California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE: February 1 and 2, 2011

LOCATION: First Floor Hearing Room
400 R Street
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Neil Badlani, RPh
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD, 2/1 only
Shirley Wheat, Public Member, 2/1 only
Deborah Veale, RPh
Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Janice Dang, Supervising Inspector, 2/1 only
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Debi Mitchell, Licensing Manager, 2/1 only
Susan Cappello, Enforcement Manager, 2/2 only
Tessa Miller, Staff Analyst

Call to Order

President Stan Weisser called the meeting to order at 9:00 a.m.

I. General Announcements

President Weisser welcomed newly appointed Board Member Anil "Neil" Badlani.

President Weisser announced that Board Member Shirley Wheat has been reappointed to the board.

II. Approval of the Full Board Meeting Minutes of October 20 and 21, 2010

MOTION: Approve the minutes of the October 20 and 21, 2010 Board Meeting.

M/S: Schell/Lippe

Support: 10 Oppose: 0 Abstain: 0

III. Licensing Committee Report and Action

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

Board Member 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 stated that these specialized pharmacies may be either hospital pharmacies or community pharmacies. Mr. Lippe explained 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:

1. the pharmacy is licensed by the board

AND

2. 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 in 2003, two accreditation agencies received board approval: 1. Accreditation Commission for Health Care, Inc. (ACHC), and 2. Community Health Accreditation Program (CHAP).

Mr. Lippe provided that since that time board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. He stated

that currently the board has 225 such licensed facilities in California and 78 nonresident pharmacies with such permits.

Mr. Lippe provided that also in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. He stated 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 and good professional practice standards and the following factors.

1. **Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Mr. Lippe provided that the board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. He advised that modified regulations detailing requirements for pharmacies that compound medication took effect July 7, 2010. Mr. Lippe stated that included in these regulations are modified requirements for pharmacies that compound sterile injectable medication.

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

1. Review and assess the three 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 already approved accreditation agencies, ACHC and CHAP, for one year until April 2011.

Mr. Lippe provided that the committee was advised of the assessment results completed by Supervising Inspector Janice Dang for both Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP). He stated that Dr. Dang provided a comparison of both agencies and reviewed site inspection results from 2 pharmacies for each agency.

Mr. Lippe provided that based on the information provided, the committee sought clarification on areas of possible concern and requests were made to CHAP and ACHC to provide information to the board by January 10, 2011 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn, and denied within the last five years as well as validation information.

Mr. Lippe referenced to the following attachments provided in the board packet:

1. Detailed Comments of ACHC
2. Supplemental Information received from ACHC
3. Detailed Comments of CHAP
4. Supplemental Information received from CHAP
5. Comparison of all 4 accreditation agencies
6. Results of Site inspections of pharmacies accredited by each agency

Mr. Lippe reviewed the recommendation from the committee to approve the two accreditation agencies.

Supervising Inspector Janice Dang introduced Terry Duncombe, representing CHAP and Tim Safley, representing ACHC to the board.

Dr. Dang provided an overview of ACHC and highlighted findings from her assessment of the agency. She indicated that ACHC has submitted the information requested by the Licensing Committee regarding the number of pharmacies accredited in California and throughout the United States. Dr. Dang reviewed this response and advised that the information submitted does not specify which pharmacies are compounding pharmacies and specialty pharmacies.

Dr. Dang discussed the concern from the Licensing Committee regarding pharmacies that appear to “ramp up” their standards for accreditation purposes. She indicated that pharmacies licensed by California are subject to annual inspections.

Mr. Safley responded to questions from the board regarding Dr. Dang’s assessment.

Mr. Lippe asked whether ACHC utilizes pharmacists as part of the survey teams.

Mr. Safley provided that all surveys of a pharmacy are done by a pharmacist. He referred to a packet distributed to the board regarding the ACHC accreditation program. Mr. Safley discussed that the program includes four pharmacy services including: (1)

infusion pharmacy, (2) ambulatory infusion center, (3) infusion nursing services and (4) specialty pharmacy. He stated that compounding pharmacies and specialty pharmacies are only surveyed by a registered pharmacist.

Board Member Ken Schell asked whether there is a formal mechanism in the survey process to address issues and concerns.

Mr. Safley discussed that ACHC utilizes an Investigative Committee for both compliance and complaint issues. He stated that there is a mechanism in place for reporting to the board.

