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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: October 20 and 21, 2010

LOCATION: UC San Diego
Health Sciences Education Center Auditorium
9500 Gilman Drive
La Jolla, CA 92093

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD
Shirley Wheat, Public Member
Deborah Veale, RPh

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Janice Dang, Supervising Inspector, 10/20
Judi Nurse, Supervising Inspector, 10/20
Joshua Room, Deputy Attorney General
Kristy Schieldge Shellans, DCA Staff Counsel
Tessa Fraga, Staff Analyst

General Announcements

1. General Announcements

President Stan Weisser recognized former board presidents in attendance at the meeting: Raffi Simonian and Stan Goldenberg. He also recognized Arizona Board of Pharmacy Member Dennis McAllister and California Pharmacists Association (CPhA) Chief Executive Officer Lynn Rolston.

The board discussed agenda item III. prior to calling the meeting to order and proceeding with agenda item II. as a quorum was not present.

III. Report of the Director of the Department of Consumer Affairs

Kim Kirchmeyer, Deputy Director for Board and Bureau Relations, provided an update on the department's current activities.

Ms. Kirchmeyer discussed the Governor's directed hiring freeze. She indicated that the department is seeking exceptions; however, these exceptions are limited and only the most critical requests have been approved.

Ms. Kirchmeyer provided an update on the Consumer Protection Enforcement Initiative (CPEI). She stated that the department is encouraging all boards to move forward with implementation of SB 1111 regulations. Ms. Kirchmeyer indicated that the department will be moving forward with recruitment for the 138 positions secured by the Legislative Budget Change Proposal and will complete this process when the hiring freeze is lifted. She advised that an exemption request has been submitted for these positions.

Ms. Kirchmeyer reviewed the implementation progress for BreEZe, an automated licensing and enforcement system that will replace the current outdated legacy systems.

She stated that potential vendors are working in-house with department subject matter experts to review requirements. Ms. Kirchmeyer indicated that a request for proposal should be released by the end of 2010. She suggested that Chief Information Officer Debbie Balaam provide a presentation to the board to review this new system. Ms. Kirchmeyer provided that several workgroups have been established for the implementation process.

Ms. Kirchmeyer provided that the department is obtaining data for the eight enforcement performance measurements to be posted on both the department and board Web sites beginning in November 2010. She encouraged the board to review its current enforcement timelines. Ms. Kirchmeyer thanked the board for moving forward with the Healthcare Integrity and Protection Data Bank (HIPDB) regulation and self-query requirement.

Ms. Kirchmeyer discussed SB 1441 and encouraged the board to move forward with the regulatory process to implement the uniform standards.

Ms. Kirchmeyer thanked the board for adding health care reform as an agenda item and encouraged continued evaluation of the impact of this issue.

Ms. Kirchmeyer discussed a drug testing threshold error with the contractor and subcontractor for the department's Health Professionals Diversion Contract. She provided that the threshold error has been corrected. Ms. Kirchmeyer advised that the department will be performing a comprehensive evaluation of this issue. She stated that the department is requesting that boards review any current drug testing contracts to ensure that the appropriate thresholds are being used.

No public comment was provided.

A quorum of the board was established. Board Members Weisser, Kajioka, Lippe, Castellblanch, Hackworth, Schell, Wheat, and Veale were in attendance.

Call to Order

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

II. Approval of the Full Board Meeting Minutes of July 28 and 29, 2010

MOTION: Approve the minutes of the July 28 and 29, 2010 Board Meeting.

M/S: Weisser/Veale

Support: 7 Oppose: 0 Abstain: 0

IV. Executive Officer's Report

Executive Officer Virginia Herold presented a report on the recent challenges facing the board including reduced staff resources and limited resources as a result of budget restrictions and changes in the purchasing process.

Ms. Herold reviewed significant board activities. She encouraged the board to develop guidelines for e-prescribing of controlled substances and to consider the establishment of an ad hoc task force in this area due to the highly technical requirements in the DEA's rule. Ms. Herold also requested that the board direct staff to revise the board's disciplinary guidelines.

Ms. Herold highlighted the following major accomplishments:

- Enforcement (2005/06 – 2009/10)
  - 28 percent increase in complaints received
  - 143 percent increase in complaints completed
  - 746 percent increase in application investigations
  - 600 percent increase in application investigations completed
- Licenses Issued (2005/06 – 2009/10)
  - Pharmacist: 12 percent increase
  - Intern: 30 percent increase
  - Pharmacy Technician: 95 percent increase
- Licenses Issued (2009/10)
  - Sites: 1,052 issued
  - Other applications (including change of permits, change of pharmacist-in-charge, etc.): 2,264
  - Total issued in 2009/10: 14,751
- Governor's Job Creation Initiative (March-June 2010; Encouraging work on furlough days for licensing activities)
  - 66 percent increase in applications approved
  - 79 percent increase in licenses issued
- Regulations Adopted
  - Patient-centered labels
  - Dishonest conduct during exam
  - Mandatory fingerprint submissions
  - Compounding
- Communication and Public Education
  - NPDB/HIPDB reporting deemed "compliant"
  - Medication error video produced
  - 10 CE presentations
  - Two issues of *The Script*
  - Consumer outreach activities
  - Outreach activities (Topics included e-pedigree, compounding regulations, and drug thefts)
- Organizational Development
  - Secured 24.5 new positions
  - Administered inspector exam
  - Developed 15 percent reduction plan for operating expenses
  - Developed salary reduction plan (to achieve Governor's 5 percent permanent cut)

Deborah Veale asked where collected fine money is deposited.

Ms. Herold provided that this money is deposited into the board's fund. She explained that this money must be appropriated in the state budget prior to being used for board expenses.

Ken Schell asked whether electronic forms are being considered with the new BreEZe system.

Assistant Executive Officer Anne Sodergren provided that BreEZe will include an electronic interface to allow people to either submit forms electronically or to download. She advised that the self assessment form will not be part of this process; but, may be available on the board's Web site.

Ramón Castellblanch sought clarification regarding the furlough exemption which allowed board staff to perform licensing functions on furlough days.

Ms. Herold provided that staff were allowed to work and banked this time to be used as a deferred furlough day.

Public Comments

John Cronin, representing the California Pharmacists Association (CPhA), sought clarification regarding the CPEI and the addition of new enforcement positions. He expressed concern regarding the board's increased workload and understaffing in enforcement.

Ms. Herold provided that the board will fill these positions upon approval of an exemption or lift of the hiring freeze.

Ms. Sodergren provided that there is currently no end date for the hiring freeze.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), asked whether the Organizational Development Committee will be providing a timeline for the outreach on patient centered labels.

Ms. Herold provided that the Communication and Public Education Committee will hold a future meeting to further discuss this issue. She stated that the board will continue to disseminate information to its licenses in *The Script* and via subscriber alerts. Ms. Herold advised that the public outreach campaign will intensify after industry has had time to implement the requirements.

Raffi Simonian, representing the University of California, San Diego, asked which division of the government would grant the hiring freeze exemption.

Ms. Herold indicated that the executive branch, and specifically the Governor's office, must grant the exemption.

Dr. Simonian sought clarification regarding the implementation date for online license renewal.

Ms. Kirchmeyer provided that the department is aiming for mid-2013.

Dr. Simonian asked if it is expected that form revisions and electronic forms will help to diminish application deficiencies.

Ms. Sodergren provided that the form standardization process will help to identify and address these issues.

Ms. Herold provided that the revised forms will be implemented prior to the implementation of BreEZe.

A member of the public asked for clarification regarding the composition of the e-prescribing task force.

Ms. Herold provided that the task force will consist of two board members and encourage participation of outside members of expertise.

Meredeth Cone discussed dishonest conduct during exams and asked for more information on this issue.

Ms. Herold reviewed recent amendments to 16 CCR § 1721 and § 1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

There was no additional board discussion or public comment.

V. Organizational Development Committee Report and Action

a. Budget Update/Report

1. Final Budget Report for 2009/10

President Weisser provided that during the July Board Meeting, the board was provided with preliminary budget figures for the fiscal year that ended June 30, 2010. He indicated that board staff obtained the final budget report in August 2010.

President Weisser provided that the final budget figures show that the board collected $11,121,471 in revenue. He stated that about 85 percent of the revenue comes from fees, with cite and fine and cost recovery and interest generating almost fifteen percent of the board's revenue.

President Weisser reviewed the graphic depiction of final revenue and expenditure charts for 2009/10 contained in the board packet.

No public comment was provided.

2. Budget Reports for 2010/11

President Weisser provided that on October 9, 2010, the Governor signed the 2010/11 budget. He stated that the board's authorized expenditures are $13,470,000. President Weisser indicated that the budget contains a provision that will allow the board, upon request by the department and approval by the Department of Finance, to augment the amount of expenditure to pay the Attorney General enforcement costs up by up to $200,000 and a similar augment to the Office of Administrative Hearing by up to $40,000.

President Weisser provided that included in this budget is a budget augmentation of $2,668,000 this year to establish 22.5 new positions in the board's enforcement unit and 2 new positions in the licensing unit. He stated that these staff are necessary to meet the department established goal to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. President Weisser indicated that this is a primary outcome of the Consumer Protection Enforcement Initiative (CPEI). He explained that the additional licensing staff are necessary to address the significant increase in pharmacy technician applications the board continues to receive as well as the increase in workload associated with processing several other types of applications (including change in pharmacist-in-charge form and processing discontinuance of business forms).

President Weisser referenced the graphs depicting board revenue for the first two months of the fiscal year 2010-11 as well as projected expenditures for 2010-11 provided in the board packet.

No public comment was provided.

3. Fund Condition Report

President Weisser provided that according to a fund condition report prepared by the department, the board will have the following fund conditions at the end of the identified fiscal years:

2009/10	$12,411,000	11 months in reserve (actual)
2010/11	$9,354,000	8.2 months in reserve
2011/12	$6,030,000	5.1 months in reserve
2012/13	$2,274,000	1.9 months in reserve

President Weisser provided that with the passage of the board's fee bill, AB 1071 (Emmerson, Chapter 270, Statutes of 2009) the board's reimbursements increased the last 6 months of the 2009/10 fiscal year with the higher fee schedule. He stated that the board will continue to closely monitor its fund condition before increasing any additional fees. President Weisser indicated that

with the new fee structure incorporated in AB 1071, the board does have the ability to raise fees via the regulation process when necessary.

No public comment was provided.

4. Budget Change Proposals for the 2010/11 Budget

   President Weisser provided that during its last meeting, the committee identified budget change proposals (BCPs) to pursue. He stated that these proposals have been submitted to the department.

   No public comment was provided.

5. Reimbursement to Board Members

   President Weisser referred to the report on expenses and per diem payments to board members provided in the board packet.

   No public comment was provided.

6. BreEZe Progress

   Background

   For a number of years the department has worked to replace and/or enhance the legacy licensing and enforcement tracking systems. A few years ago, the department initiated an I-Licensing project which would offer online application and renewal of licenses (a much needed relief from mail-in renewals).

   This project was recently replaced as a component in DCA's proposed Enforcement System upgrades with a new proposal, BreEZe, which will allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. Both systems are legacy systems. This new project will piggyback on the efforts of the initial I-Licensing system sought and will ultimately allow for improved services for applicants and licensees as well as provide for a more robust internal computer system.

   The board is about 2-3 years away from changing to this new system. The executive officer has been an executive sponsor of this project, and periodic meetings have resumed after some staff changes in the Office of Information Services. In addition, we have staff working with the department to ensure

the new solution can fulfill business requirements necessary to carry out our functions.

Recent Updates
The executive officer continues to serve on the steering committee for this project. In addition, staff continues to work as subject matter experts defining business requirements as time allows and have begun participating in various workgroups established to facilitate implementation of this new system.
The department will begin holding Town Hall meetings with various programs within the DCA to discuss the new system.

President Weisser referred to the information provided during the reports by Ms. Kirchmeyer and Ms. Herold regarding the BreEZe system.

No public comment was provided.

7. Board of Pharmacy Committee Membership Roster

President Weisser referenced to the committee membership roster provided in the board packet.

No public comment was provided.

b. Review and Comments on the Finalized Strategic Plan for 2010/11

Ms. Herold provided that during the July 2010 Board Meeting, the board voted on recommended changes to the strategic plan. She stated that the strategic plan has been updated to include the changes approved by the board.

No public comment was provided.

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

President Weisser provided that the board will continue to recognize pharmacists with 50 or more years of licensure as pharmacists in California.

Ms. Herold provided that since July 2005, the board has acknowledged 1,057 pharmacists who have reached this milestone.

No public comment was provided.

d. Personnel Update

President Weisser highlighted the following updates:

1. Board Member Vacancies

There are currently ten board members, and three board member vacancies. The vacant positions are all Governor appointments and are for one public member and two pharmacist members.

2. Staff Changes

Effective August 30, 2010, a hiring freeze was implemented which prohibits the board from filling any vacancies. At the time the freeze order was issued, the board was actively recruiting to fill several vacancies for office and inspector staff. These vacancies were as a result of employees transferring to other state agencies, retirements, as well as the additional staff positions the board received through the BCP process. All efforts were stopped in response. Recruitment efforts for these positions were in various stages and are indicated below. Efforts will resume when the freeze is lifted or exemptions are approved through the Governor's office.

Below is a listing of current board vacancies:

- Office Technician primarily responsible for processing pharmacist exam applications and issuing examination results. (The prior employee, Susy Sykes, transferred to another state agency on August 30, 2010.) Interviews had been conducted and a final candidate selected, but eligibility had not yet been confirmed prior to the freeze.
- Office Technician primarily responsible for change of pharmacist-in-charge applications and discontinuance of business forms. This position was newly established via the BCP process. Interviews had been conducted and a final candidate selected, but eligibility had not been confirmed prior to the freeze.
- Staff Services Analyst position primarily responsible for completing desk investigations on reports of out of state discipline and continuing education violations as well as provides support to board members and executive officer. (The prior employee, Susan Williams accepted a promotion with another state agency.)
- 21 Inspector positions. Two inspectors retired last fiscal year and the remaining positions are newly established via the BCP process as a result of the Consumer Protection Enforcement Initiative. The board conducted both the civil service exam and conducted interviews.
- 3 Supervising Inspector positions. These positions are newly established via the BCP process as a result of the CPEI. The civil service exam was administered and we are awaiting the list of eligible candidates. Interviews will be scheduled when possible, but final offers cannot be made until either the freeze is lifted or an exemption is approved.

No public comment was provided.

e. First Quarterly Report on the Committee's Goals for 2010/11

President Weisser referenced the first quarterly report on the Organizational Development Committee's goals contained in the board packet.

No public comment was provided.

f. Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), expressed concern regarding the accuracy of the fund condition data because the fund condition always indicates about the same level of months of budget expenses in reserve.

Ms. Herold provided that the data is a conservative estimate and is provided by the department.

Dr. Schell suggested that sequential projections and explanations be provided to reflect the changes in the fund condition report.

Joshua Room, Deputy Attorney General, provided that the board is required by statutory mandate to maintain a one year reserve.

Ms. Kirchmeyer discussed that the projections reflect a point in time.

There was no additional public comment.

VI. Communication and Public Education Committee Report and Action
There has been no meeting of the Communication and Public Education Committee during this quarter

Ms. Herold discussed agenda item VI. C regarding a letter sent to nonresident pharmacies about updates in California pharmacy law. She stated that to ensure that all board nonresident pharmacies are aware of new requirements in California (e.g., registration with the subscriber alert system, the coming patient-centered labeling for prescription container labels), board staff recently mailed to nonresident pharmacies a brief law update. Ms. Herold indicated that to date, the result of this mailing has produced several contacts to the board from pharmacies that were not aware of these requirements.

Ms. Herold provided that board staff will soon produce a similar letter for mailing

to California-based licensed facilities so they are similarly aware of new developments. She indicated that the announcements will also be placed online and noticed via a subscriber alert. Ms. Herold stated that the intent for these mailings will be to enclose them with renewal materials as a cost savings measure.

The board did not discuss the following items as they were previously discussed during the Executive Officer's report.

a. Review of Board of Pharmacy Video Developed by the Department of Consumer Affairs on Purchasing Drugs on the Internet

Background

At the end of 2009, the Board of Pharmacy worked with the Department of Consumer Affairs and a private vendor to develop a three minute video for consumers about how patients can prevent receiving a medication error. This video is available from the board's Web site.

The board and department were pleased with this video.

After production of this video, the board's staff has expressed an interest to the Department of Consumer Affairs in developing additional videos. Meanwhile, the DCA has hired video staff of its own, and thus could produce future videos in-house.

Update

The board and DCA are collaborating to develop a new video on the dangers of buying drugs from the Internet, and how to do so wisely. At the July 2010 Board Meeting, the board had the opportunity to review the script.

Board staff reviewed a draft of the Internet video last week and have asked for modifications to strengthen the message. We hope to complete this video before the end of the year.

Meanwhile, staff will begin working on another video to highlight the new consumer-centered patient labels for release next year.

b. Update Report on *The Script*

The August 2010 issue of *The Script* has been completed and released. It is available on the board's Web site. The issue has an update of various board activities, including an article on the new patient-centered regulations. Sample labels that conform to the board's proposed requirements are provided within the newsletter and are also available online at the board's Web site.

The August issue of *The Script* is the first to be published and released electronically, rather than in print. This conversion will allow the board to comply with budget restrictions, and save at least $25,000 annually. This redirection is possible since existing law requires that all licensed facilities join the board's email subscriber list; hence, we can readily contact licensed sites and interested individual licensees (as well as others) who are interested in receiving these notices.

Work has begun on the January 2011 edition, which will highlight new or amended pharmacy laws that become effective on January 1.

Agenda item c discussed above.

d. Update on Public Outreach Activities

The board provided information about California Pharmacy Law and board programs at two consumer conferences, nine industry/association meetings and to two student groups.

e. Progress Report on the Review of Consumer Education Materials

Background

The board has not assessed its public education materials for some time. New board members, new interests and the periodic need to determine priorities for future activities warrant such review. Ultimately, the outcome of this evaluation needs to be blended into the board's strategic plan for the future.

The board has one part-time staff person assigned to this function. Recently this part-time staff member has been reassigned to report disciplinary data to the Health Practitioner Data Bank. A retired annuitant develops the board's newsletter *The Script* twice annually. The executive officer and other staff prepare periodic reports to the department, administration, legislature and public (e.g., Addressing Drug and Device Recalls in Hospitals, SB 472's Implementation Report to the Legislature, Board-Sponsored Legislation Report, Annual Report).

At the July Communication and Public Education Committee, Chairperson Brooks designated Board Members Veale and Castellblanch to work with staff on an assessment of the board's public outreach materials and bring a report back to the committee for a thorough discussion.

f. First Quarterly Report on Committee Goals for 2010/11

President Weisser referenced the first quarter's Committee Goals contained within the board packet.

No public comment was provided.

VII. Presentation from Manatt Health Solutions on Implementation Effects of Federal Healthcare Reform and Discussion by the Board

Sandra Newman, representing Manatt Health Solutions, provided an overview on the Patient Protection and Affordable Care Act which became effective March 23, 2010. The act puts in place comprehensive health insurance reforms that will hold insurance companies more accountable, lower health care costs, guarantee more health care choices, and enhance the quality of health care for all Americans.

Ms. Newman reviewed provisions impacting pharmacy including:

- Expanded access under Medicare Part D including:
  - 50 percent discounts on brand name prescriptions filled under Medicare Part D
  - Reduced coinsurance for brand name prescriptions filled under Medicare Part D
  - $250 rebates
- Grant funds to support pharmacists' role in medication therapy
- Pharmacist involvement in new models of patient-centered, coordinated care
- Durable medication equipment changes
- Disclosure by pharmacy benefit managers to increase transparency
- Medicaid reimbursement of generic drugs
- Expansion of the number of covered entities that are eligible to receive drug discounts under the 340B Drug Pricing Program
- Dispensing techniques that reduce drug waste
- Increased oversight on fraud and abuse efforts
- Bonus payments to Medicare advantage plans for care coordination

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), discussed the expansion of medication therapy management as well as the expansion of collaborative practice pilots. He suggested that the board coordinate a task force with other disciplines to evaluate regulation in this area.

Dr. Schell sought clarification on whether safeguards are in place to address the overutilization of the system such as overprescribing of medication.

