiscal Year 08/09. She indicated that the board may need to scale back its public outreach efforts.

No board or public comment was provided.

President Schell suspended the Communication and Public Education Committee Report until a quorum was established.

VII. Organizational Development Committee Report and Action

A. Budget Update/Report

1. Governor's Executive Order to Furlough State Employees

Ms. Herold provided that the Governor has added a third furlough day and has directed state agencies to close on the first, second and third Friday of each month. She stated that salaried employees (all board managers and inspectors—29 positions), have become hourly workers in every furlough week and cannot exceed working 32 hours. Ms. Herold advised that state agencies have been directed not to replace furloughed hours with overtime work. She discussed that board staff are evaluating how they will continue to fulfill their work obligations with these new restrictions.

Board Discussion

Ms. Sodergren provided a 5-year overview comparing the number of license applications received during the fiscal years 04/05 – 08/09. She reviewed the percentage of growth for each license type.

Ms. Wheat sough clarification regarding the workload required following a buy-out.

Ms. Sodergren discussed the challenge with buy-outs. She stated that all other work must be stopped to ensure that consumers can still get their medications because licenses are not transferrable. Ms. Sodergren explained that temporary staff may be used to meet this change in workload. She highlighted the licensing process and described common deficiencies and delays.

Ms. Sodergren reviewed the number of licenses issued and renewed. She stated that the licensing population continues to grow in each license category. Ms. Sodergren advised that this increase impacts staff workload. She provided that the future implementation of I-Licensing will help to ease this workload.

Ms. Wheat sought clarification regarding the frequency of pharmacy exams.

Ms. Herold responded that the exams are continuous. She stated that there is a quality assurance review to ensure the validation of the exams. Ms. Herold advised that this review can impact the release of exam results.

Ms. Sodergren reviewed the total license counts for the past five fiscal years. She indicated that there has been significant growth in almost all areas of licensing classifications. Ms. Sodergren provided an overview of the subsequent workload associated with the maintenance of the licenses.

President Schell sought clarification regarding the number of licenses that are active and inactive.

Ms. Sodergren provided that the pharmacist license is the only classification that can become inactive. She stated that about 3,000 pharmacist licenses are currently inactive. Ms. Sodergren highlighted the renewal requirements to maintain an inactive license. She indicated that pharmacist licenses that are not renewed after three years are cancelled by operation of law. Ms. Sodergren provided that a report could be generated to provide statistics regarding the number of licenses that are not being renewed.

Ms. Herold provided that with exception to pharmacist licenses, a permit can be cancelled after 60 days for failure to renew. She advised that a site that fails to renew and continues to conduct business is operating illegally.

Ms. Sodergren provided a comparison of the board's enforcement statistics for fiscal years 04/05 – 08/09. She reviewed the number of complaint and investigations that were initiated, closed, and pending at the end of each fiscal year indicating a substantial amount of growth and complexity. Ms. Sodergren indicated that pending cases are assigned to a specific team of inspectors specializing in specific types of pharmacy law violations including compliance, drug diversion and fraud, mediation and enforcement, probation and the Pharmacists Recovery Program (PRP), and the newly established Criminal Conviction Unit (CCU).

Ms. Herold discussed the increase in criminal conviction reports from 300 to approximately 3,000 reports per year.

Ms. Sodergren provided that before the establishment of the CCU, the other teams were handling the criminal conviction workload.

Discussion continued regarding specific enforcement cases and team responsibilities.

Ms. Sodergren reviewed the application investigation process. She also discussed the numbers of citations and fines issued to close cases.

9:03 a.m. – The quorum was established.

Ms. Sodergren highlighted the administrative case process for egregious violations and referral to the Attorney General's office.

The board discussed prescription drug use and commonly abused drugs.

There was no additional board discussion. No public comment was provided.

2. Budget Report and Constraints for 2009/10

Ms. Herold referenced to the data depicting the actual board revenue and expenditure for 2007-08, actual board expenses for 11 months of 2008-09, and projected expenses for 2009-10. She stated that the board has been advised that it will need a 15 percent reduction in all operating expenses. Ms. Herold explained that this will be a difficult target given that many of the board's operating expenses (e.g., rent, pro rata to the DCA and state, contracts for essential, mandated services) are fixed. She highlighted the budget for operating expenses.