Ms. Newman provided that there is a large federal effort to look at Comparative Effectiveness Research (CER) to address the most effective and efficient techniques used to treat certain diseases. She discussed that there is a focus on expanding coverage to prevent emergency department (ED) overutilization. Ms. Newman discussed that this issue is not a central component of the Affordable Care Act.

Randy Kajioka provided further comment on the abuse of ED services and abuse of other services with respect to EMTALA laws. He discussed that abuse of services is often out of the control of the provider in accordance with their obligation to ensure public access to emergency services and inability to validate an abuser's identity.

President Weisser asked whether or not the act address the need for more practitioners.

Ms. Newman provided that the act includes a number of workforce provisions. She stated that there is an acknowledgment that the current workforce is inadequate to meet the need.

Dr. Castellblanch discussed a provision to setup an agency for broad cost control in the event the act fails.

Stan Goldenberg stated that this act will truly change health care. He encouraged the board to be proactive in addressing these changes and enable legislation by establishing a collaborative task force in order to protect and serve the public.

There was no additional public comment.

VIII. Recognition of Pharmacists Licensed with the Board for 50 Years

No pharmacists celebrating 50 years of service were in attendance.

IX. Licensing Committee Report
Report and Action from the October 5, 2010 Committee Meeting

a. Review and Action Regarding Review and Approval of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

Greg Lippe provided that California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are 1) already licensed pharmacies, and 2) compound injectable sterile drug products. He indicated that these specialized pharmacies may be either hospital

pharmacies or community pharmacies. Mr. Lippe stated that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. He advised that this is the only category of board licensure that requires annual inspections as a condition of renewal.

Mr. Lippe provided that there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health

AND

- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board (JCAHO).

Mr. Lippe provided that currently there are three accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc. (ACHC), 2. Community Health Accreditation Program (CHAP), and 3. Det Norske Veritas (DNV).

Mr. Lippe provided that the board recently modified its regulations for pharmacies that compound medication. He indicated that included in these regulations are modified requirements for pharmacies that compound sterile injectable medication. Mr. Lippe stated that these regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, took effect July 6, 2010. (The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.)

Mr. Lippe stated that in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. Mr. Lippe indicated that it was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law, good professional practice standards and specific factors.

Mr. Lippe provided that during the April 2010 Board Meeting, the board directed that the following occur:

1. Review and assess the accreditation agencies
2. Report the findings to the Licensing Committee
3. Bring committee recommendations to the full board

Mr. Lippe provided that the board also voted to extend the approval of the two previously approved accreditation agencies, ACHC and CHAP, for one year until April 2011.

Mr. Lippe provided that during the September 2010 committee meeting, the committee was provided with a summary of the board staff's finding in evaluating

the accreditation process used by JCAHO as it compares to board criteria. (The committee was advised that the ACHC and CHAP were unable to attend the meeting and will be reviewed in the future.)

Supervising Inspector Janice Dang presented her findings of her review and assessment of JCAHO. She identified three primary concerns:

1. The use of nurses and no pharmacist on a survey team for pharmacy review.
2. If a new facility is established that is located off site of the main hospital campus, would the accreditation be automatically extended or would a new survey be required.
3. One pharmacy that was reviewed was more "relaxed" on accreditation standards because they have not been reviewed or surveyed by JCAHO more frequently.

Mark Crafton, representing JCAHO, addressed Dr. Dang's concerns. He stated that, given the large number of entities JCAHO accredits, it would be a challenge to have a pharmacist participate in all surveys. Mr. Crafton provided that JCAHO will try to include a pharmacist when possible. He provided that an extension survey will be completed within 4-6 weeks for new acute care hospitals opened by an accredited facility. Mr. Crafton explained that a new survey will not be conducted for ambulatory clinics, rather, the survey will occur as part of the next routine review for the general hospital.

Mr. Lippe reviewed the committee's recommendation to request that pharmacists participate in the surveys when possible and if not, the next best candidate should complete the survey.

Dr. Schell asked whether JCAHO intends to increase the number of pharmacists employed by the organization to allow for more frequent survey participation by pharmacists.

Mr. Crafton provided that JCAHO consistently has openings for pharmacists. He explained that work on survey teams is intermittent.

President Weisser asked for clarification regarding the qualifications that a possible "best candidate" applicant would have.

Mr. Crafton provided that in the community or hospital pharmacy setting, the next best candidate would be a registered nurse with infusion therapy experience who has been trained by a pharmacist on the JCAHO standards and has been evaluated for competency of these standards.

Supervising Inspector Robert Ratcliff asked whether the pharmacist surveyors are hospital or community pharmacists.

Mr. Crafton provided that there are six pharmacists on the survey team. He stated that this group consists of both community and hospital pharmacists and all have knowledge of infusion therapy.

Dr. Castellblanch expressed concern that there is not a commitment to have a pharmacist as a surveyor at all times.

Mr. Crafton provided that JCAHO can prioritize that community based pharmacies have a pharmacist surveyor; however, this is not likely for the surveying of hospitals.

Mr. Lippe asked how often the survey findings identify a problem given the current system. He questioned whether the findings from a survey team without a pharmacist are similar to those produced by a team with a pharmacist.

Mr. Crafton provided that generally every survey will indentify areas for improvement. He stated that there is no analysis between the discipline of the surveyor and the findings that are generated; however, this information can be provided to the board.

Ms. Herold asked if it is typical to have a licensed sterile injectable compounding area in the hospitals surveyed.

Mr. Crafton provided that this is dependant on the size and complexity of the services of the hospital.

Ms. Herold asked if surveyors are aware that they will be surveying for that specific function prior to the inspection.

Mr. Crafton provided that surveyors will not know this and that the application does not require that the entity disclose the depth and breadth of their pharmacy services.

Public Comment

Raffii Simonian provided that he has participated in 10 joint commission surveys, all of which did not include a pharmacist. He asked if there is a reason JCAHO has been unsuccessful recruiting pharmacists as surveyors. Dr. Simonian suggested that JCAHO partner with the California Department of Public Health (CDPH) in this area.

Mr. Crafton provided that salary and lifestyle issues (such as travel) may be possible deterrents for employment as a JCAHO pharmacist surveyor. He stated that retirees may be a possible source of surveyors. Mr. Crafton indicated that JCAHO currently partners with CDPH; however, CDPH is rarely able to participate in routine surveys due to budget restraints.

Ms. Herold provided that the board requires annual inspections for licensed sterile injectable compounding pharmacies. She discussed the importance of having a pharmacist with adequate knowledge of sterile compounding involved in these inspections. Ms. Herold offered to work with JCAHO to ensure that its accredited facilities meet the board's requirements.

Mr. Crafton provided that JCAHO monitors regulatory changes. He requested notifications regarding changes in California pharmacy law to ensure JCAHO surveyors are aware.

Robert Blackburn provided that surveying teams for the Accreditation Commission for Health Care (ACHC) always include a pharmacist. He stated that this should be required by the board. Mr. Blackburn commended board inspectors for their diligent efforts to ensure facilities accredited by ACHC are meeting sterile compounding requirements.

Dr. Kajioka asked if there is any available data regarding the amount of inspections performed and how many included a pharmacist as part of the survey team.

Mr. Crafton indicated that he can provide this information.

Ms. Veale recommended that the Licensing Committee revisit the issue of surveyor qualifications at its next meeting.

Mr. Lippe asked whether JCAHO would be able to comply if the board required that a pharmacist must participate in every survey.

Mr. Crafton provided that JCAHO accredits a larger volume of organizations than other accrediting bodies. He advised that this will make it difficult for JCAHO to comply.

Ms. Veale provided that all accrediting bodies, regardless of size, should adhere to the same requirements.

Dr. Schell discussed that JCAHO has been surveying pharmacies for many years. He stated that he is unaware of any reports of serious harm or significant issues as a result of survey teams without a pharmacist. Dr. Schell provided that while it is preferred that a pharmacist participate in the surveys, the board could consider whether it should require an additional survey by an agency that does include a pharmacist for facilities accredited by JCAHO.

There was no additional board discussion or public comment.

MOTION: LICENSING COMMITTEE: Request that JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.

Support: 6 Oppose: 1 Abstain: 1

b. Proposal to Initiate Regulation Changes Regarding Application Requirements for Intern Pharmacists and Pharmacists to Require "Self-Query" Reports From the National Practitioner's Data Bank --Healthcare Integrity and Protection Data Bank (NPDB--HIPDB)

Background

The board currently reports information regarding its licensees who have been disciplined or otherwise had an adverse action to the NPDB/HIPDB required by law. In addition to the board's reporting, all adverse actions taken by federal or state agencies, exclusions of health care practitioners in federal or state programs, criminal convictions, and civil judgments are also required to be reported to the NPDB/HIPDB. NPDB/HIPDB serves as the repository of data for all such actions taken against healthcare practioners.

Mr. Lippe provided that as part of the application process for both the intern and pharmacist exam application, applicants are required to self-disclose several items. He indicated that the intern application includes several questions surrounding prior disciplinary action that has ever been taken in this state or any other. Mr. Lippe stated that the pharmacist exam application includes several of the same types of questions as well as information about licensure in other states. This information is all self-certified by the applicant. In addition, the board requires license verification, where identified by the pharmacist applicant.

Mr. Lippe provided that at the July 2010 Board Meeting, the board approved a proposal to require pharmacists and pharmacist interns to provide a "self query" report from the NPDB/HIPDB as a condition of application for licensure in California.

Mr. Lippe reviewed the following proposed language:

Add Section 1727.2. Requirements for Pharmacist Intern.
Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Amend Section 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Dr. Castellblanch asked whether the application form will be changed.

Ms. Sodergren provided that this would not necessarily require a form change; but instead, notification on the instruction sheet regarding this new requirement in the application process. She stated that the board can also provide outreach to schools of pharmacy regarding the new requirement.

No public comment was provided.

MOTION: LICENSING COMMITTEE: Authorize the executive officer to initiate the rulemaking processes to adopt the language that has been proposed.

Support: 8 Oppose: 0 Abstain: 0

c. Proposal to Initiate Regulation Changes to Update the Pharmacy Technician Application and to Add an Application Requirement for Pharmacy Technicians to Require "Self-Query" Reports From the National Practitioner's Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB--HIPDB)

Background

At the July Board Meeting, staff advised the board that about 50 percent of the technician applications submitted to the board have one or more deficiencies. This slows the processing of the application and delays licensure for qualified applicants. Staff believes that proposed modifications to the application will help reduce processing time for applicants and ensure that those technicians disciplined by other states are known to the board before California issues a pharmacy technician license. As a result, the board directed staff to make modifications to the pharmacy technician application that will reduce the number of deficiencies in submitted applications.

The board subsequently directed staff to add a requirement that a "self query" report from the National Practitioner Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB/HIPDB) be added as an application requirement for pharmacy technicians.

Mr. Lippe advised that this proposal is similar to the proposal for intern pharmacists and pharmacists. He reviewed the following draft language:

§ 1793.5. Pharmacy Technician Application.

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 01/11) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as~~ a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). ~~In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.~~

(4) A sealed original Self Query from the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is/has been submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ subdivision (r) of section 4400 of the Business and Professions Code.

Kristy Schieldge Shellans, DCA Senior Staff Counsel, provided that a new application is required as the old revision date of the current form has been struck. She advised that language in subdivision (a)(3) has also been struck as it is duplicative of information on the new application.

No public comment was provided.

MOTION: LICENSING COMMITTEE: Authorize the executive officer to take all steps necessary to initiate a rulemaking to amend section 1793.5 of Title 16 of the California Code of Regulations, and to update the pharmacy technician application form and NPDB/HIPDB self-query report, as presented.

Support: 8 Oppose: 0 Abstain: 0

d. Request from PETNET Solutions for a Waiver of Security Requirements for Pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present

Mr. Lippe provided that PETNET Solutions, a radiopharmacy operating in 44 states, is petitioning the board to grant certain waivers to California Pharmacy Law to cover the following California pharmacies:
- PETNET Solutions, Inc, Palo Alto, license # PHY 48657
- PETNET Solutions, Inc., Sacramento, license # PHY 48660
- PETNET Solutions, Inc., Irvine, license # PHY 48659
- PETNET Solutions, Inc., Culver City, license # PHY 48658

Mr. Lippe provided that PETNET requested the following waivers:

1. Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a)

- Waiver Request: Allow personnel listed as Cyclotron Operator/Engineer on the Radioactive Material License access to the permitted space (licensed pharmacy area) during non-operational hours without the presence of a pharmacist for the sole purpose of maintenance and repair of the cyclotron, automated synthesis equipment, and quality control testing equipment.

2. California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d) and (f)

- Waiver Request 1714(d): Allow the CO (Cyclotron Operator/Engineer) access to the permitted pharmacy space by issuing cipher lock combination numbers to the CO. A conventional key will not be issued.
- Waiver Request 1714(f): Allow an applicant for a licensed premise or for a renewal of that license to certify that it meets the requirements of Section 1714 and to attach a copy of the waiver to said application, should the board grant a waiver, or comply with other actions as determined by the board.

Mr. Lippe provided that according to the board's attorneys, the board lacks the authority to waive California pharmacy law in the manner requested. He stated that the board has the ability to waive regulations of the board under conditions of 16 CCR section 1706.

Mr. Lippe provided that the committee did not take action on this item.

No public comment was provided.

The board took no action.

e. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Mr. Lippe provided that pharmacists are required to earn 30 hours of approved continuing education credit every two years as a condition of renewal. He advised that pharmacy technicians are not required to earn CE to maintain board licensure, although to be certified by the Pharmacy Technician Certification Board (a method to qualify for initial registration), they have a CE requirement.

Mr. Lippe provided that at several prior meetings of the board or its committees, including the last meeting of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific

subject matter areas. He stated that establishing such a requirement would take either a legislative or regulation change.

Mr. Lippe provided that the committee discussed previous content requiring continuing education as well as the requirements in other states that specify course content. He indicated that the committee identified some possible content areas ranging from patient consultation to ethics. Mr. Lippe stated that it was suggested that the committee may want to first determine the goal of the specific CE requirement.

Mr. Lippe provided that the committee did not take action on this item, but requested that it be brought back to the committee for further discussion.

No public comment was provided.

f. Department of Consumer Affairs' Request that Health Care Boards Evaluate the Federal Healthcare Reform Act's Impact on Present and Future Licensees and their Licensing Acts

Mr. Lippe provided that the committee was advised that in March, the Federal Health Care Reform Act was enacted federally and advised the committee that since that time, the director has asked that the board examine how it will affect how health care is delivered in California, particularly to prepare for larger number of patients.

Mr. Lippe provided that under a separate agenda item the board heard a presentation from Manatt Health Solutions on Implementing Effects of Federal Healthcare Reform.

No public comment was provided.

g. Competency Committee Report

<u>California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)</u>

Mr. Lippe provided that the board instituted a quality assurance review of the CPJE effective August 2, 2010. He stated that this process is done periodically to ensure the reliability of the examination. Mr. Lippe advised that this review has since been completed and exam results are currently being released as candidates take the exam.

Examination Development

Mr. Lippe provided that both Competency Committee workgroups met in August 2010 at the annual meeting to discuss examination development. He indicated that each Competency Committee workgroup will also meet once in the fall of 2010 for examination development. Mr. Lippe stated that each workgroup will ensure the new outline will be used to develop examinations administered after April 1, 2011.

Mr. Lippe provided that the committee took no action on this item

No public comment was provided.

h. Licensing Statistics 2010-11

Mr. Lippe referenced the licensing statistics for first quarter 2010/11 contained within the board packet.

No public comment was provided.

i. Minutes of the October 5, 2010 Licensing Committee Meeting

Chair Lippe referenced the summary of the meeting held on October 5, 2010 contained within the board packet.

No public comment was provided.

j. First Quarterly Report on Committee Goals for 2010/11

Mr. Lippe stated that the first quarterly report on the Licensing Committee's goals is contained within the board packet.

Dr. Schell asked for an update regarding the request submitted by UCSF to modify the intern hours requirement.

Ms. Herold provided that this issue has been postponed until after a meeting among the deans of the California schools of pharmacy at the California Pharmacy Council Meeting. She stated that the schools of pharmacy may need to send representatives to the board to have a discussion of pharmacy education and value of intern requirements.

No public comment was provided.

X. Enforcement Committee Report
Report and Action from the September 14, 2010 Enforcement Committee Meeting

a. Report on a Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations:

Dr. Kajioka provided that earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare.

1. 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions

Dr. Kajioka reviewed the first request:

> Modify regulation section 1745(c)(2) to allow pharmacies, when partially filling a Schedule II controlled substances prescription (C-II prescription), to modify a computer record instead of the prescription document itself. Currently, the board's requirements for partially filling a CII prescription are to annotate the prescription document itself.

Dr. Kajioka provided that the committee discussed a rulemaking change allowing pharmacies to maintain electronic records or document on the original prescription.

Ms. Herold indicated that the committee's recommendation does not direct the executive officer to initiate the rulemaking process for this amendment.

No public comment was provided.

MOTION: Enforcement Committee: Amend section 1745(c)(2) to read:

1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

Support: 0 Oppose: 7 Abstain: 1

MOTION: Direct the executive officer to initiate the rulemaking process to amend section 1745(c)(2) to read:

1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

M/S: Kajioka/Schell

Support: 8 Oppose: 0 Abstain: 0

2. 16 California Code of Regulations Section 1793.7 Regarding Requirements of a Pharmacy Employing Pharmacy Technicians

Dr. Kajioka reviewed Omnicare's second request:

> Allow a waiver of requirements in section 1793.7(a) to allow a pharmacy technician, and not a pharmacist, to perform the final check of medication if the container is bard coded.

Dr. Kajioka provided that in making its request to the board, Omnicare cites three scenarios for the dispensing of medication:

1. The medication container provided to the patient is bar coded by the manufacturer.
2. The medication container provided to the patient is bar coded by the pharmacy, under the supervision of a pharmacist.
3. The medication container is not bar coded.

Dr. Kajioka provided that Omnicare is requesting a waiver for bar-coded medications dispensed under conditions 1 and 2.

Dr. Kajioka provided that during the September 2010 Enforcement Committee Meeting, Omnicare was advised that the board does not have the authority to waive a regulation unless the procedure is part of an experimental program conducted with a school of pharmacy. He stated that board counsel suggested that if Omnicare intended to pursue this proposal, that they develop an experimental program with a school of pharmacy, and then return to the board.

No public comment was provided.

b. Questions and Answers About the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Dr. Kajioka provided that at the June 2010 Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010. He stated that Dr. Ratcliff requested that any additional questions from the public be submitted in writing so they can be added to the compounding question and answer document that has been posted on the board's Web site.

Dr. Kajioka provided that the committee has suggested that a small subcommittee be created to address questions regarding the compounding regulations to aid pharmacies in complying with the new requirements.

President Weisser provided that the subcommittee has been appointed and includes Board Members Randy Kajioka and Ken Schell as well as Supervising Inspectors Robert Ratcliff and Janice Dang.

No public comment was provided.

c. Report and Action on an Update on California's Drug "Take Back" Programs from Patients and Comments Submitted to CalRecycle Pursuant to Requirements in SB 966 (Simitian, Statutes of 2007)

Dr. Kajioka noted that at the 2010 July Board Meeting, the board reviewed a proposed draft of a CalRecycle report to the Legislature on the implementation of drug take back programs from patients seeking to destroy their unwanted medications.

He stated that staff was directed to provide comments on this draft.

Dr. Kajioka provided that during the week of October 11, 2010, the President signed the Secure and Responsible Drug Disposal Act of 2010, which amends the Controlled Substances Act to expand the ability of families to dispose of unwanted controlled substances.

Dr. Kajioka reviewed the following summary of the federal legislation.

SUMMARY AS OF:
9/29/2010--Passed House amended.
Secure and Responsible Drug Disposal Act of 2010 - Amends the Controlled Substances Act to allow an ultimate user of a controlled substance (or, if deceased, any person lawfully entitled to dispose of the ultimate user's property) who has lawfully obtained such substance to deliver that substance to another person, without being registered, for disposal if: (1) the person receiving the controlled substance is authorized to engage in such activity; and (2) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

Requires the Attorney General, in developing regulations under this Act, to consider the public health and safety, as well as the ease and cost of program implementation and participation by various communities.

Permits the Attorney General to authorize long-term care facilities to dispose of controlled substances on behalf of ultimate users who reside, or have

resided, at such facilities in a manner that will provide effective controls against diversion and that is consistent with public health and safety.

Directs the United States Sentencing Commission to review and, if appropriate, amend its guidelines and policy statements to ensure an appropriate penalty increase for persons convicted of a drug offense involving receipt of a controlled substance for disposal.

Ms. Herold provided that 242,000 pounds of drugs were collected during the September 2010 Drug Take-Back Day sponsored by the DEA.

No public comment was provided.

d. Report on the Presentation by Michael Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles

Dr. Kajioka provided that at the September 2010 Enforcement Committee Meeting, Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, provided information on DEA activities and objectives aimed at preventing drug diversion and prescription drug abuse. He indicated that Mr. Lewis addressed the following areas:

- An overview of the DEA regulations to permit e-prescribing of controlled substances
- DEA concerns about abuse of prescription drugs by teens who increasingly have attitudes that prescription drugs are “much safer” than illegal drugs
- The increasing frequency and volume of drug diversion of controlled substances in California.

Dr. Castellblanch expressed concern that common carriers are not regulated. He encouraged the board to express some cognizance of this issue and take action.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), asked whether any physician systems used for e-prescribing have been certified by the DEA.

Supervising Inspector Judi Nurse provided that she was told by the San Diego DEA that there are currently no approved vendors.

Ms. Herold provided that this board needs to develop guidelines for pharmacies about what the DEA’s e-prescribing requirements for controlled substances are. She stated that the Medical Board should also be involved for prescribers. Dr. Kajioka provided that the committee has recommended that a subcommittee be formed to work with the DEA on this issue.

Fred Floyd, representing Costco, provided that although no system is currently certified, all systems will be certified in one year. He indicated that most pharmacy system vendors will be compliant by June/July 2011.

Mr. Goldenberg discussed the request made by Omnicare to waive section 1793.7 regarding requirements of a pharmacy employing pharmacy technicians. He asked whether any other long term care pharmacies will also be participating.

Dr. Kajioka indicated that he does not believe any other groups have indicated an interest in participating at this time.

Mr. Goldenberg provided that the Long Term Management Council may be another possible agency to work in this area.

Ms. Herold provided that interested parties can contact Omnicare for participation.

No public comment was provided.

e. Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies

Supervising Inspector Judi Nurse provided that in response to increased diversion and abuse of prescription drugs and controlled substances, the board inspection staff is developing an education piece to dispense to pharmacy groups to increase awareness of this issue. She stated that the board is also working with local prosecutors as well as the Drug Enforcement Agency and Bureau of Narcotic Enforcement to increase understanding amongst law enforcement agencies.

Dr. Nurse provided an overview of thefts and robberies from pharmacies, and from various entities in the pharmaceutical supply chain (e.g., common carriers).

Dr. Nurse discussed three main areas: (1) increased awareness among pharmacists about diversion, (2) prevention of diversion and theft from pharmacies, and (3) the importance of dispensing responsibly using corresponding responsibility. She reviewed the increase in diversion in pharmacies and indicated that the board's diversion cases have increased by 40 percent over the past few years.

Dr. Nurse explained that pharmacists are responsible for the security of the drugs and are the last line of defense against diversion of drugs to the streets, either by theft from the pharmacy or inappropriate dispensing of controlled substances. She stated that the board's responsibility includes education and the protection of the consumer by aggressively pursing those who do not comply.

Public Comment

Lynn Rolston, representing the California Pharmacists Association (CPhA), asked if there is available information for pharmacies regarding how they can best protect themselves.

Dr. Nurse provided that the DEA has an available booklet on this topic.

Ms. Herold recommended that CPhA consider a similar presentation from the DEA at its upcoming meeting.

Dr. Kajioka discussed that from the perspective of law enforcement, the best way for a pharmacy to protect itself is to not intervene and "to be the best witness" during a robbery.

Stan Goldenberg asked whether the wholesaler is also investigated when it is determined that the pharmacy is not signing for deliveries as required.

Dr. Nurse provided that board inspectors routinely inspect the wholesaler as well. She stated that the board will cite the pharmacy and pharmacist-in-charge for not signing for the deliveries. Dr. Nurse indicated that the wholesaler or out of state entity can also be cited or disciplined depending on how many previous occurrences there has been.

Ms. Herold discussed that it is not uncommon for the wholesaler to alert the pharmacy of this requirement.

John Cronin, representing the California Pharmacists Association (CphA), asked to what extent the board is reaching out to other boards of pharmacy with respect to the topic of pharmacist corresponding responsibility. He discussed that physicians often become irate if a pharmacist questions the legitimacy of a prescription.

Ms. Herold provided that complaints regarding inappropriate prescribing by a physician are referred to the Medical Board.

Dr. Cronin sought clarification regarding the board's policy for discipline of pharmacies and pharmacists-in-charge following a theft at the pharmacy.

Ms. Herold explained that discipline is determined on a case by case basis and is dependent on various factors including the level of theft, number of drugs involved, and the controls that were in place.
Dr. Cronin stated that diversion involves many other drugs other than controlled substances. He discussed that these drugs are often sold at swap meets.

Heidi Bragg, representing Cardinal Health, provided that Rx Patrol provides free online training regarding pharmacy theft.

Dr. Nurse commended proactive wholesalers who are calling to alert pharmacies that they are above their quota.

Dr. Goldenberg asked how fast a wholesaler can identify a pharmacy that is over their quota.

Dr. Cronin provided that most wholesalers will cutoff the pharmacy if they vary from a given range.

Raffi Simonian discussed that law enforcement agencies are not always utilizing CURES data when investigating doctor shopping cases. He stated that the best practice for diversion is to ensure that there is a closed loop where the drugs are immediately locked and dispensed out of a secure cabinet. Dr. Simonian provided that the DEA has 2 pamphlets about the prevention of diversion and drug abuse among professionals.

Dr. Ratcliff provided that in addition to federal regulations, Health and Safety Code Section 11153.5 establishes corresponding responsibility for wholesalers which requires that the wholesaler is shipping an appropriate amount of controlled substances to a pharmacy.

Fred Floyd, representing Costco, stated that the best way to prevent internal theft is to look at internal controls.

Dr. Simonian discussed that there is increasing prevalence of non controlled substance theft. He stated that this issue should also be addressed.

There was no additional board discussion or public comment.

f. Discussion and Possible Action to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Dr. Kajioka provided that since July 2009 the Department of Consumer Affairs has been working with health care boards to improve their capabilities to investigate and discipline errant licensees to protect the public from harm. He stated that these results yielded the Consumer Protection Enforcement Initiative (CPEI).

Dr. Kajoka provided that many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). He advised that this bill failed passage early in the year during its first policy committee.

Dr. Kajioka provided that during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement some of the provisions requested by the department. He explained that the board expressed concern on many of the provisions and with one exception, did not take any action.

The committee discussed the following potential action items.

1. Amendments to section 1760 regarding standardized disciplinary guidelines for violations dealing with sexual contact. The board started initial review of this during the June Board Meeting.

Proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev.~~10/2007~~ 6/2010), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation—the presence of mitigating factors; the age of the case; evidentiary problems.

(a) Notwithstanding the disciplinary guidelines, any proposed decision issued by an Administrative Law Judge in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that contains any findings of fact that: (1) the licensee engaged in any act of sexual contact with a patient, client or customer; or, (2) the licensee has been convicted of or committed a sex offense, shall contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license or placing the licensee on probation.

(b) Subdivision (a) shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides services as a licensed pharmacist to his or her spouse or person in an equivalent domestic relationship.

(c) For the purposes of this section, “sexual contact” has the same meaning as defined in subdivision (c) of Section 729 of the Business and Professions Code and “sex offense” has the same meaning as defined in Section 44010 of the Education Code.

Ms. Schieldge Shellans reviewed the possible amendment to section 1760 – Disciplinary Guidelines. She stated that the proposed amendment attempts to provide clarification regarding the scope of a “sex offense.” Ms. Schieldge Shellans provided that findings of sexual contact with a patient, client or customer or conviction of a sex offense would be grounds for revocation by the Administrative Law Judge (ALJ); however, the board would have discretion to impose a lesser penalty under this proposal.

Mr. Room discussed that sexual contact between an 18 year old and a 16 year old would qualify as a misdemeanor and an automatic order of revocation by the ALJ. He clarified that the board has the option to non-adopt this order.

Kim Kirchmeyer provided that the issue of sexual contact is causing a lot of concern for other boards as it is very broad. She referenced to section 729(b) regarding sexual exploitation and suggested that this section may be clearer.

The board further discussed the proposed amendments and the broad definition of “sexual contact.” It was suggested that all references to this be removed.

Ms. Schieldge Shellans provided that as written, factual findings of sexual offenses would also warrant automatic revocation.

President Weisser suggested that the board return this item to staff for review and recommendations to the Enforcement Committee.

Mr. Room offered to prepare a comprehensive list of the conduct that would fall into the “sex offense” category.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), cautioned the board from removing all discretion from the ALJ.

MOTION: Direct staff to strike language provisions regarding sexual contact in the proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations and to bring revisions back to the Enforcement Committee for possible recommendation to the board.

M/S: Kajioka/Schell

Support: 3 Oppose: 4 Abstain: 1

MOTION: Reject the proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations.

M/S: Lippe/Castellblanch

Support: 5 Oppose: 0 Abstain: 3

2. Amendments to section 1762 regarding the proposed amendments to this section that would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board about an arrest, indictment, conviction or discipline as specified. The section also would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Proposed addition of Section 1762. to Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensees' practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Mr. Room provided that this section would not mandate revocation.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), spoke in opposition to this section and cautioned the board from moving forward. He discussed that the board can obtain administrative subpoenas to obtain records that it is entitled to.

Dr. Kajioka provided that although SB 1111 failed, it did contain some worthwhile components.

Kristy Schieldge Shellans provided that enforcement of a subpoena is challenging. She discussed that this amendment provides an additional method for obtaining records in a more timely manner to conduct investigations.

Ms. Room provided that the language could be amended to specify records that the board is entitled to. He explained that the amendments establish a specific timeframe by which the records must be provided to ensure an investigation is not subverted.

Dr. Ratcliff discussed that section 4332 requires that a licensee must produce a record. He explained that this amendment requires that they must provide the record within a specific timeframe. He stated that the board will resort to an administrative subpoena if the board is not entitled to the record.

Dr. Schell spoke in support to adding clarifying language to specify records that the board is entitled to.

There was no additional board discussion or public comment.

MOTION: Direct staff to modify amendments to section 1762 to specify records within the board's purview and to bring revisions back to the Enforcement Committee for possible recommendation to the board.

M/S: Kajioka/Schell

Support: 8 Oppose: 0 Abstain: 0

3. Amendment to section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report must be received from the evaluator.

§1769. Application Review and Criteria for Rehabilitation

Proposed Amendments

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date of the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has compiled with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Dr. Kajioka provided an overview of the amendment.

Ms. Schieldge Shellans suggested that that the language be changed to require that the evaluation and report be completed within 60 days rather than received within 60 days. She advised that the board cannot require that the report be received within 60 days and added that this standard would be difficult to implement and enforce.

Mr. Room provided that as drafted, the requirement that the report be received within 60 days is actually a requirement on the board.

No public comment was provided.

MOTION: Amend the proposed language for section 1769 to require that once it has been determined that an applicant is to be evaluated, the evaluation and report shall be completed within 60 days.

M/S: Castellblanch/Veale

Support: 8 Oppose: 0 Abstain: 0

Ms. Schieldge Shellans asked whether the board would like this proposal to be moved forward as part of a rulemaking process.

Ms. Herold provided that this proposal could be moved into another regulation package.

Mr. Room recommended that this proposal not be linked with the proposals for sections 1760 and 1762.

MOTION: Direct staff to take all steps necessary to initiate the formal rulemaking process to amend section 1769.

M/S: Lippe/Schell

Support: 8 Oppose: 0 Abstain: 0

4. Review and act on the performance standards developed by staff to conform to the department's online reporting of major enforcement milestones.
Ms. Herold provided an overview of the eight performance standards established by the department. She reviewed the board's timeframes and target dates for meeting these standards.

Ms. Herold reviewed current challenges impacting the board's ability to meet these standards as a result of the budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibitions,

and furloughs. She stated that it will be a challenge for the board to meet the measuring standards and to ensure that investigations are completed and final action is taken against a licensee within 12 – 18 months without the needed staffing.

No public comment was provided.

MOTION: Approve the performance standards developed by staff to conform to the department's online reporting of major enforcement milestones.

Performance Standard	**Board of Pharmacy Target**
1: Volume Number of complaints received	No target required
2: Cycle Time Average number of days to complete complaint intake	20 days
3: Cycle Time Average number of days to complete closed cases not resulting in formal discipline	210 days
4: Cycle Time Average number of days to complete cases resulting in formal discipline	18 months
5: Efficiency (Cost) Average cost of intake and investigation for complaints not resulting in formal discipline	Targets will not be required until first quarter baseline has been established
6: Customer Satisfaction Consumer satisfaction with the service received during the enforcement process	75 percent
7: Cycle Time Average number of days from the date a probation monitor is assigned to the date the monitor makes first contact	30 days
8: Cycle Time Average number of days from the time a violation is reported to the program to the time the probation monitor responds	7 days

M/S: Wheat/Schell

Support: 8 Oppose: 0 Abstain: 0

g. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Background

Senate Bill 1441 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 must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings.

California Business and Professions Code sections 4360 thru 4373 establish the Pharmacists Recovery Program (PRP) and establish some of the functions of the program as well as program participation criteria. The board contracts with a vendor, currently Maximus, Inc., to administer the PRP.

Dr. Kajioka advised that under current law, this PRP is only available to pharmacists and interns.

Ms. Herold encouraged the board to consider a motion from the Enforcement Committee to direct that staff work on the Disciplinary Guidelines of the Board, to augment the guidelines with changes to implement those components from the CPEI (SB 1111) and SB 1441 guidelines that can be pursued without separate statutory or regulation activities.

No public comment was provided.

MOTION: Enforcement Committee: Direct staff to initiate review of the Disciplinary Guidelines and report back on recommended changes for future committee and board discussion and action.

Support: 8 Oppose: 0 Abstain: 0

Dr. Kajioka referenced the contract and performance audit of Maximus for its diversion services conducted by the DCA.

Ms. Herold provided that the department has been invited to appear before the Senate Business and Professions Committee to discuss the audit. She discussed that the board maintains a close relationship with the vendor and reviews the participants in the Pharmacists Recovery Program regularly.

No public comment was provided.

The board did not discuss the following item.

h. Discussion about GS1's October 2010 Forum in San Francisco on Serialization and Track and Trace in the Pharmaceutical Supply Chain

The committee was updated on a conference in San Francisco by the standards setting organization GS1. The executive officer will speak on California's e-pedigree standards.

i. Minutes of the Meeting of September 14, 2010

Dr. Kajioka referenced to the summary of the meeting held on September 14, 2010 contained within the board packet.

No public comment was provided.

Other Enforcement Issues Not Discussed During the Meeting of September 14, 2010

j. Discussion and Possible Action on DEA's Policy Statement on the Role of Authorized Agents in Communicating Controlled Substances Prescriptions to Pharmacies, 21 CFR Part 1306 (Docket No. DEA 339S)

Dr. Kajioka provided that in early October, the DEA issued its policy statement regarding the role of an authorized agent in transmitting an order for a controlled substances prescription to a pharmacy.

Dr. Kajika provided that under the federal Controlled Substances Act, a valid prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (and who is authorized to prescribed controlled substances). "While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone else, an individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy" to make the process more efficient. He advised that the DEA requires that only a prescriber may make the medical determination to prescribe a controlled substance, not by an agent.

Ms. Herold provided that the board may consider writing a response letter to the DEA. She stated that the statement is a relatively narrow interpretation of what is occurring in skilled nursing facilities.

Dr. Schell asked whether the description of “agent” was provided in the policy. He expressed concern that an agent may not be appropriately trained.

Dr. Ratcliff asked whether the Code of Federal Regulations (CFR) defines “agent.”

Mr. Room provided that the term is defined in the CFR under statute 21.

Dr. Ratcliff expressed concern if the board is enforcing DEA interpretations.

No public comment was provided.

The board took no action on this item.

k. Discussion and Possible Action Regarding an Ad Hoc Task Force to Develop Guidelines on Implementing the DEA Electronic Prescribing Requirements for Controlled Substances

Dr. Kajioka provided that an ad hoc task force is needed to advise pharmacies what is expected under the DEA’s requirements.

No public comment was provided.

MOTION: Establish an ad hoc task force to develop guidelines on implementing the DEA Electronic Prescribing Requirements for Controlled Substances.

M/S: Kajioka/Schell

Support: 8 Oppose: 0 Abstain: 0

l. Discussion Regarding the Availability of Two Ethics Courses to Comply with 16 CCR Section 1773.5

Ms. Herold provided that two ethics course will be offered by two course providers, the Institute for Medical Quality and Professional Boundaries. She stated that according to Board Counsel Schieldge Shellans, the board does not need to approve any course directly; however, the provider must ensure that its course complies with the requirements in the board’s regulations.

Ms. Schieldge Shellans clarified that the probationer himself or herself must request course approval from the board before taking any course.

Dr. Castellblanch asked for some background information on the requirement for the courses.

Mr. Room provided that several years ago, the board developed regulation requirements for an in-depth, extensive ethics course for pharmacists and interns who are being disciplined for ethical lapses.

No public comment was provided.

m. Discussion Regarding the Board's Compliance with Reporting Disciplinary Actions to the National Practitioner's Data Bank --Healthcare Integrity and Protection Data Bank (NPDB--HIPDB)

Dr. Kajioka provided that under federal law, state licensing bodies are required to report to a specified federal data bank within 30 days any adverse licensing actions they take against their licensees.

Ms. Herold provided that as of October 1, 2010, the board has been deemed as compliant.

Dr. Schell asked how staffing challenges and other future work demands will impact the board's ability to comply with this requirement.

Ms. Herold provided that one part-time employee was redirected from public education outreach efforts in order to submit the required information to the data bank and get the information caught up. She stated that the board will be able to continue this reporting as new staff positions are filled.

Dr. Schell asked how this redirection will impact the board's public education outreach efforts.

Ms. Herold provided that the executive officer and the assistant executive officer have been assisting in this area.

No public comment was provided.

n. Enforcement Statistics 2010-11

Dr. Kajioka referenced the enforcement statistics for first quarter 2010/11 contained within the board packet.

No public comment was provided.

o. First Quarterly Report on Committee Goals for 2010/11

Dr. Kajioka referenced the first quarter's status of Enforcement Committee Goals contained within the board packet.

No public comment was provided.

XI. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

No public comment was provided.

President Weisser announced that the January 2011 Board Meeting has been rescheduled for February 2 and 3, 2011.

Recess for Day

The board meeting was recessed 4:45 p.m.

Thursday, October 21, 2010

The board reconvened at 8:30 a.m. on October 21, 2010.

XII. Report of the Legislation and Regulation Committee

LEGISLATION REPORT

a. Board-Sponsored Legislation
SB 1489 Omnibus Provisions (Senate Committee on Business, Professions and Economic Development) – Chapter 653, Statutes of 2010

Background
At the January 2010 Board Meeting, the board voted to pursue several omnibus provisions, which were introduced in SB 1489. The measure was amended on June 17, 2010, to modify §4013 (subscriber alert provisions) and was again amended on August 12, 2010, to modify §4076.5 (patient-centered labels).

Dr. Schell highlighted the following provisions.