Board Discussion

The board discussed the expenditures and evaluated areas that could be cut. Clarification was provided that the 15 percent reduction is about $700,000 of the board's budget. It was suggested that the board's satellite office in Van Nuys could be shutdown. It was noted that it would be a lengthy process before approval would be given to do so.

Ms. Herold discussed possible areas that could be cut in order to meet the reduction requirements. She reviewed essential costs, including enforcement and investigation efforts. Ms Herold also highlighted the costs associated with conducting board meetings. She advised that the board will not be renting meeting rooms for future board meetings and will instead be seeking free public rooms.

Ms. Wheat sought clarification regarding why the board meetings are held in various locations throughout the state. She suggested that California pharmacy schools may be potential meeting locations for future meetings.

Ms. Herold responded that the board is required to hold meetings in both northern and southern California. She provided that the board may wish to conduct two of its meetings in Sacramento and the other two at available schools of pharmacy in southern California.

There was no additional board discussion. No public comment was provided.

3. Budget Report for 2008/09

Ms. Herold provided an overview of the board's budget figures for the fiscal year that ended June 30, 2009. She stated that as of June 1, 2009, the board has collected $9,684,449 in revenue. Ms. Herold explained that eighty-six percent of the revenue comes from fees, with cite and fine and cost recovery generating 11 percent of the board's revenue. She advised that a new fee increase effective January 1, 2010 will generate $1.17 million in increased revenue annually.

No board or public comment was provided.

4. Fund Condition Report

   Ms. Herold provided that the board will have the following fund conditions at the end of the identified fiscal years:

2007/08	$10,833,000	13.3 months in reserve (actual)
2008/09	$8,999,000	10.1 months in reserve
2009/10	$7,566,000	8.4 months in reserve
2010/11	$4,786,000	5.2 months in reserve

   Ms. Herold stated that if AB 1071 is enacted, the fund condition is projected to increase by $1.17 million, and the first year after enactment, fund condition would increase to

2010/11	$5,980,000	6.5 months in reserve

   No board or public comment was provided.

5. Reimbursement to Board Members

   Ms. Herold referenced to the report on board member reimbursement and expenses provided in the board packet.

6. BreEZe (*i*-Licensing) Progress

   Ms. Herold provided an update on the i-Licensing project. She indicated that the name of the program has been changed from i-Licensing to BreEZe earlier this year. Ms. Herold stated that in the next three years, the board will spend $342,000 as its share of costs to implement this system department-wide.

   Ms. Herold provided that the board is about 2 years away from implementing i-Licensing according to current estimates and timelines.

   No board or public comment was provided.

B. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

Ms. Herold provided that since July 2005, the board has acknowledged 855 pharmacists with 50 or more years of licensure as pharmacists in California. She stated that seventy-seven pharmacists reached this milestone between May and July 31, 2009.

No board or public comment was provided.

C. Personnel Update

Ms. Herold provided an overview of the following staff changes:

- Susan Williams has been hired as the new executive office technician. Ms. Williams will be making board member travel arrangements, processing travel claims and handling board member correspondence.
- Sarah Marendt has been hired as an analyst in the criminal conviction unit.
- Lori Haley has been promoted to an analyst in the criminal conviction unit. Ms. Haley formerly was a licensing technician for pharmacist, pharmacy technician and intern licenses.
- Lisa Esquivel is the new technician in the criminal conviction unit.
- Ray Flores, one of the board's two receptionists, has transferred to Ms. Haley's old position as a technician to expedite applications.
- Kathleen Fabela has been hired as the board's second receptionist.
- Denise Davis has been hired as a second part-time processor of pharmacy technician applications.
- Inspector Dolly Harris has retired after more than 25 years with the board.

Ms. Herold provided that the board is recruiting for the manager over the criminal complaint unit (to replace retired annuitant Karen Cates, the former Enforcement Manger, who will remain as a temporary worker), one half-time analyst for the criminal complaint unit and one enforcement coordinator. She stated that Supervising Inspector Janice Dang completed the winter management academy training provided by the Department of Consumer Affairs. Ms. Herold indicated that this course is a six-day intensive session in developing future leaders.

Ms. Herold provided that once a year, the board evaluates its executive officer. She stated that President Schell has directed that this evaluation process be initiated.