General Omnibus Provisions

- §4013. Subscriber Alert. Section 4013 was amended at the request of industry, which had concerns about the implementation of the e-mail notification requirement that went into effect July 1, 2010. Amendments allow an owner of two or more pharmacies the option of registering with the board one e-mail address, by which the owner will immediately transmit any board e-mail notification to its licensed facilities.
- §4076.5. Patient-Centered Prescription Labels. Section 4076.5 was amended to give the board the authority to exempt from prescription labeling requirements (16 CCR §1707.5.) prescriptions dispensed to a patient in a health facility as defined in Section 1250 of the Health and Safety Code, so long as the prescriptions are administered by a licensed health care professional. Prescriptions dispensed upon discharge, or those not administered by a health care professional are subject to the board's regulation. Additional amendments also authorize the board to exempt from prescription labeling regulations a prescription dispensed to a patient, so long as certain criteria is met (i.e., home infusion, specialty therapies, etc.).
- §4101. Veterinary Food-Animal Drug Retailer
- §4196(e). Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repackaged
- Add §4200.1. Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x failure). Recodification of exact language previously in statute (which had sunset in 2009)

Amendments to update references to the California Department of Public Health and the Physical Therapy Board of California

- §4017. Authorized Officers of the Law
- §4028. Definition of Licensed Hospital
- §4037. Definition of Pharmacy
- §4052.3. Emergency Contraception Drug Therapy; Requirements and Limitations
- §4059. Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- §4072. Oral or Electronic Transmission of Prescription – Health Care Facility
- §4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
- §4127.1. License to Compound Injectable Sterile Drug Products Required
- §4169. Prohibited Acts (also, to strike operative date of 2008)
- §4181(a). License Requirements; Policies and Procedures; Who May Dispense
- §4191(a). Compliance with the California Department of Public Health; Who May Dispense Drugs

Amendments to update references to the Department of Health Care Services (formerly known as the Department of Health Services)

- §4425. Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring
- §4426. California Department of Health Care Services to Study Reimbursement Rates

No public comment was provided.

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

1. Chaptered

Dr. Schell provided that the following bills have all been signed by the Governor.

Board of Pharmacy

A. AB 2104 (Hayashi, Chapter 374, Statutes of 2010) – Board of Pharmacy: DCA Approval of Appointment of EO

Dr. Schell provided a summary of the bill. He stated that the bill requires that the Director of the DCA approve the board's appointment of the executive officer.

The board had established an oppose position on this measure.

No public comment was provided.

Licensing / General / Other

A. AB 2699 (Bass, Chapter 270, Statutes of 2010) – Licensure exemption: State of Emergency

Background
Existing law provides for an exemption from licensure and regulation requirements for a healing arts practitioner licensed in another state that offers or provides health care for which he or she is licensed, during a state of emergency. The provisions of AB 2699 provide other exemptions from licensure until January 2014, if the care is provided through a sponsored event and under specific circumstances. A practitioner would be exempt from state requirements for licensure, so long as the following criteria are met:

- Obtains authorization from the board by providing a valid license and photo identification;
- Has not committed any act or been convicted of a crime constituting grounds for denial of a license;
- Has the appropriate education;

- Agrees to comply with all practice requirements; and
- Pays a fee determined by the board by regulation which shall cover the cost of processing the request.

A sponsoring entity seeking to provide health care services must register with the board by completing a registration form and provide this information to the health department. Within 15 days of the health care services, the sponsoring entity would be required to file a report with the board that contains the description of care provided, and a list of practitioners providing the service. The board may revoke registration if the sponsoring entity fails to comply.

Dr. Schell provided that although a pharmacist falls within the definition of a health care provider and, therefore, could be included in the provisions of this bill, the author's office indicated that pharmacists would most likely not be participating in events referenced in the measure.

Dr. Schell provided that the board will continue to watch this bill.

No public comment was provided.

B. SB 1172 (Negrete McLeod, Chapter 517, Statutes of 2010) – Diversion Programs

Background

This bill requires specified healing arts boards (including the Board of Pharmacy) to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensees probation or diversion program. The bill authorizes the board to adopt regulations to order a licensee (on probation or in a diversion program) to cease practice for (1) major violations, or (2) when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to uniform and specific standards, as specified. Participants in the board's Pharmacists Recovery Program (PRP) who test positive for any prohibited substance currently are removed from work pending the receipt of two negative tests. The board did not take a position on this bill.

No public comment was provided.

C. AB 1414 (Hill, Chapter 76, Statutes of 2010) – Controlled Substances: Apomorphine: Unscheduled.

Background
The California Uniform Controlled Substances Act currently lists Apomorphine as a Schedule II controlled substance. This bill moves Apomorphine from Schedule II to Schedule V. Schedule V drugs are generally defined by those drugs that have a currently accepted medical value, present a low potential for abuse, and may lead to limited psychological or physical dependence. Schedule V substances include cough suppressants and pain modulators, as well as many prescription drugs. There was no noted opposition to the measure, and the board did not take a position on this bill.

Dr. Schell provided that there was concern about Apomorphine being a scheduled drug.

Public Comment

Lynn Rolston, representing the California Pharmacists Association (CPhA) provided background on why this legislation was sponsored. She indicated that California veterinary compounders made this request so that they could purchase Apomorphine from instate providers.

There was no additional board discussion or public comment.

Sunset Review and Legislative Oversight Proposals

A. AB 1659 (Huber) – State Government, Agency Repeals

Dr. Schell reviewed the provisions of this bill. He stated that should the sunset date of any board currently under the Department of Consumer Affairs not be extended, that board would cease to exist and the practice of pharmacy would be unregulated. Dr. Schell advised that under current law, failure to extend the board's sunset date would result in the department taking over the duties and responsibilities of the board.

No public comment was provided.

B. AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection

Ms. Schieldge Schellans provided that AB 2130 is a companion bill to AB 1659. She clarified that AB 2130 repeals the department's authority to take over a program if a board failed to pass sunset review.

No public comment was provided.

Distribution of Needles and Syringes

A. AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Background
In 2004, the Disease Prevention Demonstration Project pilot was launched, with a sunset date of 2010, to allow a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time, as specified. AB 1701 extends these provisions to 2018. The board did not take a position on this bill.

No public comment was provided.

Other Legislation Impacting the Board's Jurisdiction

A. SB 294 (Negrete McLeod) – Professions and Vocations: Regulation

Background
This bill resets the sunset dates of various boards within the Department of Consumer Affairs. The board did not take a position on this bill.

Dr. Schell provided that this bill does not impact the Board of Pharmacy.

No public comment was provided.

B. SB 700 (Negrete McLeod, Chapter 505, Statutes of 2010) – Healing Arts: Peer Review

Background
Existing law provides for a peer review process of licentiate and that certain information regarding judgments and settlements is reported. This bill requires that in addition to current requirements, any additional exculpatory or explanatory statements submitted by the licentiate also be included; the bill also requires the agency to inform the licentiate that information submitted electronically will be publicly disclosed to those who request the information. The board did not take a position on this bill.

Dr. Schell provided that this bill has no direct effect on the board.

No public comment was provided.

2. Vetoed

Dr. Schell referenced to the following bills and indicated that information on each bill is provided in the board packet.

No public comment was provided.

A. AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services

Board position: None. This bill would have allowed the California Department of Public Health to authorize entities to provide hypodermic needles and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease through the sharing of unclean hypodermic needles and syringes; and provided that a participant in a clean needle and syringe exchange program shall not be subject to criminal prosecution for possession of needles and syringes acquired under an approved program.

B. AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Board position: Support. This bill would have provided for centralized pharmacy packaging in a hospital, where the pharmacy could be located outside of a hospital on either the same premises or separate premises regulated under a hospital's license.

C. AB 2747 (Lowenthal) – Prisoners: Pharmacy Services

Board position: None. This bill would have authorized the California Department of Corrections and Rehabilitation (CDCR) to operate and maintain a centralized pharmacy distribution center for facilities under its jurisdiction.

D. SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

Board position: None. This bill would have established requirements for providers of blood clotting products for home use whose products are used to treat hemophilia and other bleeding disorders, and designated the Board of Pharmacy to administer and enforce the provisions of the Standards of Service for Providers of Blood Clotting Products and Home Use Act.

E. SB 1029 (Yee) – Hypodermic Needles and Syringes

Board position: None. This bill would have allowed a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer

hypodermic needles and syringes for human use to a person 30 years of age or older. The bill addressed the storage of products to ensure they would be available only to authorized personnel, would have required that disposal options are provided to consumers, and would have required pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

3. Legislation That Failed Passage

Dr. Schell referenced to the following bills and indicated that information on each bill is provided in the board packet.

No public comment was provided.

- SB 1390 (Corbett) – Patient-Centered Prescription Labels
- AB 1455 (Hill) –Ephedrine; retail sale
- SB 1071 (DeSaulnier) – CURES
- SB 1106 (Yee) – Prescribers Dispensing of Samples
- AB 2551 (Hernandez) – Pharmacy Technician: Scholarship & Loan Repayment Program
- AB 1310 (Hernandez) – Healing Arts Database

c. Legislation for Sponsorship During 2011-12 Session

1. Previously-Approved Board-Sponsored Legislation for 2011-2012

A. Section 4362 – Entry Into Pharmacists Recovery Program (Omnibus provision)

Dr. Schell provided that this provision would establish a co-pay for participants in the Pharmacists Recovery Program to offset a portion of the board's administrative fee for each participant.

The proposal was not picked up for the 2009/2010 Legislative Session.

No public comment was provided.

B. Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors

Background
Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and

prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. The board voted in January 2010 to pursue sponsorship of such legislation, to include the provisions below. These were not picked up in the 2009/2010 session.

a. Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

b. Amend section 4081 – Records of Dangerous Drugs and Devices Kept

Open for Inspection; Maintenance of Records, Current Inventory
Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler" for purposes of this section only. This provision was approved in concept only by the board in January 2009.

c. Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. (Language for the later provision will require development.) This provision has not previously been considered by the board.

Dr. Schell provided that sponsors are still needed for this legislation.

No public comment was provided.

C. Sections 4104, 4105 and 4112 – Enforcement Enhancements

Background
The board voted at its meeting in January 2010 Board Meeting to pursue statutory changes as outlined in Sections 4104 and 4112. Proposed amendments to § 4105 mirror those contained in proposed changes to § 4081, related to the production of records, when requested by the board.

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

   Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

   Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

   Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.

Dr. Schell highlighted the statutory changes.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), sought clarification regarding the board's intent and enforcement of section 4112.

Mr. Room provided that once the board has deemed a pharmacist unfit to practice in California, they would be prohibited from providing services to California patients while practicing in another state.

Dr. Schell requested that this issue be added as a topic for consideration at a future Licensing or Enforcement Committee Meeting.

There was no additional board discussion or public comment.

2. Legislation for Consideration During 2011-2012 Legislative Session

A. Section 4200 – Pharmacist Examination (Omnibus provision)

Dr. Schell provided that this amendment would remove an obsolete reference in the pharmacist license requirements.

Mr. Room provided that this change will strike the provision that referenced the previous written and practical exam that was given by the board prior to December 31, 2003.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), asked how this will impact current pharmacists who have already taken the exam.

Mr. Room provided that this provision only applies to applicants for new licensure.

Ms. Herold provided that this would apply to reinstatement of revoked or retired licenses.

Discussion continued regarding possible consequences for purposes of license renewal.

Ms. Schieldge Shellans provided that the renewal of a license is not a requalification of the license. She advised that this provision only applies to applicants and would not impact renewal.

There was no additional board discussion or public comment,

MOTION: Instruct staff to pursue legislation to amend section 4200 (a)(6) to read:

(6) Has ~~passed a written and practical examination given by the board prior to December 31, 2003, or has~~ passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

M/S: Schell/Hackworth

Support: 8 Oppose: 0 Abstain: 0

B. Section 4301.1 – To Allow the Board to Suspend the License of a Pharmacist or Pharmacist Intern for a Felony Conviction for a Crime of Unprofessional Conduct

Background

In October 2009, the Legislation and Regulation Committee considered a staff proposal to add Section 4301.1. to the Business and Professions Code to provide the board with the authority to suspend the license of a pharmacist or a pharmacist intern who is convicted of a felony for a crime of unprofessional conduct, as defined in §4301; that the board may decline to impose or may set aside the suspension when it appears to be in the interest of justice to do so; and that the issue of penalty shall be heard by an administrative law judge, or a committee of the board with an ALJ, or the board sitting with an ALJ, at the discretion of the board. The section would allow a pharmacist or

pharmacist intern to request a hearing within a specified timeframe; and that if an accusation for permanent discipline is not filed within 90 days of the suspension that the suspension shall terminate.

Dr. Schell provided that as the board currently has this authority, the board will not be pursing this piece of legislation.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), asked whether board staff or counsel have looked at how this would impact the discretion of an Administrative Law Judge (ALJ).

Dr. Schell provided that counsel indicated that this was duplicative with section 4311 and was not necessary. He stated that the board may want to develop a methodology or philosophy for this issue.

There was no additional board discussion or public comment.

REGULATION REPORT

The board proceeded with discussion of non-action items (regulation agenda items b-f) of the Regulation Report as the meeting was progressing ahead of schedule.

b. Board Adopted Regulations – Approved by OAL
New Sections 1721 and 1723.1 in Division 17 of Title 16 of the Code of Regulations Regarding Dishonest Conduct During a Pharmacist's Licensure Exam/Confidentiality (effective 9/17/2010)

Background
At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR § 1721 and § 1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

The formal rulemaking was noticed on October 30, 2009, and the 45-day comment period concluded on December 14, 2009. The board did not receive any comments to the proposed rulemaking.

The board adopted the regulation at its January 2010 Board Meeting, and the rulemaking was submitted to the department for review in March 2010. Following department approval, the rulemaking was submitted to the Office of Administrative Law for review in July 2010; that office approved the file and filed the regulation with the Secretary of State.

Dr. Schell provided that the regulation was effective on September 17, 2010.

No public comment was provided.

c. Board Adopted Regulations – Undergoing Administrative Review
Proposed Adoption of New Section 1707.5. in Title 16 of the California Code of Regulations – Requirements For Patient-Centered Prescription Drug Container Labels

Background
The formal rulemaking was noticed for the 45-Day Comment Period on November 20, 2009 and a regulation hearing was held on January 20, 2010. The first 15-day comment period started on February 22, 2010 and the second 15-day comment period began on April 28, 2010. The board received about 1,200 comments.

The board adopted the regulation text at its June 2010 Board Meeting. The rulemaking file was compiled and submitted to the Department for review in July 2010. The rulemaking file was transmitted to the Office of Administrative Law for review on October 5, 2010. The board is utilizing "Subscriber Alert" notifications to advise subscribers of the status of the regulation. "Subscriber Alerts" were issued on August 11, August 31 and October 6, 2010. The Final Statement of Reasons and Adopted Text have been added to the board's Web site.

Dr. Schell provided that this regulation is moving forward. He stated that the board will have additional discussion on this regulation during a separate agenda item.

No public comment was provided.

d. Board Approved Regulations – Recently Noticed
Proposed Amendments to § 1732.2. – Board Accredited Continuing Education

Background
At the February 2010 Board Meeting, the board voted to initiate the rulemaking process to amend 16 CCR § 1732.2. related to board-accredited continuing education. The proposed text was formally noticed for comment on October 8, 2010, and the 45-day comment period concludes on November 22, 2010.

The proposed regulation would modify the term “continuing education credit” to “continuing education hours” and would add board-approved continued education for the following:

- A pharmacist serving on a designated subcommittee for conducting a review of exam test questions (up to 6 hours of CE)
- Attending a full-day board meeting (up to 6 hours annually)
- Attending a full committee meeting (up to 2 hours for each meeting, maximum of four hours annually)
- A pharmacist who completes the PSAM administered by the National Association of Boards of Pharmacy (up 6 hours of CE)
- Successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy (3 hours of CE)

Dr. Schell provided that there are no updates for this regulation.

No public comment was provided.

e. Proposed Regulations – Awaiting Board Approval to Notice Proposed Amendments to §1728, §1728.2, and §1793.5., and Application Forms To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB--HIPDB)

Background

The Licensing Committee considered at its October 5, 2010, meeting a proposal to amend Sections 1728. and 1793.5., and a proposal to add Section 1727.2. to Title 16 of the California Code of Regulations. The Licensing Committee has provided a recommendation to the board to initiate the rulemaking process to require that applicants, as specified in the proposal, submit to the board a Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB).

Dr. Schell provided that this item was discussed during the first day of the meeting.

No public comment was provided.

f. Regulations Under Development

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol

Background

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004. The board

discussed updates to the regulation at its January and July 2010 Board Meetings. Updates to the Dedicated Emergency Contraception regulation will be addressed by a subcommittee or ad hoc committee to address changes to existing drugs or the inclusion of additional drugs approved since the regulation was established six years ago. Any updates to the protocol are required to first be approved by the Medical Board prior to the board's initiation of a rulemaking.

Dr. Schell provided that a committee will be working with the Medical Board to update the protocol.

No public comment was provided.

2. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

   Background
   Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board.

   Dr. Schell provided that the proposed regulation would specify the criteria the board will utilize to consider approval of accreditation agency requests. He advised that staff is working with counsel to develop language for consideration at a future meeting.

   No public comment was provided.

3. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers)

   Background
   Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

   Because of stated concerns about whether referencing the 2005 USP Standards would be 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.

Dr. Schell provided an overview of the standards. He stated that the board established a subcommittee to update the standards but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

No public comment was provided.

4. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

   Background
   The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

   In 2007 the Enforcement Committee and the board approved draft amendments to the regulation and related self-assessment form; subsequently, however, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

   Dr. Schell provided that the Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program.

   No public comment was provided.

The board recessed until 10:00 a.m.

The board suspended discussion of the Regulation Report to permit the scheduled e-prescribing presentation.

XIII. Presentation by Libby Sagara and Patrick Robinson on E-Prescribing Efforts in California and the Work of the CaleRx Pharmacy Workgroup

Patrick Robinson provided an overview of the CalPERS e-prescribing pilot with health-plan partners Anthem Blue Cross, Blue Shield of California, and Medco. The pilot launched in the first quarter of 2009 and concluded in June 2010. He

reviewed pilot outcomes including improved understanding of barriers to adoption and improved communication, increased communications among prescribers, pharmacies, and other stakeholders, and the addition of e-prescibing to CalPERS' contracts.

Libby Sagara of Manatt Health Solutions provided an update of the CaleRX Pharmacy Workgroup, a group comprised of individuals seeking to ease and speed the implementation of e-prescribing in California. She reviewed major e-prescribing issues in California including coordination with Surescripts, pharmacy participation, technical challenges, and educating providers new to e-prescribing and facilitating access to incentives for meaningful use. Ms. Sagara stated that the board can assist with this process in the area of prescribing controlled substances.

Ms. Sagara provided that the CaleRXPharmacy Workgroup is hosting a meeting on November 9, 2010 at the California Endowment in Oakland to help engage pharmacies in this area.

The board resumed discussion of the Regulation Report.

a. Discussion and Possible Action to Initiate a Rulemaking to Adopt 1707.6. – Notices to Consumers, and Amend Section 1707.2 Notice to Consumers and Duty to Consult

Background

On June 10, 2010, the board adopted proposed regulation 16 CCR § 1707.5 to establish requirements for a patient-centered prescription drug container label. That regulation is currently undergoing administrative review.

The patient-centered prescription label regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested; it also requires a pharmacy to provide oral interpretive services.

During the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of 12-point font, as specified in the adopted regulation. At the July 2010 Board Meeting, staff provided the board with draft language for consideration and possible action. The board discussed the draft text and directed staff to develop new draft language. At that time, the board voted to move the existing consumer notices from 16 CCR § 1702 to a new section that also includes any notice(s) regarding language interpretive services and larger font sizes.

Dr. Schell reviewed the draft notice language for consideration (option 1 handout – "yellow") that was developed in response to the board's feedback during the July 2010 Board Meeting on the previous draft (option 2 handout – "orange").

Dr. Schell discussed the possible options available to the board. He discussed that option 2 is simpler, consolidates notice requirements, and allows for flexibility in the presentation of the notices.

Mr. Room provided that the committee reviewed subdivisions (a) and (b) of the draft in option 2 and approved a recommendation to the board to approve these sections of the draft language. He indicated that the committee did not vote on subdivision (c).

Dr. Schell recommended that the board review the draft in option 2 draft by sections.

The board reviewed section 1707.6 (a) of the draft language.

> (a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangers drugs are dispensed or furnished, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to give such approval to a committee or the Executive Officer. The pharmacy may also or instead display the notice on video screen(s) located at or adjacent to each counter in the pharmacy where dangerous drugs were dispensed of furnished, so long as: (1) the video screen is at least 30 inches, measured diagonally; (2) The text, format, size, and colors utilized are the same as the poster-sized notice; (3) The notice remains on-screen for a minimum of sixty (60) seconds; and (4) Where the text of the notice does not fit on one screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least sixty (60) seconds.

The board discussed the draft language for subdivision (a).

Ms. Veale discussed variances in pharmacy design. She expressed concern regarding the word "each" and the requirement that a notice be posted by each counter in the pharmacy. She offered a proposal to amend this language.

The board discussed how this section would apply to drive-up windows at pharmacies.

Mr. Room provided that it is his opinion that under current law a pharmacy would be required to have a separate sign at the drive-up window.

Dr. Ratclifff clarified that “dispensed” is when the drug is provided to the patient

Dr. Schell spoke in support of the amendment. He discussed that the language may limit where the notice can be posted.

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores, spoke in support of the amendment as it is in line with the reduction and condensing of notice requirements.

Lynn Rolston, representing the California Pharmacists Association, thanked the board for condensing the notice requirements. She urged the board to support the amendment.

There was no additional board discussion or public comment.

MOTION: Amend subdivision (a) of the draft language to read:
(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, ~~at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished,~~ notices containing the text in subdivision (b).

M/S: Veale/Wheat

Support: 7 Oppose: 0 Abstain: 0

Ms. Veale offered a proposal to modify similar language in subdivision (a) regarding the available alternative to display notices on a video screen.

Mr. Room discussed that there is inconsistency in the draft language with regards to multiple notices and video screens. He asked the board for input regarding whether multiple notices or video screens should be permitted.

Dr. Schell discussed that permitting multiples will provide flexibility for the pharmacy.

No public comment was provided.

MOTION: Amend subdivision (a) of the draft language to read:

As an alternative to printed notices, the pharmacy may display **also or instead display the notice** on video screen**s** located **in a place conspicuous to and readable by prescription drug consumers, so long as**:

M/S: Veale/Wheat

Support: 7 Oppose: 0 Abstain: 0

Ms. Hackworth offered a proposal to amend the language to state "in a place or places."

The board discussed that this amendment would not make it mandatory to have the notices in multiple locations.

Ms. Veale expressed concern regarding the necessity of this change as pharmacies currently have the ability to post the notices in multiple locations.

No public comment was provided.

MOTION: Amend subdivision (a) of the draft language to read:

(a) In every pharmacy there shall be prominently posted, in a place **or places** conspicuous to and readable by prescription drug consumers~~,~~ notices containing the text in subdivision (b).

As an alternative to printed notices, the pharmacy may display also or instead display the notice on video screens located in a place **or places** conspicuous to and readable by prescription drug consumers, so long as:

M/S: Hackworth/Kajioka

Support: 2 Oppose: 4 Abstain: 1

Ms. Veale discussed that the requirement in subdivision (a)(2) requiring that the text and format of the video image notice be the same as the printed form may be too prescriptive.

Ms. Wheat provided that she is also concerned about this. She stated that the text size on the printed form may not be conducive for the video screen.

The board discussed implementing the notices on a video screen. Concern was expressed that a video image reproduction of the current notices may be

distorted or difficult to read. Concern was also expressed regarding the appropriate size of a permitted video screen.

Ms. Wheat offered a proposal to replace subdivision (a)(2) with a requirement that the video image of the notice be provided by the board.

Mr. Room provided that subdivision (a)(4) would not be needed as the notice images would be provided the board.

Ms. Schieldge Shellans asked whether this would have any cost impact on the board.

Ms. Herold provided that this can be done relatively inexpensively and can be made available to download on the board's Web site.

Public Comment

Yonoh Kim, representing Ralphs, provided that a 30 inch screen is not common. He stated that a 24 inch screen is sufficient and is typically used in pharmacies.

Lynn Rolston, representing the California Pharmacists Association (CPhA), provided comment on the measurement of video screens. She suggested that a 30 inch screen may be too big.

Mr. Room clarified that televisions are measured diagonally.

There was no additional board discussion or public comment.

MOTION: Strike subdivision (a)(4) and amend subdivision (a)(2) of the draft language to read:

(2) Utilize the video image notice provided by the board;

M/S: Wheat/Lippe

Support: 7 Oppose: 0 Abstain: 0

Ms. Wheat expressed concern regarding the video screen size requirement as well as the notice display frequency requirement.

The board discussed the appropriate minimum size requirement for the video screen. Discussion also focused on the appropriate frequency to display the notice.

Dr. Kajioka offered a proposal to require that the notices remain on the screen for at least 60 seconds and that no more than five minutes elapses between displays of the notice.

Dr. Schell reminded the board that it will have an opportunity to reevaluate this language at a future meeting. He clarified that there will be a new subdivision (a)(4) as the previous subdivision was struck.

No public comment was provided.

MOTION: Amend subdivisions (a)(3) and (a)(4) of the draft language to read:

(3) The text of the notice(s) remains on the screen for a minimum of **60** seconds;

(4) No more than **five** minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

M/S: Kajioka/Lippe

Support: 7 Oppose: 0 Abstain:

Ms. Veale offered a proposal to reduce the video screen size requirement from 30 inches to 24 inches.

No public comment was provided.

MOTION: Amend subdivision (a)(1) of the draft language to read:

(1) The video screen is at least ~~30~~ **24** inches, measured diagonally;

M/S: Veale/Lippe

Support: 7 Oppose: 0 Abstain: 0

Additional Public Comment

Lynn Rolston, representing the California Pharmacists Association (CPhA), sought clarification regarding how a display not provided by the board would be approved.

Mr. Room provided that the board may delegate the authority to the executive offer to grant approval. He stated that once reviewed and approved, the executive officer could send a letter of approval to the pharmacy.

Dr. Schell reviewed the amendments approved for subdivision (a) of the draft language.

There was no additional board discussion or public comment.

MOTION: Legislation and Regulation Committee: Approve subdivision (a) as amended.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers notices containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to give such approval to a committee or the Executive Officer. As an alternative to printed notices, the pharmacy may display also or instead display the notice on video screens located in a place conspicuous to and readable by prescription drug consumers, so long as:(1) The video screen is at least 24 inches, measured diagonally; (2) Utilize the video image notice provided by the board; (3) The text of the notice(s) remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

Support: 7 Oppose: 0 Abstain 0

The board discussed subdivision (b) of the draft language. (Line numbers added to provide reference during discussion.)

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

1. You may ask this pharmacy to use larger print on prescription drug labels.
2. Interpretive language services will be made available to you in this pharmacy at no cost.
3. Before taking your medicine, be sure you know: the name of the medicine and what it
4. does; how and when to take it, for how long, and what to do if you miss a dose; possible
5. side effects and what you should do if they occur; whether the new medicine will work
6. safely with other medicines or supplements; and what foods, drinks, or activities should
7. be avoided while taking the medicine. Ask the pharmacist if you have any questions.
8. This pharmacy must provide any medicine or device legally prescribed for you, unless:
9. it is not covered by your insurance; you are unable to pay the cost of a copayment; or the

10. pharmacist determines doing so would be against the law or potentially harmful to health.
11. If a medicine or device is not in stock, or cannot be immediately provided, the pharmacy
12. will work with you to ensure that you get your medicine or device in a timely manner.
13. You may ask this pharmacy for information on drug pricing and use of generic drugs.

Mr. Room reviewed the draft language. He stated that the language consolidates notice information onto one notice.

Ms. Veale expressed concern regarding the language that states that the consumer is entitled to "larger print." She suggested that "12-point font" be used instead.

Mr. Room provided that the committee discussed the option of producing the notice to include two designated spots for the pharmacy to affix its label in both 10 and 12-point font. He clarified that this option would need to be specified within the regulation. Mr. Room stated that the board has received testimony that consumers may not understand what 12-point font means.

Discussion continued. Concern was expressed that consumers may be mislead to believe that they are entitled to a larger than 12-point font or all label information in a 12-point font. It was also suggested that affixing labels to the notice may clutter the information

The board further discussed the option of listing the specific label elements that are available in 12-point font on the notice.

Mr. Room cautioned the board that additional text may not fit into the notice.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), cautioned the board from providing too much detail on the notices.

There was no additional board discussion or public comment.

MOTION: Amend line one of subdivision (b) of the draft language to read:
You may ask this pharmacy to use ~~larger print~~ **12-point font** on prescription drug labels.

M/S: Hackworkth/Veale

Support: 6 Oppose: 1 Abstain: 0

The board continued its discussion of subdivision (b). Specific lines were discussed individually.

Line 2

Missy Johnson, representing the California Retailers Association, suggested that unnecessary words be struck to simplify the language. She recommended that "language services" be used in lieu of "interpretive language services."

Mr. Room provided that the term "interpretive" was used in the language to eliminate any confusion that translation services might be available.

Lynn Rolston, representing the California Pharmacists Association (CPhA), suggested that "verbal" or "oral" be used instead of "interpretive."

Mr. Room provided that "verbal" would be appropriate.
There was no additional discussion.

MOTION: Amend line 2 of subdivision (b) of the draft language to read: ~~Interpretive~~ **Oral** language services ~~will be made~~ **are** available to you ~~in this pharmacy~~ at no cost.

M/S: Veale/Wheat

Support: 7 Oppose: 0 Abstain: 0

Lines 3-7

Mr. Room provided that these lines have not been changed from the previous draft.

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), suggested that bullet points be used for items on lines 3-7 to increase readability for consumers.

Mr. Room provided that the regulation language does not dictate how the text will be displayed. He stated that use of bullets will be a design decision.

There was no additional board discussion or public comment. The board made no changes to lines 3-7.

Lines 8-12

Mr. Room provided that the language in lines 8-12 has been modified to be more concise.

Ms. Wheat suggested alternative language to decrease the number of words used.

Public Comment

Lynn Rolston, representing the California Pharmacists Association (CPhA), spoke in opposition to the alternative language and provided that the removal of the language regarding the ethical basis for a pharmacist to refuse to fill a prescription is inconsistent with the law.

Mr. Room provided that consumers should know that they are entitled to get their prescription filled timely. He discussed that it may not be necessary to include current notice information regarding why a pharmacy may decline to fill a prescription.

John Cronin, representing the California Pharmacists Association (CPhA), provided comment on legislation with regards to conscientious obligation. He discussed that not including this information on the notice negates the intent of the legislation. Dr. Cronin stated that consumers should be informed that a pharmacist can decline to refill a prescription.

Dr. Kajioka provided that the intent of the notice is to inform consumers of their rights and not the rights of the pharmacist.

Ms. Herold provided that the requirement to the board is to educate consumers regarding their rights.

Ms. Veale spoke in opposition to the alternative language. She stated that the board should discuss whether the rights of the pharmacist should be included on the notice.

Ms. Rolston discussed that pharmacies must dispense or refer. She stated that this should be referenced on the notice.

There was no additional board discussion or public comment.

MOTION: Amend lines 8-12 of subdivision (b) of the draft language to read:

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not ~~in stock, or cannot be immediately provided,~~ **immediately available,** the pharmacy will work with you to ensure that you get your medicine or device in a timely manner.

M/S: Wheat/Veale

Support: 4 Oppose: 3 Abstain: 0

The board reviewed subdivision (b) as modified.

Public Comment

John Cronin, representing the California Pharmacists Association (CPhA), asked whether this language is being developed to notice for hearing for future consideration as a regulation by the board.

Dr. Schell provided that the language will not go into effect until it is finalized after a hearing.

Ms. Veale instructed counsel to develop alternative language for subdivision (b) regarding conscientious objection to fill a prescription.

The board discussed the timeframe for initiating the rulemaking. It was stated that the board will be able to readdress language during the hearing.

There was no additional board discussion or public comment.

Line 13

Mr. Room provided that this line was significantly condensed.

The board made no changes.

No public comment was provided.

Dr. Schell tabled discussion of subdivision (c) of the draft language due to time restraints of the meeting and referred it back to the Legislation and Regulation Committee for further review.

g. Proposal to Initiate Rulemaking to Update 16 CCR Section 1715 Self Assessment of a Pharmacy by the Pharmacist-In-Charge and 16 CCR Section 1784 Self-Assessment by a Wholesaler by the Designated Representative-In-Charge

Background
Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms provide references to relevant laws and regulations, and also serve as an

easy reference guide for the Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC).
Section 1715 of Title 16 Cal. Code of Regulations applies to the self-assessment of a pharmacy by the Pharmacist-in-Charge. The regulation was established in 1997 and was last amended in 2009. The following self-assessment forms are incorporated by reference in § 1715:

- 17M-13 (Rev 10/08) "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment"
- 17M-14 (Rev 10/08) "Hospital Pharmacy and Self-Assessment"

Section 1784 of Title 16 Cal. Code of Regulations applies to wholesalers. This regulation was established in 2007 and was also updated in 2009. It incorporates by reference the following self-assessment form:

- 17M-26 (Rev 10/08) "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment"

After the conclusion of the 2009/2010 Legislative Session, board staff will draft changes to the self-assessment forms to reflect statutory changes for the board's consideration at a future meeting.

Dr. Schell provided that updates to the forms are needed to reflect statutory changes.

No public comment was provided.

MOTION: Direct the executive officer to initiate the rulemaking to update 16 CCR Section 1715 Self Assessment of a Pharmacy by the Pharmacist-In-Charge and 16 CCR Section 1784 Self-Assessment by a Wholesaler by the Designated Representative-In-Charge.

M/S: Lippe/Hackworth

Support: 7 Oppose: 0 Abstain: 0

h. Notification of Temporary Delay in Implementing New Section at Title 16 California Code of Regulations Section 1702—Fingerprint Submissions for Pharmacists

Ms. Schieldge Shellans provided that the board will need to authorize this delay.

Ms. Herold provided that staffing challenges as a result of the hiring freeze will hinder implementation.

No public comment was provided.

MOTION: Authorize a temporary delay in the implementation of new section at Title 16 California Code of Regulations Section 1702—Fingerprint Submissions for Pharmacists pending additional staffing and further notice by the executive officer.

M/S: Lippe/Kajioka

Support: 7 Oppose: 0 Abstain: 0

LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

President Weisser suggested that the board approve a motion to table discussion of the Notice to Consumers draft language - subdivision (c).

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), asked how suggestions regarding subdivision (c) should be submitted.

Dr. Schell provided that suggestions should be submitted to the executive officer.

There was no additional board discussion or public comment.

MOTION: Table discussion of subdivision (c) of the draft language for section 1707.6 and refer it back to the Legislation and Regulation Committee for further review.

M/S: Schell/Lippe

Support: 7 Oppose: 0 Abstain: 0

Dr. Schell stated that the Legislation and Regulation Committee Report should be tabled due to time restraints in order to hear the scheduled petitions.

No public comment was provided

MOTION: Table discussion of the Legislation and Regulation Committee Report.

M/S: Schell/Lippe

Support: 7 Oppose: 0 Abstain: 0

XIV. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

No public comment was provided.

The Board Meeting was recessed at 12:59 p.m. to hear petitions.

XV. Petitions

a. Petitions for Reinstatement
   1. Vee Quigley, RPH 24980
   2. Raul Gutierrez, TCH 14159

b. Petition for Early Termination of Probation
   1. Robert Blackburn, RPH 30586

The meeting was adjourned at 4:12 p.m.

Proposal to Add § 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 851 and 4207, Business and Professions Code.

Proposal to Amend § 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 01/11) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as~~ a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). ~~In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.~~

(4) A sealed, original, Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within ~~30~~ 60 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, 4402, and 4400 Business and Professions Code; Section 11105 of the Penal Code; and Sections 1706.2. and 1793.6. of Title 16 of the California Code of Regulations.

AMENDED

Proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~1/2007~~ 6/2010), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

(a) Notwithstanding the disciplinary guidelines, any proposed decision issued by an Administrative Law Judge in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that contains any findings of fact that: (1) the licensee engaged in any act of sexual contact with a patient, client or customer; or, (2) the licensee has been convicted of or committed a sex offense, shall contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license or placing the licensee on probation.

(b) Subdivision (a) shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides services as a licensed pharmacist to his or her spouse or person in an equivalent domestic relationship.

(c) For the purposes of this section, "sexual contact" has the same meaning as defined in subdivision (c) of Section 729 of the Business and Professions Code and "sex offense" ~~has the same meaning as defined in Section 44010 of the Education Code~~ shall mean any of the following:

(a) Any offense for which registration is required by Section 290 of the Penal Code or a finding that a person committed such an act.
(b) Any offense defined in Section 261.5, 313.1, or 647 subsection (a) of the Penal Code or a finding that a person committed such an act.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Oct 2010 – Enf. Item f

Applicable Penal Code sections

Penal Code section 290. (a) Sections 290 to 290.023, inclusive, shall be known and may be cited as the Sex Offender Registration Act. All references to "the Act" in those sections are to the Sex Offender Registration Act.

(b) Every person described in subdivision (c), for the rest of his or her life while residing in California, or while attending school or working in California, as described in Sections 290.002 and 290.01, shall be required to register with the chief of police of the city in which he or she is residing, or the sheriff of the county if he or she is residing in an unincorporated area or city that has no police department, and, additionally, with the chief of police of a campus of the University of California, the California State University, or community college if he or she is residing upon the campus or in any of its facilities, within five working days of coming into, or changing his or her residence within, any city, county, or city and county, or campus in which he or she temporarily resides, and shall be required to register thereafter in accordance with the Act.

(c) The following persons shall be required to register:

Any person who, since July 1, 1944, has been or is hereafter convicted in any court in this state or in any federal or military court of a violation of Section 187 committed in the perpetration, or an attempt to perpetrate, rape or any act punishable under Section 286, 288, 288a, or 289, Section 207 or 209 committed with intent to violate Section 261, 286, 288, 288a, or 289, Section 220, except assault to commit mayhem, Section 243.4, paragraph (1), (2), (3), (4), or (6) of subdivision (a) of Section 261, paragraph (1) of subdivision (a) of Section 262 involving the use of force or violence for which the person is sentenced to the state prison, Section 264.1, 266, or 266c, subdivision (b) of Section 266h, subdivision (b) of Section 266i, Section 266j, 267, 269, 285, 286, 288, 288a, 288.3, 288.4, 288.5, 288.7, 289, or 311.1, subdivision (b), (c), or (d) of Section 311.2, Section 311.3, 311.4, 311.10, 311.11, or 647.6, former Section 647a, subdivision (c) of Section 653f, subdivision 1 or 2 of Section 314, any offense involving lewd or lascivious conduct under Section 272, or any felony violation of Section 288.2; any statutory predecessor that includes all elements of one of the above-mentioned offenses; or any person who since that date has been or is hereafter convicted of the attempt or conspiracy to commit any of the above-mentioned offenses.

Penal Code 261.5. (a) Unlawful sexual intercourse is an act of sexual intercourse accomplished with a person who is not the spouse of the perpetrator, if the person is a minor. For the purposes of this section, a "minor" is a person under the age of 18 years and an "adult" is a person who is at least 18 years of age.

(b) Any person who engages in an act of unlawful sexual intercourse with a minor who is not more than three years older or three years younger than the perpetrator, is guilty of a misdemeanor.

(c) Any person who engages in an act of unlawful sexual intercourse with a minor who is more than three years younger than the perpetrator is guilty of either a misdemeanor or a felony, and shall be punished by imprisonment in a county jail not exceeding one year, or by imprisonment in the state prison.

(d) Any person 21 years of age or older who engages in an act of unlawful sexual intercourse with a minor who is under 16 years of age is guilty of either a misdemeanor or a felony, and shall be punished by imprisonment in a county jail not exceeding one year, or by imprisonment in the state prison for two, three, or four years.

(e) (1) Notwithstanding any other provision of this section, an adult who engages in an act of sexual intercourse with a minor in violation of this section may be liable for civil penalties in the following amounts:

(A) An adult who engages in an act of unlawful sexual intercourse with a minor less than two years younger than the adult is liable for a civil penalty not to exceed two thousand dollars ($2,000).

(B) An adult who engages in an act of unlawful sexual intercourse with a minor at least two years younger than the adult is liable for a civil penalty not to exceed five thousand dollars ($5,000).

(C) An adult who engages in an act of unlawful sexual intercourse with a minor at least three years younger than the adult is liable for a civil penalty not to exceed ten thousand dollars ($10,000).

(D) An adult over the age of 21 years who engages in an act of unlawful sexual intercourse with a minor under 16 years of age is liable for a civil penalty not to exceed twenty-five thousand dollars ($25,000).

(2) The district attorney may bring actions to recover civil penalties pursuant to this subdivision. From the amounts collected for each case, an amount equal to the costs of pursuing the action shall be deposited with the treasurer of the county in which the judgment was entered, and the remainder shall be deposited in the Underage Pregnancy Prevention Fund, which is hereby created in the State Treasury. Amounts deposited in the Underage Pregnancy Prevention Fund may be used only for the purpose of preventing underage pregnancy upon appropriation by the Legislature.