President Schell provided an overview of the executive officer evaluation process. He stated that there is a form for this that will be sent to each board member in several weeks. President Schell indicated that each member will have the opportunity to provide comments regarding the performance of the executive officer within the last year, and send these to the board president. He explained

that he will prepare the final evaluation form, which will be provided to the executive officer in closed session at the next board meeting.

President Schell provided an overview of board member changes. He stated that there are currently nine board members, and four board member vacancies. President Schell introduced Ramón Castellblanch as the new Senate appointment.

President Schell provided that he will be evaluating current committee assignments and will be making adjustment as necessary.

D. Discussion of the Format of Future Board Meeting Agendas and Hearings.

President Schell discussed the structure of future board meeting agendas, committee meeting agendas, and the manner in which discussion occurs during board and committee meetings. He offered several areas to evaluate including:

- Should committee meetings be held on the same days – one in the morning, another in the afternoon?
- Should they routinely be held in conjunction with a board meeting?
- Would there be more focused discussion if a motion for action was in place before discussion occurs?

President Schell stated that the October 2009 Board Meeting will include a more focused discussion on this topic.

Board Discussion

Ms. Schieldge sought confirmation regarding the dates for the October 2009 Board Meeting.

President Schell provided that the board will discuss this date before the adjournment of this meeting.

There was no additional board discussion. No public comment was provided.

E. Strategic Plan Update for the Organizational Development Committee for 2009/10 and Discussion of Future Activities of the Committee.

President Schell referenced to the Strategic Plan Update for the Organizational Development Committee contained within the board packet.

No board or public comment was provided.

F. Approval of the Board of Pharmacy's Strategic Plan for 2009/10

President Schell provided that the board will need to vote to approve the Board of Pharmacy's Strategic Plan for 2009/10 after the completion of the Communication and Public Education Committee.

No board and public comment was provided.

The board resumed its discussion of the Communication and Public Education Committee Report.

VI. Communication and Public Education Committee Report and Action

C. Report of the Public Education Committee Meeting Held July 15, 2009

Dr. Swart provided that Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. He stated that this statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. He indicated that the board is also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels.

1. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472

Dr. Swart reviewed the following survey responses:

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print
  (347 of 578 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black
  (65 of 578 responses = 11.3%)

When asked what to change on the prescription label, the top three responses were:

- Print should be larger or darker
  (194 of 616 responses = 31.5%)
- No changes should be made to label – references were made to Target, Raley's, CVS and Kaiser labels
  (148 of 616 responses = 24.0%)

- Include purpose of the drug – state what condition the medication is intended to treat
  (71 of 616 responses = 11.5%)

When asked what information on the label was most important, the top three responses were:

- Directions for use
  (257 of 1,1,361 responses = 18.9%)
- Name of drug; if generic, brand name and generic
  (253 of 1,361 responses = 18.6%)
- Dosage prescribed
  (242 of 1,361 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors
  (30 of 158 responses = 19.0%)
- Include purpose of the drug – state what condition the medication is intended to treat
  (22 of 158 responses = 13.9%)

No board or public comment was provided.

2. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)

The board is directed by SB 472 to develop patient-centered prescription labels. At the January 27, 2009, Public Education Committee meeting, the committee reviewed each prescription label requirement specified in California Business and Professions Code section 4076 and selected those with the greatest importance to consumers.

The committee generated a basic list that identified three key items of most importance to a patient using a medication and the container's label:

- trade name/ generic name,
- directions
- strength

Dr. Swart provided that Michael Wolf, PhD has also contributed to this list. He added that the board's survey results are consistent with the content of this list.

No board or public comment was provided.

3. Directions for Use on Prescription Labels

Dr. Swart provided that Dr. Wolf, who is an expert in the area of label design, has developed a list of standardized directions. He indicated that Dr. Wolf states that about 90 percent of all directions for use will fit into one of these statements. Dr. Swart stated that standardizing the direction on labels will alleviate confusion and will help to improve compliance.

No board or public comment was provided.

4. Additional Discussion on SB 472

Ms. Herold reviewed the requirements of SB 472.

Board Discussion

Dr. Castellblanch discussed the issue of medical errors and the importance of focusing efforts on creating patient-centered labels.

The board discussed the balance required in order to provide patient-centered labels while maintaining and implementing realistic elements.

Mr. Lippe discussed the demographics and linguistic barriers involved with regards to medical errors.

Ms. Wheat provided that health literacy also represents a problem. She emphasized that the board should work to best serve the needs of the population.