(3) In addition to any punishment imposed under this section, the judge may assess a fine not to exceed seventy dollars ($70) against any person who violates this section with the proceeds of this fine to be used in accordance with Section 1463.23. The court shall, however, take into consideration the defendant's ability to pay, and no defendant shall be denied probation because of his or her inability to pay the fine permitted under this subdivision.

Penal Code § 313.1. (a) Every person who, with knowledge that a person is a minor, or who fails to exercise reasonable care in ascertaining the true age of a minor, knowingly sells, rents, distributes, sends, causes to be sent, exhibits, or offers to distribute or exhibit by any means, including, but not limited to, live or recorded telephone messages, any harmful matter to the minor shall be punished as specified in Section 313.4.

It does not constitute a violation of this section for a telephone corporation, as defined by Section 234 of the Public Utilities Code, to carry or transmit messages described in this chapter or to perform related activities in providing telephone services.

(b) Every person who misrepresents himself or herself to be the parent or guardian of a minor and thereby causes the minor to be admitted to an exhibition of any harmful matter shall be punished as specified in Section 313.4.

(c) (1) Any person who knowingly displays, sells, or offers to sell in any coin-operated or slug-operated vending machine or mechanically or electronically controlled vending machine that is located in a public place, other than a public place from which minors are excluded, any harmful matter displaying to the public view photographs or pictorial representations of the commission of any of the following acts shall be punished as specified in Section 313.4: sodomy, oral copulation, sexual intercourse, masturbation, bestiality, or a photograph of an exposed penis in an erect and turgid state.

(2) Any person who knowingly displays, sells, or offers to sell in any coin-operated vending machine that is not supervised by an adult and that is located in a public place, other than a public place from which minors are excluded, any harmful matter, as defined in subdivision (a) of Section 313, shall be punished as specified in Section 313.4.

(d) Nothing in this section invalidates or prohibits the adoption of an ordinance by a city, county, or city and county that restricts the display of material that is harmful to minors, as defined in this chapter, in a public place, other than a public place from which minors are excluded, by requiring the placement of devices commonly known as blinder racks in front of the material, so that the lower two-thirds of the material is not exposed to view.

(e) Any person who sells or rents video recordings of harmful matter shall create an area within his or her business establishment for the placement of video recordings of harmful matter and for any material that advertises the sale or rental of these video recordings. This area shall be labeled "adults only." The failure to create and label the area is an infraction, punishable by a fine not to exceed one hundred dollars ($100). The failure to place a video recording or advertisement, regardless of its content, in this area shall not constitute an infraction. Any person who sells or distributes video recordings of harmful matter to others for resale purposes shall inform the purchaser of the requirements of this section. This subdivision shall not apply to public libraries as defined in Section 18710 of the Education Code.

(f) Any person who rents a video recording and alters the video recording by adding harmful material, and who then returns the video recording to a video rental store, shall be guilty of a misdemeanor. It shall be a defense in any prosecution for a violation of this subdivision that the video rental store failed to post a sign, reasonably visible to all customers, delineating the provisions of this subdivision.

(g) It shall be a defense in any prosecution for a violation of subdivision (a) by a person who knowingly distributed any harmful matter by the use of telephones or telephone facilities to any person under the age of 18 years that the defendant has taken either of the following measures to restrict access to the harmful matter by persons under 18 years of age:

(1) Required the person receiving the harmful matter to use an authorized access or identification code, as provided by the information provider, before transmission of the harmful matter begins, where the defendant previously has issued the code by mailing it to the applicant after taking reasonable measures to ascertain that the applicant was 18 years of age or older and has established a procedure to immediately cancel the code of any person after receiving notice, in writing or by telephone, that the code has been lost, stolen, or used by persons under the age of 18 years or that the code is no longer desired.

(2) Required payment by credit card before transmission of the matter.

(h) It shall be a defense in any prosecution for a violation of paragraph (2) of subdivision (c) that the defendant has taken either of the following measures to restrict access to the harmful matter by persons under 18 years of age:

(1) Required the person receiving the harmful matter to use an authorized access or identification card to the vending machine after taking reasonable measures to ascertain that the applicant was 18 years of age or older and has established a procedure to immediately cancel the card of any person after receiving notice, in writing or by telephone, that the code has been lost, stolen, or used by persons under the age of 18 years or that the card is no longer desired.

(2) Required the person receiving the harmful matter to use a token in order to utilize the vending machine after taking reasonable measures to ascertain that the person was 18 years of age or older.

(i) Any list of applicants or recipients compiled or maintained by an information-access service provider for purposes of compliance with paragraph (1) of subdivision (g) is confidential and shall not be sold or otherwise disseminated except upon order of the court.

Penal Code § 647. Every person who commits any of the following acts is guilty of disorderly conduct, a misdemeanor:

(a) Who solicits anyone to engage in or who engages in lewd or dissolute conduct in any public place or in any place open to the public or exposed to public view.

....

Potential Regulatory Proposal(s) re: Notices to Consumers

OPTION 1: DISCUSSED AT JULY 29, 2010 BOARD MEETING

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, notices containing the text in subdivisions (b), (c), (d) and (e). The board has previously developed and distributed standardized posters for the notices that are required by subdivisions (b) and (c). The board shall similarly develop a standardized poster for the notice required by subdivision (d). For the notices required by subdivisions (b), (c), and (d), the pharmacy shall display the poster developed by the board, or a full-color duplicate thereof.

As an alternative to printed notices, the pharmacy may display one or more required notices on a video screen located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, where the video screen display meets the following requirements:

(1) The video screen is at least 30 inches, measured diagonally;

(2) The text and format of the notice(s) is the same as it would be in printed form, including the size of the notice(s), the size of the text, and the colors utilized;

(3) The text of the notice(s) remains on the screen for a minimum of 30 seconds;

(4) Where the entire text of a notice does not fit onto a single screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least 30 seconds; and

(5) No more than four minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

10/19/10 Leg Reg – Agenda item B.1

Staff Note: Subdivision (b) is the Notice to Consumers currently at § 1707.2, subd. (f)

(b) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

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

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

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

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

What is the name of the medicine and what does it do?

How and when do I take it - and for how long? What if I miss a dose?

What are the possible side effects and what should I do if they occur?

Will the new medicine work safely with other medicines and herbal supplements I am taking?

What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

Staff Note: Subdivision (c) is the Notice to Consumers currently at § 1707.2, subd. (g)

(c) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy,

2. The pharmacist, based upon his or her professional judgment determines providing the item:

- is against the law,
- could cause harmful drug interaction, or
- could have a harmful effect on your health.

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

(d) There shall be a notice containing the following text:

NOTICE TO CONSUMERS

The container label for your prescription medication contains vital information. Please take a moment to check the container label before you leave the pharmacy to be sure that:

The container label has the correct patient name;

The container label has the correct medication name and strength;

The container label has the correct directions for use; and

The container label includes the purpose or condition for which the medication was prescribed, if that information was included in the prescription.

All of these four categories of information must be clustered into one area of the label, and must appear on the label, in the order given above, in at least a 10 point font.

If you would like the text on your container label to be larger, please ask. Upon request, the pharmacy will print a label with the text for these four categories of information in at least a 12-point font. This may result in use of a larger label and/or a larger container.

If you have questions about any of the information on the label, ask the pharmacist.

(e) There shall be a notice containing the following text, repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice:

NOTICE TO CONSUMERS

It is very important that you understand the information on the container label for your prescription medication. If you have trouble reading or understanding English, this pharmacy will make interpretive services available to you in your own language.

(f) The pharmacy shall also post or provide the following statement, repeated in English and in each of the languages for which interpretive services are available, written in at least an 18-point boldface type in a color that sharply contrasts with the background color of the statement, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This statement, repeated in all available languages, may be made available by posted notice or by video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance.

If the posted notice or video screen is not positioned so that a consumer can easily point to and touch the notice or video screen, the statement, repeated in all available languages, shall be made available on a cardstock flyer or handout kept within reach of consumers at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. Such flyer/handout shall be at least 8 inches by 11 inches, on at least 8 point cardstock, which may be laminated. At least one copy of the flyer/handout shall be available at all hours that the pharmacy is open.

OPTION 2: NEW STAFF PROPOSAL BASED ON JULY 29, 2010 BOARD DISCUSSION

Delete 16 CCR § 1707.2, subds. (f) and (g)

Add 16 CCR § 1707.6. Notices Required in Pharmacies.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to give such approval to a committee or the Executive Officer. The pharmacy may also or instead display the notice on video screen(s) located at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, so long as: (1) the video screen is at least 30 inches, measured diagonally; (2) The text, format, size, and colors utilized are the same as the poster-sized notice; (3) The notice remains on-screen for a minimum of sixty (60) seconds; and (4) Where the text of the notice does not fit on one screen, the text is displayed on consecutive/scrolling screens, each of which displays for at least sixty (60) seconds.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

You may ask this pharmacy to use larger print on your prescription drug labels.

Interpretive language services will be made available to you in this pharmacy at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost or a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not in stock, or cannot be immediately provided, the pharmacy will work with you to ensure that you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by prescription drug consumers, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text repeated in English and in each of the languages for which interpretive services are available, printed in an least an 18-point boldface type in a color that sharply contrasts with the background color of the notice, with each repetition enclosed in a box with at least a 1/4 inch clear space between adjacent boxes:

Point to your language. Language assistance will be provided at no cost to you.

This text shall be repeated in at least fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medi-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California.

The pharmacy may post this notice in paper form or on a video screen meeting the requirements of subdivision (a) if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a cardstock flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer/handout shall be at least 8 1/2 inches by 11 inches, shall be printed on durable cardstock, and may be laminated.

Proposal to Amend § 1728. in Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original, Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 144, 851 and 4200, Business and Professions Code.

Executive Officer's Report

Virginia Herold

October 20, 2010

Recent Challenges

- Reduced Staff Resources
  - 36 Furlough days beginning 2/2009
  - Hiring Freeze
  - Overtime Prohibition
  - DCA projects
  - 5% Salary Reduction
- Limited Resources
  - Budget Restrictions
  - Changes in purchasing process

Significant Board Activities

- E-Prescribing
  - DEA new interim rule
    - Consider establishing ad hoc task force
- Drug Take Back
  - Education of consumers/licensees
  - Statutory Changes
- E-Pedigree

Significant Board Activities

- Enforcement
  - Disciplinary Guidelines
  - Drug Diversion
  - Internet Pharmacies
  - Electronic Mail Voting

Significant Board Activities

- Licensing
  - New Exam Content Outline
  - Revised Application Requirements
  - Revisions to Application Forms

Significant Board Activities

- Communication and Public Education
  - Patient Centered Labels
  - Evaluation of Current Materials
  - NPDB/HIPDB report
  - Developed Sample Patient-Centered Labels

Significant Board Activities

- Legislation and Regulations
  - Notice to Consumers - Labeling
  - Sunset Review
  - Enforcement Provisions
  - Regulation Changes
    - Self-Assessment Forms
    - Sterile Compounding Accreditation Agencies
    - Continuing Education

Significant Board Activities

- Organizational Development
  - Administer Inspector Exam
  - Administer Supervising Inspector Exam
  - Recruit for all vacant positions (30)
  - Develop Training Plans and train new staff

Significant Board Activities

- Board Sponsored Task Forces
  - Compounding Regulations
  - Emergency Contraception
  - USP Standards

DCA Initiatives

- BreEZe
  - Data Conversion
  - Forms Standardization
- CPEI
- Healthcare Reform
- Job Creation
- SB 1441
- Social Media

DCA Initiatives

- BreEZe
  - SME on system requirements
  - Leading forms standardization
- SB 1441
  - Workgroup
  - Contract Changes

Major Accomplishments

- Enforcement (2005/06 – 2009/10)
  - +28% in complaints received
  - +143% in complaints completed
  - +746% in application investigations
  - +600% in application investigations completed

Major Accomplishments

- Licenses Issued (2005/06 – 2009/10)
  - +12% Pharmacist
  - +30% Intern
  - +95% Pharmacy Technicians

Total Issued in 2009/10: 14,751

Major Accomplishments

- 1052 Licenses Issued by Site Team
- 2264 Other applications (including Change of Permits, Change of PIC etc.)

- Job Creation (March – June 2010)
  - +66% Applications Approved
  - +79% Licenses Issued

Major Accomplishments

- Regulations
  - Patient Centered Labels
  - Dishonest Conduct during Exam
  - Mandatory Fingerprint Submissions
  - Compounding

Major Accomplishments

- Communication and Public Education
  - NPDB/HIPDB Reporting
  - Medication Error Video
  - 10 CE presentations
  - Two Issues of *The Script*
  - Consumer Outreach activities
  - Outreach activities (Topics included e-pedigree, compounding regulations & drug thefts)

Major Accomplishments

- Organizational Development
  - Secured 24.5 new positions
  - Administered Inspector Exam
  - Developed 15% Reduction Plan Expenses
  - Developed Salary Reduction Plan (to achieve governor's 5% cut)

CONTROLLED SUBSTANCE DIVERSION

10/20/2010

Judi Nurse, Pharm D
Supervising Inspector
CA State Board of Pharmacy

CONTROLLED SUBSTANCE ABUSE

- Schedule II – V misuse/abuse second only to marijuana abuse.
- All other types of schedule I controlled substance abuse added together does not equal schedule II-V abuse
- DARE program decreased illegal substance use, but misconception if a drug is legal, it can't be harmful

Pharmacies - On the Front Lines of "War on Prescription Drug Abuse"

Street value of common controlled substances

- Dilaudid 4mg $15.00-$20.00 per tablet
- Fentanyl - $10.00 per patch
- Hydrocodone - $1.00 - $5.00 per tablet
- methadone - $10.00 per tablet
- methylphenidate - $5.00 per tablet
- morphine - $30.00 per/10 tablets
- MS Contin 60mg - $20.00 per dose
- Oxycodone 80mg - $12.00 - $40.00 per tablet
- Oxycontin 80mg - $35.00 - $50.00 per tablet
- promethazine & Codeine – LA - $200 - $300 / pint
- Tussionex - $30 - $40 per pint
- diazepam 5mg - $1.00 - $2.00 per tablet
- Vicodin ES - $5.00 per tablet
- Xanax 4mg - $3.00 -$5.00 per tablet

*National Prescription Drug Threat Assessment 2009- California

Pharmacists tend to think only of how much a drug costs or sells for, not the street value of the drug.

Why Is My Pharmacy a Target?

- Internet developed illegal controlled substance market
- Ryan Haight Act reducing availability of controlled substances on the internet
  - Reduced U.S. illegal sales outlets
  - Not as much impact on overseas website
  - More prescription controlled substances purchased on the street – more need for drugs on the street
  - Pharmacy employee theft increased to supply controlled substances sold on street
- Patients who are doctor shoppers
- Employee theft for self use of drugs

CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILE

- 2000 - TEN YEARS AGO
  manufacturing losses rare
- wholesale losses rare, usually losses within the wholesale premises
- pharmacy losses – varied and small
  some self use

CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILE (CONT)

- 2010 – TODAY
  - Manufacturing
    - Eli Lily Warehouse - $75 million
    - Eli Lily truck - $37 million
    - Teva truck - $11.8 million
    - Novo Novodisk truck - $11 million
    - Astellas truck - $10 million
    - Unknown company - $8 million
    - GSK Warehouse - $5 million
    - Exel Distribution Center - $3 million
    - Dey Pharmacueticals 2 trucks - $2 million each

    *CBI Bio/Pharmaceutical Summit on Finished Product Supply Chain

Ninety Five Percent of Pharmacies Are Very Efficient, Honest, Extremely Professional

- Board of Pharmacy deals with the other 5%
- Only when something wrong is it reported to us
- We don’t receive reports from the 95% of pharmacies saying “things are fine “

CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- 2010
  - Wholesaling
    - Internal losses
    - In-Transit losses
      - Manufacturer to wholesaler – concealed losses in large shipment
      - Wholesaler to pharmacy
    - Theft from
      - wholesaler's delivery vehicle and drug contents
      - contract delivery drivers
      - contract mail delivery services (UPS, Fed Ex)

CHANGES IN CONTROLLED SUBSTANCE LOSS PROFILES (CONT)

- 2010 Pharmacy
  - Total number of pharmacies reporting losses has increased
  - Total amount of controlled substances lost, increased
  - Individuals stealing from pharmacy
    - Pharmacy technicians, clerks, delivery drivers steal to sell and or self use
    - Pharmacists usually steal to self use
    - Frequent theft by females
    - Employees knowing someone or affiliated themselves with gangs
    - Becoming a supplement to regular income
  - Specific drugs lost more frequently
    - Vicodin products
    - Oxycontin
    - Alprazolam
    - Promethazine & Codeine

WHY IS MY PHARMACY A TARGET? WHO IS DOING THIS?

- Diverter groups –
  - Obtain large numbers of prescriptions from unethical prescribers
  - Prescriptions dispensed by unethical pharmacies
  - Dispensed prescriptions sold or turned over to drug dealers
  - Drugs sold on the street by drug dealers

- Gang involvement
  - Encourage pharmacy staff to steal from pharmacy stock
    - Your staff are targets
    - Demographics of a thief changing
  - Responsible for armed robberies
  - Responsible for night break ins

- Organized Crime Involvement- theft at all levels of distribution

Pharmacy Related Criminal Activity

- Diverter groups, gang involvement and organized crime brings a criminal element into pharmacies not previously experienced.
- Criminals know:
  - Profit high with prescription drug diversion
  - Chances of prosecution reduced if caught
  - Sentences related to prescription drug convictions are less than distribution of illegal drugs

WHAT IS EVERY PHARMACIST'S PROFESSIONAL RESPONSIBILITY ?

A. Prevent loss of controlled substances from your pharmacy
   A. 6700 pharmacies in CA. If each pharmacy looses 1000 Vicodin per year, that is 6.7 million Vicodin on the street illegally
B. Appropriately dispense controlled substance prescriptions only for a legitimate medical need

THE PHARMACIST IS THE FINAL CHECK OF THE LEGITIMACY OF A PRESCIRPTION.

YOUR DECISION DETERMINES IF THE DRUG IS DISPENSED TO A PATIENT FOR APPROPRIATE MEDICAL TREATMENT OR IF THE DRUG GOES TO THE STREET TO BE CONSUMED BY SOMEONE NOT AUTHORIZED TO RECEIVE THE DRUG.

IF THE PATIENT IS AN ADDICT AND/OR PHYSICIAN A CRIMINAL, THE PHARMACIST DECISION IS THE LAST AND FINAL CHECK TO PROTECT THE HEALTH AND SAFETY OF THE PATIENT AND THE PUBLIC.

APPROPRIATE CARE OF LEGITIMATE PAIN PATIENTS

- Legitimate pain patients must receive prompt, appropriate treatment to meet their pain needs without discrimination.
- It is the pharmacist's professional responsibility to make appropriate decisions regarding dispensing of pain medication for a legitimate medical need.

PREVENTING LOSS OF CONTROLLED SUBSTANCES FROM PHARMACY

- Investigate employees before hire, monitor and observe employees after hire

- Losses occur at any step in process of drug movement into and through a pharmacy.
  - Ordering prescription drugs
  - Prescription drugs in transit
  - Receipt of prescription drugs by pharmacy
  - Pharmacy check in of prescription drug delivery
  - Review of purchase invoices by Pharmacist In Charge
  - Appropriate storage of prescription drugs in pharmacy
  - Prescription Drugs stolen while stored in pharmacy
  - Night break in, robberies

    *Best practice to develop parameters and monitor each step to prevent or detect drug losses from pharmacy

PHARMACY – ORDERING DRUGS

- Who orders drugs?
- Usually a trusted technician
- Numerous occasions trusted technician ordering and stealing drugs
- Do not place only one person in charge of ordering, at least 2 people, one RPH
- Have work divided so both individuals check and see the other's work.

PHARMACY IN –TRANSIT LOSSES

- Drugs diverted before arriving at your pharmacy
  - UPS, Fed X, Postal Service, Wholesale delivery drivers, contract couriers
  - Cross docking
  - If your pharmacy signs for the order you are responsible for loss and you, not the wholesaler must report drug loss
- Hijacking delivery vehicles

PHARMACY -RECEIPT OF DRUGS

- Who signs for the drug delivery at pharmacy?
- CA Pharmacy Law requires Pharmacist-In-Charge preferably or a pharmacist sign for all dangerous drug deliveries
  - Code section written to protect Pharmacist – In-Charge
    - Drug could not be ordered and delivered to pharmacy and then diverted without a pharmacist knowing.

PHARMACY DRUG ORDER CHECK –IN & PROPER STORAGE

- Complete check in of orders and put orders away on shelves
  - Drugs disappear from unattended totes and unknown if used for a waiting order or disappeared
  - Invoicing can be stolen along with the drug to prevent loss from being discovered

- The safest place for drugs is stored in their proper place on the shelves
  - Store drugs likely to be stolen either in a locked area with only RPH access or ...
  - Store where staff can easily see who frequents the storage area.
    - Not in back of storage bays that cannot be easily viewed
    - Not near the restroom
    - Not near a rear exit
    - Not near storage area for employee personal items
    - Watch that fast movers are not stored too near any public access
    - Document items stored in the "expired" or "returns" area of pharmacy
    - Process RTS promptly and get back on the shelf- caution if one person volunteers for that task

PIC REVIEW OF PURCHASE INVOICES

- Pharmacist-In-Charge must review invoices for dangerous drugs received by pharmacy
  - 100,000 tablets of Vicodin stolen by ordering technician from a San Diego hospital and no one at hospital knew until police arrested technician
  - 450,000 tablets of generic Vicodin stolen from a retail pharmacy by trusted technician. Pharmacy had no idea drugs were missing
  - Review invoices very carefully for days Pharmacist in Charge does not work

DRUGS STOLEN FROM STOCK

- Drugs hidden and later stolen from pharmacy
- Non pharmacy employees entering pharmacy
  - Front end managers usually have emergency key access
  - Family members
  - Employees visiting on days off
  - Custodial, maintenance, inventory workers
  -
- How drugs leave the pharmacy
  - Hidden
  - Dispense prescription without authorization or refills & steal prescription
  - Night break ins
  - Robberies

What Do I Do When I Think A Drug Is Missing?

- Count drugs in question immediately and audit to determine if loss and how much
- Attempt to determine cause of loss
- If you identify a person stealing prescription drugs, have them arrested and prosecuted
- Report losses to DEA and CA State Board of Pharmacy promptly

How Do You Determine If You Have a Loss

- As soon as suspect a loss, inventory/count the drugs in question – Date and time your inventory
- Retrieve last DEA inventory and determine count for the drugs in question on that inventory
- Determine total acquisitions/purchases of drugs in question for the time period between DEA inventory count and current count
- Determine total dispositions/dispensing of drugs in question for the period

Calculating Potential Controlled Substance Losses

- Start with quantity reported on DEA inventory
- Add in purchases for time period
- Subtract dispensing for time period
- The result of this calculation should equal your current count
- If you have a negative number
- If you have a positive number

How to Determine Cause of Loss

- Count drugs in question daily or per shift to determine when losses are occurring
- Determine staff working on dates of loss – include ancillary staff, maintenance, cleaning staff and non employees visiting pharmacy
- Install cameras if needed
- Interview staff
- If your corporation has loss prevention staff follow corporate policy and notify pharmacy supervision and loss prevention immediately when a loss discovered
- If employee admits stealing drugs, get that admission in writing

WHAT DO I DO IF I IDENTIFY PERSON STEALING

- Contact DEA, Diversion office if you need assistance reporting theft to local law enforcement or...
- call local law enforcement and have the person arrested
- Report suspicion of loss to DEA immediately and report significant loss to DEA on electronic DEA 106 form found on DEA website
- Report in writing all controlled substance losses to CA State Board of Pharmacy within 30 days of discovery of the loss.
  - May us DEA 106 form or...
  - May use a form of your own design

Reporting Impaired Licensees Mentally, Chemically, Physically

- Business & Professions Code Section 4104
  - Policy and procedure to take action to protect public when a licensed person employed by your pharmacy is known to be mentally, chemically or physically impaired to the extent it affects their ability to practice their profession or occupation. (RPH, Technician, Intern Pharmacist)
  - Pharmacy must report to board within 30 days discovery of above impairment
  - Code section has a list of documents pharmacy required to provide to board
  - Anyone reporting is immune from civil or criminal liability for reporting

Appropriately Dispensing Controlled Substances – Corresponding Responsibility

- CA Health & Safety Code Section 11153
  - Prescriber must write a prescription for a legitimate medical purpose during his/her usual course of practice
  - Pharmacist has a corresponding responsibility to determine that prescription is for a legitimate medical need.

Corresponding Responsibility (cont)

- Patient/pharmacy relationship
  - How much do you interact or know about the patient
- Patient/prescriber relationship
  - Are you certain prescriber has ever examined the patient or communicated directly with the patient
- Pharmacy/prescriber relationship
  - How much have you communicated with the prescriber or know about him/her prescription writing practices

Should I Dispense This Prescription?

- Considerations
  - The prescription document
  - The prescriber
  - The patient
  - Appropriate drug therapy

Evaluation of the Prescription

- CA Security Prescription
  - Are controlled substance prescriptions written on CA Security Prescription or written on normal prescription document and pharmacy has to reduce order to a telephonic order
  - Is prescriber information accurate
    - DEA number
    - Telephone number
    - Be cautious of strange prescriptions with last name of doctor beginning with the letter “A”
  - Is the document legitimate
  - Evaluate written prescription presented to you for obvious signs of forgery
- Do you know the person calling in telephone orders
- Are you sure of the source of controlled substance prescriptions received by fax.

Evaluation of the Prescriber

- Status of CA license to practice medicine
- Status of DEA registration
- Status of Medi-Cal provider number
- What is prescriber specialty
- Prescribing practices
  - Do you fill a mix of dangerous drug and controlled sub ance prescriptions from this prescriber or only controlled su ances – excessive percentage of controlled substances – usual -20%
  - Does prescriber write for the same combination of dru , same quantity and same directions for all or most patients
- Any prior discipline of any type
- Is pharmacist ignoring warning signs and continuing fill controlled substances for a particular prescriber

*

Evaluation of Information Available about the Patient

- Does the pharmacy know or ID the patient
- CURES report if patient unknown or suspect
- Does patient live in normal trade area
- Distance patient lives from prescriber
- Does patient have addiction or abuse history
- Does patient pick up their own meds or a runner, what is relation to patient
- Patient age
- Diagnosis
- Patient appearance
  - Does patient appear to fit the diagnosis
  - Evaluate for adverse effects of prescribed medications – overly sedated, dizzy, confused
  - Does patient appear in excessive pain

Evaluation of Drug Therapy

- Does drug match diagnosis
- Abuse potential of the drug
- Length of therapy and quantity ordered
- Does patient take medication per directions or early refills
- Are unusual combinations prescribed.
  - Uppers/downers
  - Time release pain med without something for breakthrough pain.

Pharmacist - Evaluate Your Own Practice

- What would cause you to refuse to fill a controlled substance prescription
- How would you react if you received a large number of controlled substances from a single doctor
- What documentation do you keep when treating chronic pain patients
  - CURES data
  - Notes of communication with patient and prescriber- are communications retained in computer data base or in a hand written document or when a new entry is made, is the previous entry deleted.
  - How do you document when you decide to dispense or not dispense a prescription that may be an excessively early refill, unusual combination of therapy etc.

Pharmacist Real-Time Access to CURES Data

- Pharmacist must be affiliated with a pharmacy
- Pharmacist can only access CURES data to evaluate prescription history of a patient being treated by the affiliated pharmacy
- Pharmacist must apply to Bureau of Narcotic Enforcement to receive real time access to CURES data
- That application will be investigated to determine
  - if pharmacy is in good standing with board of pharmacy and DEA
  - If pharmacist is in good standing with board of pharmacy

*Real time access important for staff working pm's, nights and week ends when prescriber not available.

Internet Prescriptions/ Internet Pharmacy

- Business & Professions Code section 4067
  - Dispensing internet prescription for a CA [illegible] thout a good faith medical exam can result in a fine of $25,000 per prescription.
  - This code section written to stop this profit base[illegible] dispensing of drugs to CA patients. You dispense those prescri[illegible]ons you will be fined $25,000 per prescription
  - Good faith medical exam is usually defined as or[illegible] actual examination by the prescriber
  - Good faith medical exam is not –
    - Dispensing based only on a questionnaire [illegible]ed by the patient on the internet
    - Dispensing utilizing medical records provided [illegible]y patient documenting previous medical treatment

Don’t Let Your Pharmacy be a Victim of Internet Dispensing Scam

- Internet marketer cold calls pharmacy
- Offers you as many prescriptions per day as you want to
- You access website and request number of prescriptions you want to dispense.
- Prescription labels, ancillary patient information and shipping label print out at your pharmacy
- Prescription documents held by website, not your pharmacy. If inspected not able to access documents
- You dispense rx, and mail to patient
- You are paid by the internet marketer not the patient
- Usually $5.00 to $10.00 plus cost of drug. The internet marketer charges the patient as much as $200 for the prescription
- Cheaper for patient to pay for prescriber office visit and pay pharmacy cost of drug
- You have no patient/pharmacy relationship. You have no physician/pharmacy relationship. You don’t know if there is a prescriber/patient relationship. You have only a pharmacy/internet marketer relationship

REMEMBER

- YOU ARE THE PERSON WITH RESPONSIBILITY FOR THE SECURITY OF THE DRUGS. YOU ARE THE LAST LINE OF DEFENSE AGAINST DIVERSION OF THOSE DRUGS TO THE STREET, EITHER BY THEFT FROM YOUR PHARMACY OR INAPPROPRIATE DISPENSING OF CONTROLLED SUBSTANCES

HOW TO PREPARE FOR A PHARMACY INSPECTION

PHARMACY COMPLIANCE MANUAL:

- Self Assessment
- Copies of RPH &TCH licenses
- Master list of RPH & TCH initials/signature
- Power of Attorney for DEA 222 Forms
- Biennial Controlled Substance Inventory
- Executed DEA 222 Forms
- DEA 106 Forms for Loss/Theft
- TCH P/P including job description, temporary absence of RPH

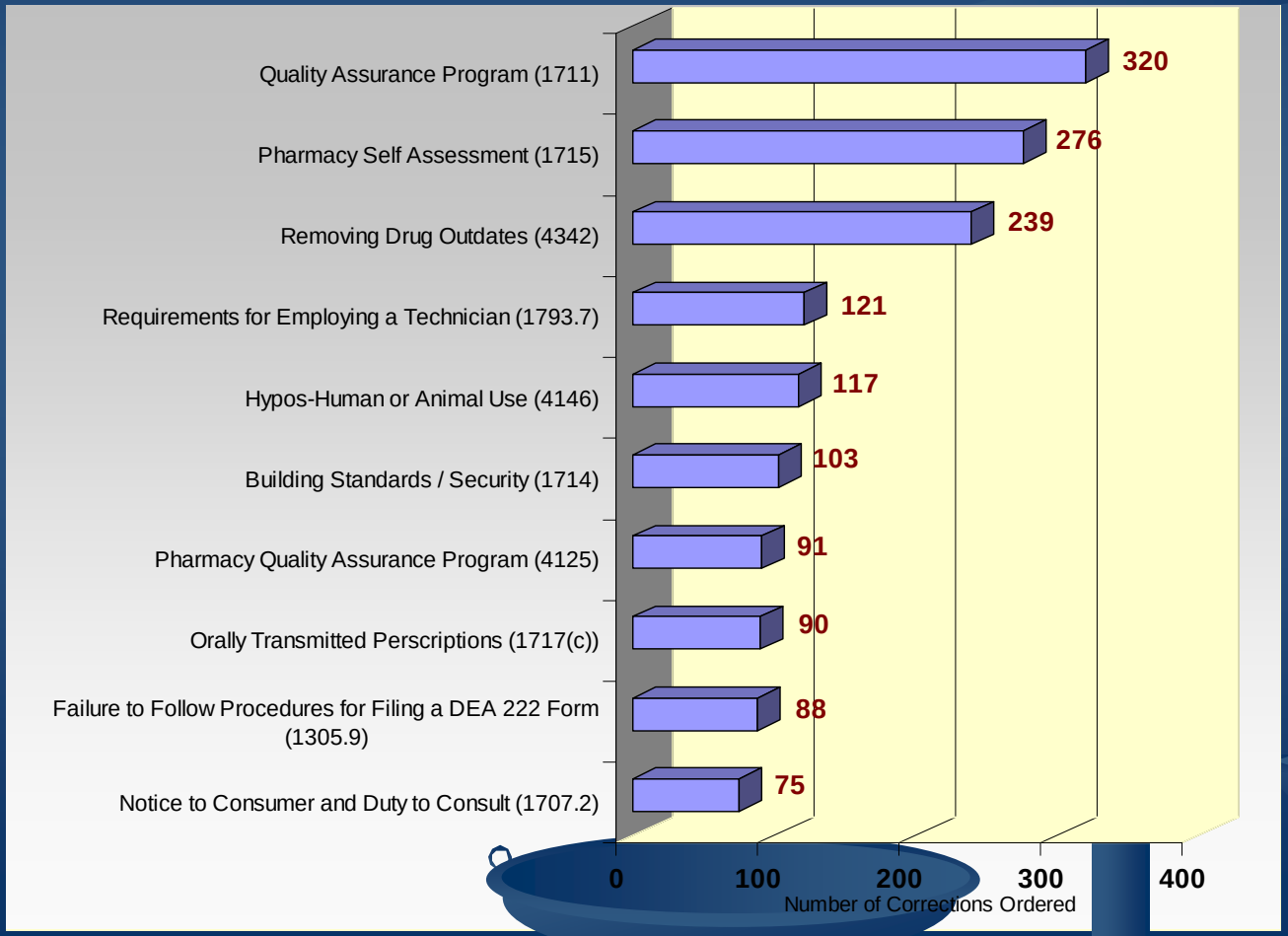
RECOMMENDATION

PHARMACY COMPLIANCE MANUAL:

- Self Assessment
- Copies of RPH &TCH licenses
- Master list of RPH & TCH initials/signature
- Power of Attorney for DEA 222 Forms
- Biennial Controlled Substance Inventory
- Executed DEA 222 Forms
- DEA 106 Forms for Loss/Theft
- TCH P/P including job description, temporary absence of RPH

INSPECTION PROCESS

Top 10 Corrections



- QUESTIONS?

CA State Board of Pharmacy

916-574-7900

www.Pharmacy.ca.gov

Judi.Nurse@dca.ca.gov

INSPECTION PROCESS

WHAT DO WE INSPECT

- Pharmacies (5993)
- Hospital Pharmacies (491)
- Drug rooms (44)
- Licensed Sterile Compounders (221)
- Clinics (1084)
- Licensed Correctional Facilities (45)
- Wholesalers (455)
- Veterinary Food Animal Retailers (23)
- Probationers (100)

INSPECTION PROCESS

WHEN DO WE INSPECT

- Routine: Every 3 years.
- When a complaint is received.
- Probation inspection: quarterly or more frequent.
- Annually for LSC license renewal.

INSPECTION PROCESS

WHAT DO WE ASK FOR

- Self-Assessment.
- DEA Inventory, DEA 222, DEA 106.
- Prescriptions; refill log; daily reports.
- Acquisition records (invoices, etc.)
- Disposition records (returns, etc.)
- Review policies and procedures.

INSPECTION PROCESS

WHAT DO WE DO

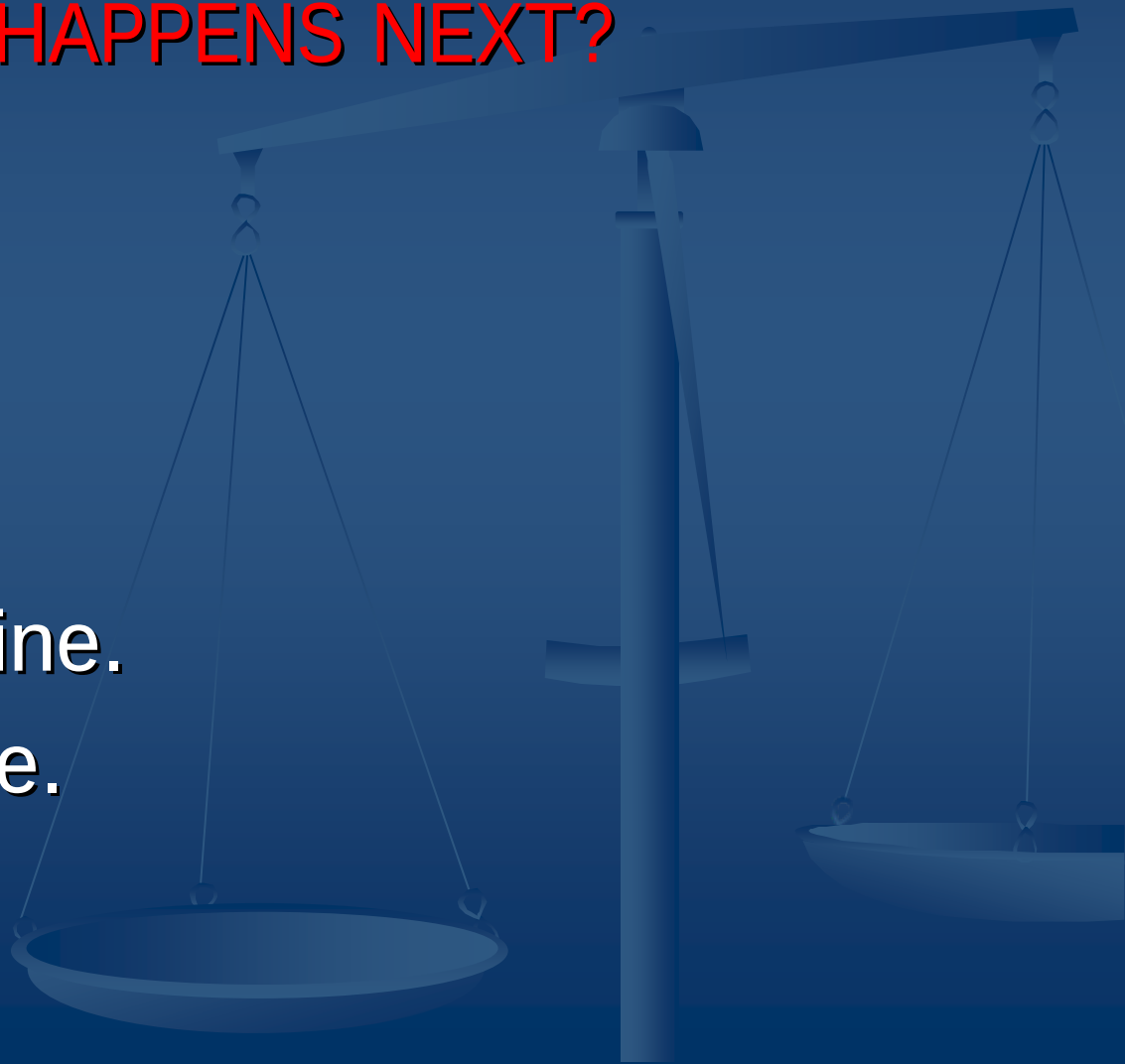
Review records and documents provided, physical plan inventory, security, sanitation, pharmacy practice.

1. Complete an inspection report.
   - Document findings.
   - Inspector comments.
   - May include a Written Notice in addition to inpection report and an Official Receipt if we take copies of any documents.
2. Exit interview.
3. Licensee comments.

INSPECTION PROCESS

WHAT HAPPENS NEXT?

- Discussion.
- Correction.
- Written notice.
- Informal Discipline.
- Formal Discipline.