President Schell discussed studies regarding consumer comprehension and interpretation. He explained that SB 472 represents an important starting point and stressed that physicians will need to become involved. President Schell advised that the instruction “use as directed by a physician” will likely be eliminated.

Dr. Castellblanch spoke to the genesis of the bill and data such as the average reading level of citizens.

Ms. Herold asked if the regulation should prohibit the use of the instruction “use as directed by a physician.”

Discussion continued regarding the benefits of removing the instructions from the label.

Dr. Castellblanch discussed the efforts of the medication error panel. He explained that the panel identified patient-centered labels as an obtainable step towards decreasing the number of medication errors.

The board discussed the possible involvement of the Medical Board. It was advised that the mandate for patient-centered labels must begin at the pharmacy level.

Ms. Herold provided that standardizing the format for labels may eliminate the use of established labels by a variety of pharmacies.

Ms. Herold highlighted the following general rules for patient-centered labels:

- Text in a specified font (based on the print world)
- Use numerals (not text) for numbers
- Cluster patient-centered information in one area of the label ("chunking")
- Okay to use highlighting and bold to emphasize important information
- Standardize directions

Ms. Sodergren provided that the committee discussed the use of the "check book" model where specific information on a prescription label would be standardized – i.e., consistently listed in a specific area of the label.

Dr. Castellblanch reviewed two main issues discussed during the committee meeting including the "Spanish" issue regarding the ease of use for Spanish speaking consumers and the "real estate" issue. Dr. Castellblanch explained that the "real estate" issue involves how much space can be used on a label. He stated that Target's bottle and label was referenced as a model label for maximizing space and wider reading area.

The board discussed the impact of mandating the use of a square bottle instead of the more common cylindrical bottle. Other label and bottle formats were discussed.

Mr. Weisser questioned if there are pharmacies in California that do not have a system to allow a label to be printed in Spanish.

President Schell responded that it is likely that there are pharmacies without this capability.

Discussion continued regarding the impact of implementing the "check book" model.

Dr. Castellblanch suggested that if labels were standardized a provision could be included to allow pharmacies to use their current supply of labels before implementing the new standardized label.

Ms. Herold provided that the board may not have this authority. She stated that the regulation requires the changes to be in effect by January 1, 2011.

The board discussed the option of holding an additional meeting to further discuss SB 472.

There was no additional board discussion. No public comment was provided.

D. Discussion and Possible Action to Initiate Rulemaking to Adopt §1707.5 Relating to Patient-Centered Prescription Container Labels

Mr. Swart highlighted the committee's discussion of this issue and the draft of the proposed labeling regulation.

No board or public comment was provided.

E. Strategic Plan Update for the Communication and Public Education Committee for 2009/10 and Discussion of Future Activities of the Committee.

Dr. Swart referenced to the Strategic Plan Update for the Communication and Public Education Committee contained within the board packet.

MOTION: To adopt the committee's recommendation to approve the Strategic Plan Update for the Communication and Public Education Committee for 2009/10.

Approve: 6 Oppose: 0 Abstain: 1

No board or public comment was provided.

F. Fourth Quarterly Report on Committee Goals for 2008/09

Dr. Swart referenced to the fourth quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

No board or public comment was provided.

G. Public Comment

No public comment was provided.

Ms. Herold provided an update on the October 2009 Board Meeting. She indicated that the meeting will likely take place in Sacramento unless a meeting room is made available in San Francisco.

President Schell confirmed that the board meeting will be held October 21- 22, 2009.

The board resumed its discussion of the Organizational Development Committee Report.

VII. Organizational Development Committee Report and Action

G. Approval of the Board of Pharmacy's Strategic Plan for 2009/10

MOTION: To approve the Board of Pharmacy's Strategic Plan for 2009/10.

M/S: Weisser/Swart

Approve: 6 Oppose: 0 Abstain: 1

H. Fourth Quarterly Report on the Committee's Goals for 2008/09

President Schell referenced to the fourth quarterly report on the Organization Development Committee's goals contained within the board packet.

No board or public comment was provided.

I. Election of Vice-President for 2009/10

MOTION: To elect Randy Kajioka as vice president of the Board of Pharmacy.

M/S: Weisser/Swart

MOTION: To close further nominations.

Approve: 6 Oppose: 0 Abstain: 1

J. Public Comment

No public comment was provided.