DISCIPLINARY PROCESS

- Informal Discipline
  - Letter of Admonishment
  - Citation without Fine
  - Citation with Fine

BPC 4315 – LOA; BPC 4314 – C&F

Appeal process – Office Conference, Administrative Hearing

- Formal Discipline- Administrative action taken against either pharmacy license or pharmacist license.
  - Probation
  - Suspension
  - Revocation
  - Require participation in Pharmacist Recovery Program

Accusation filed by CA State Attorney General, Administrative Hearing or Stipulated Agreement. Appeal process to Superior Court

QUESTIONS

Contact Us

www.pharmacy.ca.gov

916-574-7900

CalPERS ePrescribing Pilot Finding

California State Board of Pharmacy

October 21, 2010

Vision

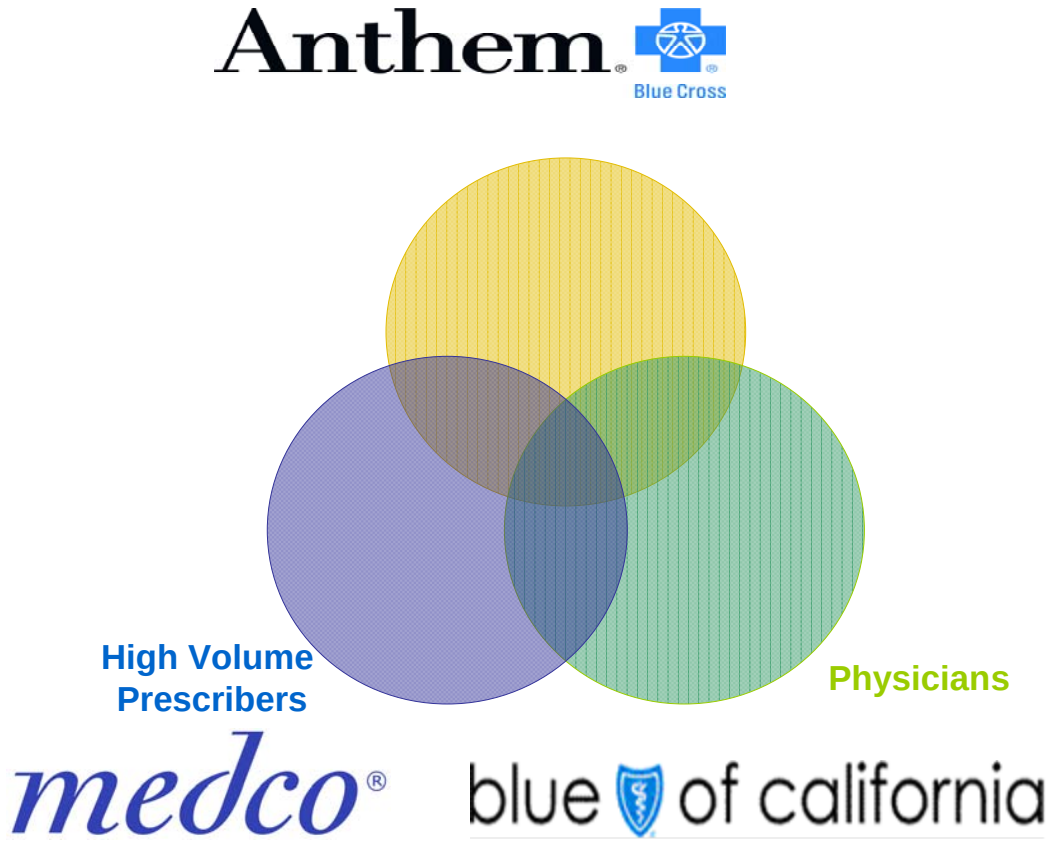
- CalPERS will lead in the promotion of health and wellness of our members through best-in-class, data-driven, cost-effective, quality, and sustainable health options for our members and employers.
- We will engage our members, employers, and other stakeholders as active partners in this pursuit and be a leader for health care reform both in California and nationally.

CalPERS ePrescribing Pilot

CalPERS conducted a pilot project on ePrescribing with our health-plan partners:

- **Anthem Blue Cross**
- **Blue Shield of California**
- **Medco**

The pilot launched in the 1st quarter 2009 and concluded June 2010.



CalPERS Pilot Physician Groups

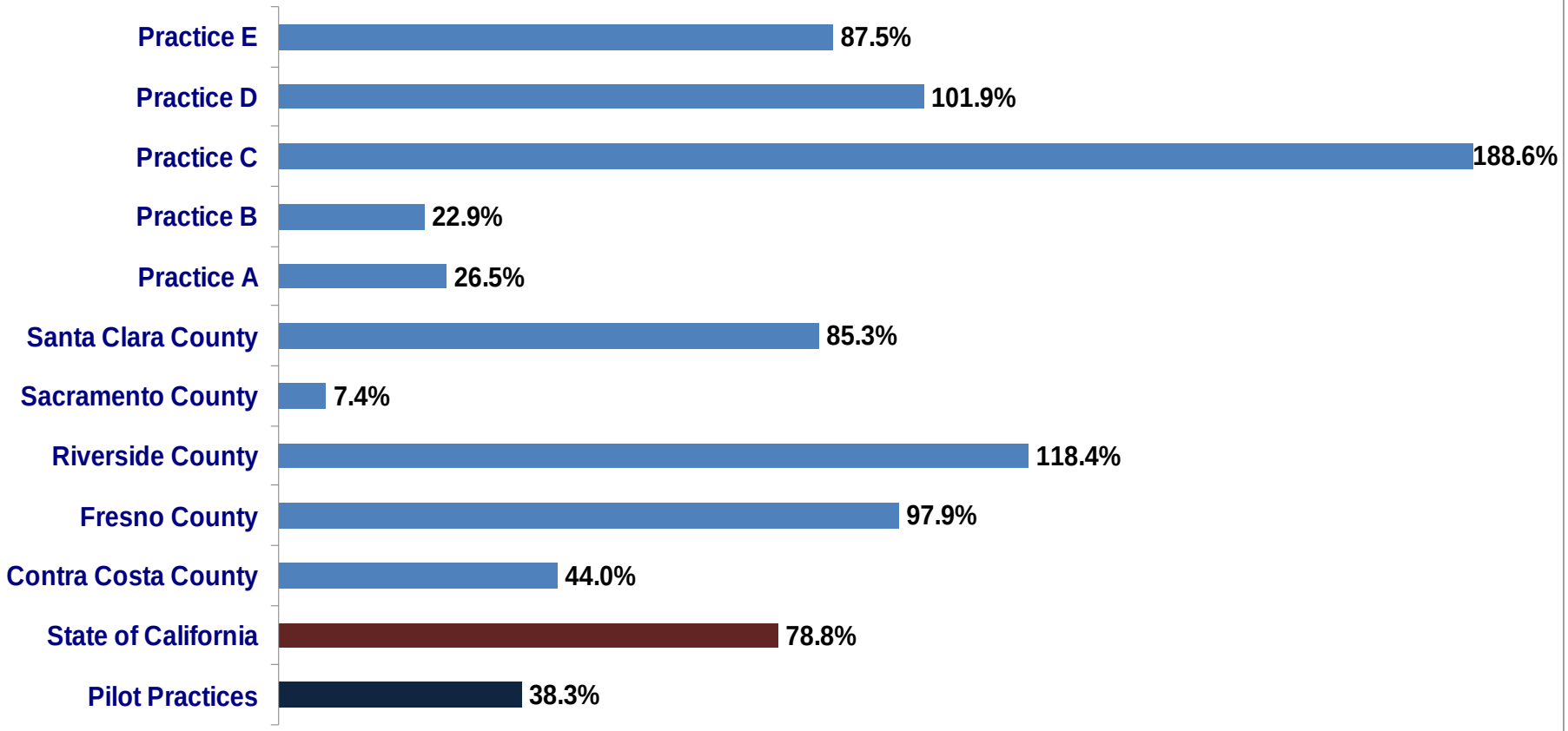
Group Name	# of Prescribers	Service Region	ePrescribing Application
San Jose Medical Group	86	San Jose	AllScripts
John Muir Physician Network	667	Walnut Creek	NextGen EMR & RelayHealth ePrescribing for non-EMR users
North American Medical Management of California (PrimeCare)	1625	Riverside & San Bernardino Counties	MedPlus ePrescribing solution
Sante Community Physicians	1162	Fresno	Care 360 with Quest Diagnostics
Hill Physicians Group	3600	Sacramento	NextGen EMR & RelayHealth ePrescribing for non EMR users

ePrescribing Transactions

- New Rx
- Renewal
- Medication History
- Formulary Benefit
- Verify / Status
  - Not used
    - Rx Fill
    - Rx Cancel
    - Rx Change

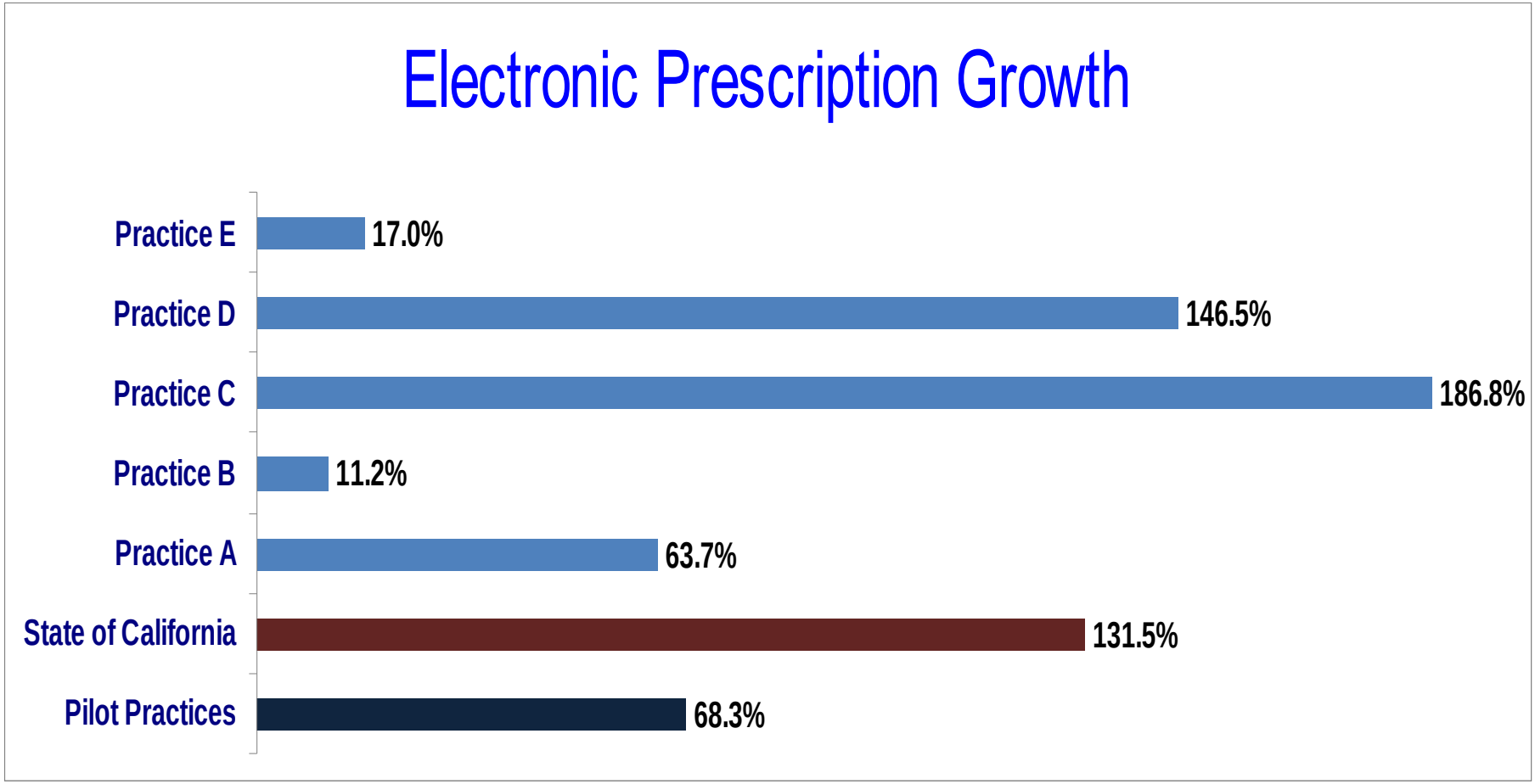
CalPERS Pilot Metric

Growth Rates Active Prescribers



* Surescripts data

CalPERS Pilot Metric



* Surescripts data

CalPERS Pilot Metric

California: Electronic Prescription Activity and Activated Pharmacies

	New eRx	eRenewals	Activated Pharmacies
2009 Q1	1,726,276	492,251	3,990
2009 Q2	2,214,985	592,511	4,083
2009 Q3	2,647,320	808,236	4,185
2009 Q4	3,159,335	953,224	4,287
2010 Q1	3,719,248	1,072,990	4,379
2010 Q2	4,132,643	1,003,881	4,473

New eRx and eRenewals more than doubled

12% more California pharmacies were connect during the measurement period

* Surescripts data

CalPERS Pilot Metric

- Number of plan benefit transactions requested:
  - Eligibility, Formulary & Benefits
  - Medication History
- One physician group showed a 181% increase in these transactions during the measurement period.

Note: All data was not available and therefore not reported within the time constraint of this presentation; will be included in the final report.

* Plan Data

Prescription Origin Code

	4Q09	1Q10
Unknown	1,086,811	428,944
Written	199,340	758,417
Telephone	56,610	99,265
Electronic	43,843	99,672
Fax	83,401	142,556
TOTALS	1,470,005	1,528,854

•Not mandatory until 1/1/2010 for Med D New eRx

* CalPERS Data

CalPERS Pilot Metric

Safety Measures:

- Number of Safety alerts (duplicate therapy, early refill, allergies, high or low dose)
- Number of prescriptions changed as a result of the adverse drug event alerts

Prescriber Survey:

- 100% believed eRx increased drug safety
- 50% of the prescribers made AT LEAST ONE change because of safety alert

System Reports:

- Not available because of reporting functionality of the ePrescribing applications.

* Survey Data

CalPERS Pilot Metric

- Prescriber Efficiency Measures by Survey:
  - Improved efficiency during patient visit – 67%
  - Saved pharmacy follow-up calls – 100% reported moderate savings
- Prescriber Satisfaction with eRx:
  - 100% are somewhat satisfied

* Survey Data

CalPERS Pilot Metric

- Compliance:
  - Average Medication Possession Ratio (MPR)
  - % of members with greater than 80% MPR

Note: This data could not be reported on within the time constraint of this presentation; will be included in the final report.

CalPERS Pilot Metric

Generic and Formulary Compliance

	2Q 2010 Non ePrescribers	2Q 2010 ePrescribers
Generic Dispensing Rate	**70%**	**77.4%**
Formulary Compliance Rate	**93%**	**94.2%**

- Prescriber Survey: 33% extremely helpful and 67% somewhat helpful for generic and formulary alternatives

* Plan Data

CalPERS Pilot Metric

➢Plan Data Availability

	Medco	Anthem	BSC
Formulary & Benefit	√	√	√
Medication History	√	√	√

Note: This data has been available from all plans throughout the pilot program.

CalPERS Pilot Metric

- Certification Status for participating Mail Order Pharmacies:

	Medco	Prime	NextRx
New eRx	√	√	√
eRenewals	√	√	WIP*

WIP*: Certification work is in progress

* Plan Data

CalPERS Pilot Metric

- ePrescribing Application Certification Status:
  - New Prescription
  - Renewals - Retail
  - Renewals - Mail
  - Eligibility + Formulary & Benefits
  - Medication History

Note: This data could not be reported because of multiple applications and versions of each application.

ISSUES

- Certification and lack of transparency
- Performance
- Limitations
- Inconsistencies
- Lack of transparency on true capabilities
- Lack of routine database updates - Provider data matching issues
- Lack of support with issues / training
- Workflow
- Limited Influence by other stakeholders
- Reporting capabilities
- Not all prescribers or pharmacies connected
- Cost
- Incentives
- Controlled Substances requirements
- Patient privacy & confidentially – consent
- End-to-end testing
- Key player – SureScripts

Pilot's Outcomes

- Helped pilot groups understand their own barriers to adoption and improved communication
- Stimulated more communications among prescribers, pharmacies and other stakeholders
- Provided ePrescribing knowledge to physicians
- Engaged other ePrescribing efforts to increase pilot impact
- Encouraged discussions on improvement opportunities
- ePrescribing added to CalPERS' contracts

Next Steps

- Deliverables
  - Final Pilot Report
  - Resource Document
  - Press Release

- Promote Electronic Medical Record

  i.e. Cal eConnect and the California E-Prescribing Consortium

California e-Prescribing Consortium Update for CA Board of Pharmacy

October 21, 2010

Vision and Goals

Vision - Advancing the use of e-prescribing (eRx) to achieve safe and affordable health care for all Californians, with the goal of supporting California providers with adoption of eRx to achieve EHR meaningful use by 2012.

- Increase number of scripts routed electronically in California by ensuring that all CA pharmacies are able to receive scripts by 2011
- Double the number of health plan lives available through eRx by 2011
- Work with providers to achieve meaningful use of EHRs

CaleRx Background

- **Initial concept of California Health Care Foundation**
- **Project Management – Manatt and CHCF consultants**
- **Governed by an Advisory Board**
  - Pharmacy, provider, health plan, pharmaceutical, foundation, software vendor and network organizations and state leaders
- **Executive Committee – Blue Shield of CA, California HealthCare Foundation, CalOptima, Department of Health Care Services and LA Care Health Plan**
  - Work groups – pharmacy, provider and health plan

CaleRx Participants

Funders/Advisory Board Members
Blue Shield of CA
CalOptima
California HealthCare Foundation
DHCS/Medi-Cal
LA Care Health Plan
McKesson
Novartis

Advisory Board Members
Affinity Healthcare
Allscripts
CA Association of Physician Groups
CA Board of Pharmacy
CalHIPSO
CalPERS
CHW/Mercy Medical Center
CMS Region IX
CVS/Caremark
Emdeon/eRxNetwork
HITEC-LA
Lim's Pharmacy
San Mateo Medical Center
Sharp Healthcare
Surescripts

Provider Organizations
Contra Costa Regional Med Ctr
Council of Community Clinics, SD
Hill Physicians
Kern Medical Center
Memorial Healthcare IPA
North County Health Services
Northeast Valley Healthcare
Safety Net Institute/CAPH
Scripps Health
Shasta Community Health Center
Sutter Health
Tulare/Kings County Med Fdn
UC Davis Medical Center
UC San Diego Medical Center
UCSF

State and Other Stakeholders
Anakam
AthenaHealth
CaleConnect
California Hospital Association
DrFirst
eMDs
Lumetra
Medco
NextGen
Pacific Business Group on Health
RAND
Relay Health

Pharmacy Organizations
Costco
Independent Pharmacy Assoc
Kroger
Prescription Solutions
Raleys
Ralph's
Regal Med
Rite Aid
Safeway
USC School of Pharmacy
Walgreens
Wal-Mart

Health Plan Organizations
Aetna
Anthem Blue Cross
Blue Shield of CA
CAHP
Health Net
Medi-Cal
UnitedHealthCare

To learn more, visit www.calerx.org or join our group on LinkedIn.

CaleRx Activities and Resources

- **Advisory Board and workgroup facilitation**
- **Provider/pharmacy collaboration**
  - Encouraged through quality improvement projects
  - Addressing directory quality/data matching issues
- **Address challenges to data access with Surescripts**
- **Coordination with RECs and pilot programs (CalPERS, Tulare County, CAPH, Medi-Cal, RAND and others)**
- **Vendor and network demonstrations of meaningful use**
- **Coordination with CaleConnect and State eRx leaders**

- **www.calerx.org -** Source of eRx news, data and educational tools (e.g. RAND eRx toolkits for Prescribers and Pharmacists)
- **www.linkedin.com -** California e-Prescribing Consortium group for networking and sharing of best practices on eRx

Major eRx Issues in CA

- **Coordination with Surescripts**
  - Access to data and reporting to demonstrate adoption
  - Lack of network transparency
- **Health plan ROI**
  - Lack of business case, e.g. Medi-Cal pilot
  - Data inaccuracy and security concerns
- **Pharmacy participation (especially independents)**
  - Burdensome transaction fees
  - Legacy pharmacy systems

Major eRx Issues in CA

- **Ongoing POC-pharmacy vendor technical challenges**
  - Directory quality issues
  - Turnover and training issues
- **Prescribing of controlled substances**
  - Two-factor authentication
  - Confusion as to state and federal laws
- **Educating providers new to eRx and facilitating access to incentives for meaningful use**
  - "What's in it for me?" for pharmacists (example, NY Medicaid incentive program)

Where we stand: looking ahead to 2011

- **Engage pharmacies through CaleRx Annual Meeting on November 9 in Oakland**
  - Register at http://www.surveymonkey.com/s/KKYH7C9, or email calerx@manatt.com to receive registration information
- **Determine pharmacy priorities for 2011**
  - Address network issues
  - Promote access to health plan data
  - Work toward resolution of directory quality issues
  - Discuss potential for pharmacy incentives (e.g. NY program)
- **Coordinate with CaleConnect to sustain program**
  - Define project needs and funding opportunities