VIII. Closed Session

The board moved into closed session pursuant to Government Code section 11126(e), to confer with and receive legal advice from counsel (Carol Marie Zalez-Simon v. California Board of Pharmacy, Los Angeles Sup.Ct.,Case No. BS116965).

IX. Petition for Reinstatement

The board reconvened for a public open session at 11:30a.m.

Administrative law judge, Vincent H. Nafarrete, conducted a hearing to consider the petition for reinstatement for:

- Jennifer West-Lackey

X. Closed Session

The board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate on the petition for reinstatement.

The board also concluded deliberations on disciplinary matters pursuant to Government Code section 11126(e).

The meeting was adjourned at 12:41 p.m.

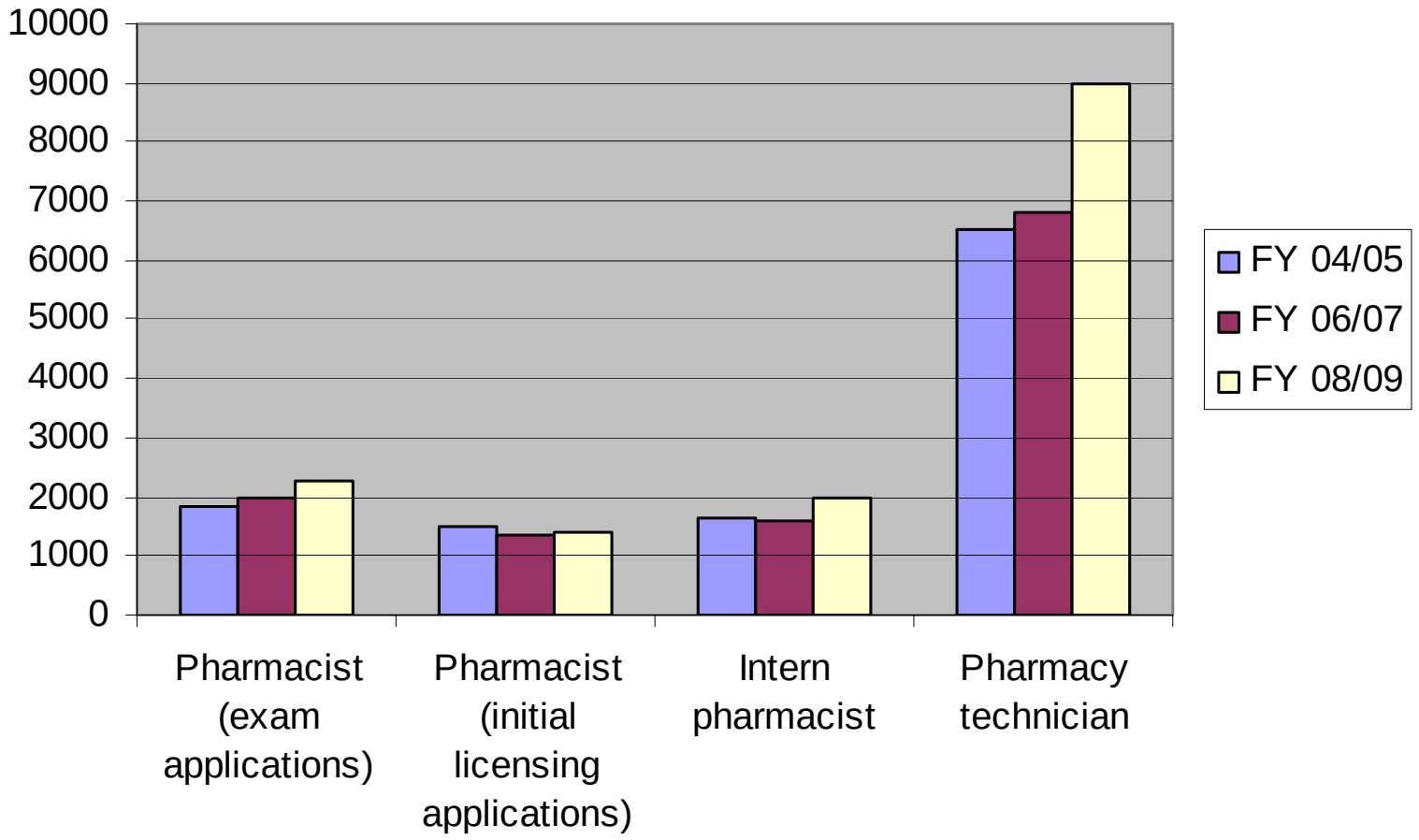
Licensing Statistics

Fiscal Year Comparison

Applications Received

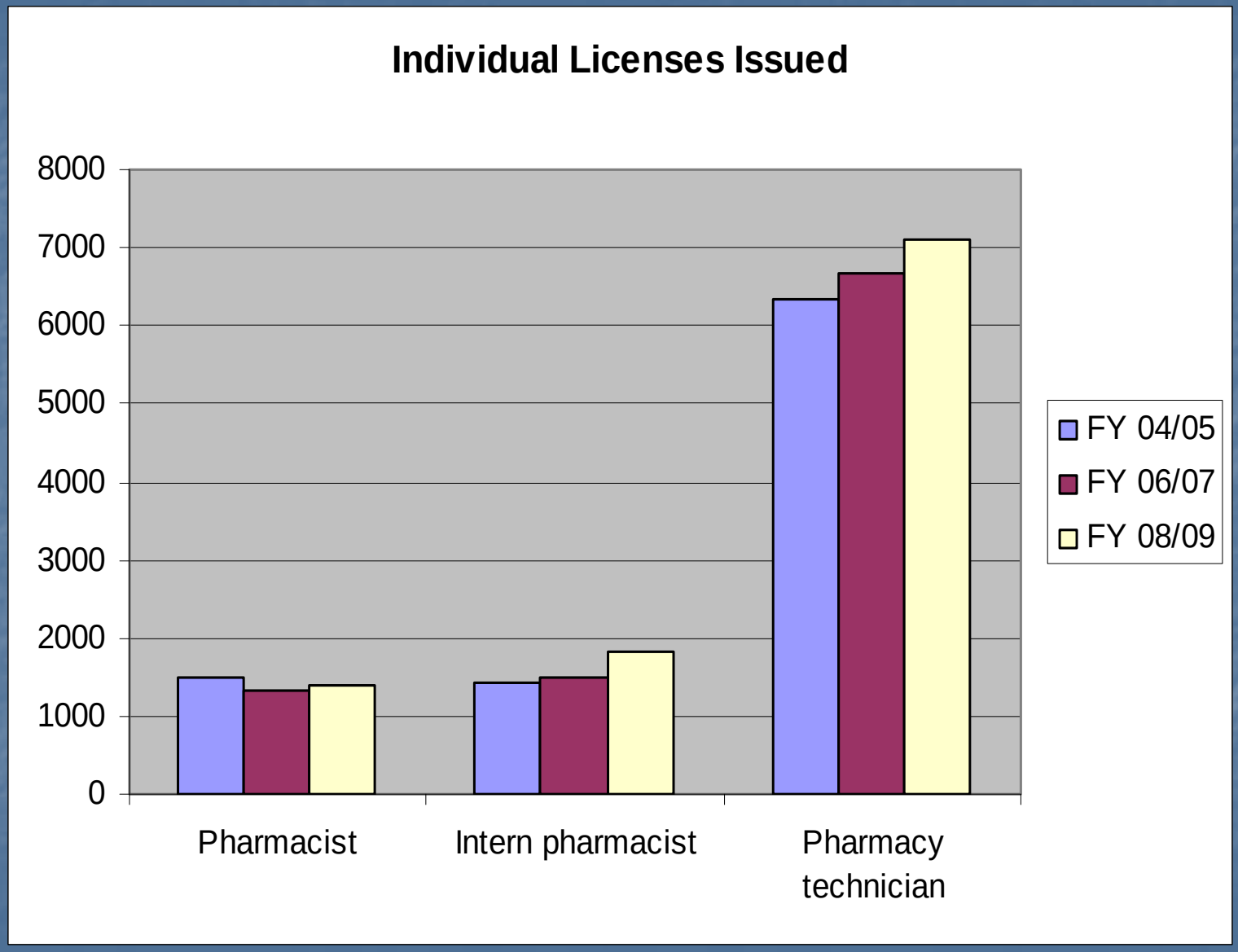
	FY 04/05	FY 06/07	FY 08/09	% Growth
Pharmacist (exam applications)	1850	1999	2276	23
Pharmacist (ILF)	1477	1363	1391	-6
Intern Pharmacist	1622	1614	1983	22
Pharmacy Technician	6514	6810	8978	38
Pharmacy	342	432	873	155
Sterile Compounding	68	42	58	-15
Clinic	145	60	89	-39
Hospital	35	25	12	-66
Nonresident Pharmacy	77	72	85	10
Licensed Correctional Facility	1	0	1	0
Hypodermic Needle and Syringe	26	14	29	12
Nonresident Wholesaler	114	106	106	-7
Wholesaler	90	64	69	-23
Veterinary Food-Animal Drug Retailer	2	1	3	50
Designated Representative	498	384	457	-8

Individual Applications Received



Licenses Issued

	FY 04/05	FY 06/07	FY 08/09	% Growth
Pharmacist	1496	1341	1409	-6
Intern Pharmacist	1417	1506	1820	28
Pharmacy Technician	6332	6665	7096	12
Pharmacy	346	463	796	130
Sterile Compounding	47	54	64	36
Clinic	137	79	67	-51
Hospital	33	18	29	-12
Nonresident Pharmacy	65	38	80	23
Licensed Correctional Facility	1	0	2	100
Hypodermic Needle and Syringe	26	20	14	-46
Nonresident Wholesaler	80	82	84	5
Wholesaler	62	53	41	-34
Veterinary Food-Animal Drug Retailer	4	3	4	0
Designated Representative	453	370	442	-2


Individual Licenses Issued
8000
7000
6000
5000
4000
3000
2000
1000
0
Pharmacist
Intern pharmacist
Pharmacy technician
FY 04/05
FY 06/07
FY 08/09

Licenses Renewed

	FY 04/05	FY 06/07	FY 08/09	% Growth
Pharmacist	14983	16208	17309	16
Pharmacy Technician	18429	22790	26231	42
Designated Representative	1770	2200	2027	15
Pharmacy	5901	6689	6216	5
Sterile Compounding	136	228	243	79
Clinic	751	896	959	28
Nonresident Pharmacy	195	238	251	29
Hypodermic Needle and Syringe	229	276	256	12
Nonresident Wholesaler	309	359	420	36
Wholesaler	417	437	435	4
Veterinary Food-Animal Drug Retailer	18	18	24	33

FY 08/09 based on prelimary numbers available

Total License Count

	FY 04/05	FY 06/07	FY 08/09	% Growth
Pharmacist	32875	35093	37298	13
Intern Pharmacist	4113	4261	4952	20
Pharmacy Technician	45609	51667	58752	29
Pharmacy	5824	6011	6185	6
Sterile Compounding	198	262	322	63
Clinic	988	1083	1122	14
Hospital	539	540	534	-1
Nonresident Pharmacy	278	318	377	36
Hypodermic Needle and Syringe	293	306	312	6
Nonresident Wholesaler	410	495	602	47
Wholesaler	483	494	513	6
Veterinary Food-Animal Drug Retailer	19	21	27	42
Designated Representative	2459	2502	3263	33

Enforcement Statistics

Board of Pharmacy

FY 2004/05 – 2008/09

Complaints/Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**1480**	**2285**	**2515**
Closed	**1985**	**1657**	**2146**
Pending (at the end of FY)	**655**	**1484**	**2742**

Cases Pending by Team

	FY 04/05	FY 06/07	FY 08/09
Compliance Team	**87**	**94**	**194**
Drug Diversion/Fraud	**89**	**82**	**202**
Mediation/Enforcement Team	**108**	**322**	**126**
Probation/PRP	**40**	**61**	**98**
Criminal Conviction*			**1410**

* Unit Established Jan. 2009

Application Investigations

	FY 04/05	FY 06/07	FY 08/09
Initiated	**129**	**298**	**351**
Closed	**149**	**147**	**288**
Total	**149**	**147**	**288**
Pending (at the end of FY)	**39**	**186**	**338**

Citation and Fines

	FY 04/05	FY 06/07	FY 08/09
Issued	754	735	965
Closed	1004	657	1064
Total Fines Collected	$428,904.00	$436,711.70	$ 1,175,475.00

Administrative Cases

	FY 04/05	FY 06/07	FY 08/09
Referred to AG's Office	113	94	136
Pleadings Filed	73	88	72
Pending			
Pre-accusation	59	62	137
Post Accusation	77	56	99
Total	173	147	267
Closed	80	128	71