Executive Officer Virginia Herold thanked Mr. Safley for submitting the requested data. She asked whether ACHC has ever revoked accreditation.

Mr. Safley provided that ACHC has revoked about 218 accreditations for all of its services. He stated that data regarding the reapplication of a revoked entity is not maintained.

Ms. Herold indicated that the board should be notified of any complaints regarding the safety of drugs or the safety of the procedures being used by the accredited pharmacies. She stated that the board will work with ACHC to help facilitate this information.

Mr. Safley requested that ACHC also be notified regarding any complaints submitted to the board against an ACHC accredited pharmacy.

Board Member Ramón Castellblanch asked whether ACHC is paid by the entities that it accredits.

Mr. Safley stated that ACHC is paid by these entities.

Dr. Castellblanch requested clarification regarding the results of the board's assessment of the two ACHC accredited pharmacies.

Dr. Dang provided that no issues of noncompliance were identified. She stated that both ACHC-accredited pharmacies assessed were aware of the new compounding requirements. Dr. Dang discussed that one of the pharmacies assessed was offered an education on implementation in this area.

Dr. Castellblanch discussed that the board needs to be vigilant in the review of these pharmacies as they are paying for ACHC accreditation.

Ms. Herold discussed that the assessment of the ACHC accredited pharmacies only identified minor corrections. She stated that there were no major areas of noncompliance that would warrant any disciplinary action by the board.

Mr. Safley discussed that ACHC's reputation is dependent on the entities it accredits and approval by organizations such as the board.

Dr. Dang provided that the pharmacies assessed were selected randomly from a list provided by the accrediting agencies.

Ms. Duncombe provided an overview of the data provided by CHAP. She indicated that all pharmacies are surveyed by a pharmacist.

Dr. Dang highlighted the survey results for the assessment of the two CHAP-accredited pharmacies. She stated that several areas of noncompliance were identified and discussed that these pharmacies appeared to "ramp up" their standards for accreditation purposes.

Ms. Duncombe provided that CHAP has submitted copies of reports for the last CHAP surveys of the pharmacies that were assessed by the board. She stated that both pharmacies were required to complete plans of corrections for deficiencies and were subject to follow-up visits. Ms. Duncombe advised that CHAP accredited pharmacies are always subject to follow-up visits within the three-year accreditation period.

Dr. Castellblanch discussed that the assessment results are alarming from the perspective of a non-pharmacist.

Mr. Badlani asked whether the accredited pharmacies are also licensed by the board.

Ms. Herold provided that accredited pharmacies are required to follow California pharmacy law; but, are not required to have a special sterile compounding license.

Deputy Attorney General Joshua Room provided that these accredited pharmacies do not have a special license (e.g. sterile compounding license) in addition to their general pharmacy license.

Dr. Schell addressed the concern expressed by Dr. Castellblanch. He stated that these pharmacies should be visited again to ensure compliance.

Ms. Herold provided that deficiencies regarding expiration dates and refrigeration would warrant a strong warning or citation. She stated that egregious cases of non compliance in this area would be referred to the Attorney General's Office.

Dr. Castellblanch confirmed that if approved, the agencies will be reevaluated for accreditation in three years.

Board Member Deborah Veale discussed that these deficiencies were addressed in depth at the Licensing Committee Meeting. She stated that the committee felt comfortable that both agencies had the right processes in place to ensure the standards

are being met. Ms. Veale advised that CHAP and ACHC will have pharmacists on the surveying team which represents an enhancement of the current standard in this area.

Dr. Schell provided comment in support of the recommendation for approval. He stated that the board has the right to readdress this issue at any time before the three-year period.

Ms. Herold provided that the board will continue to conduct random inspections of the accredited pharmacies.

Board Member Tappan Zee arrived at 9:48 a.m.

Dr. Castellblanch encouraged board staff to remain diligent in this area and for the board to address this issue in the event any concerns are raised.

No public comment was provided.

MOTION: LICENSING COMMITTEE: Recommend to the board that ACHC and CHAP be reapproved as accreditation agencies for three years pending receipt of the requested information.

Support: 10 Oppose: 0 Abstain: 1

b. Update on the Board's Psychometric Evaluation for the ExCPT and PTCB Examinations

Mr. Lippe provided that Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. He identified several routes to licensure, including:

- Obtain an associates degree in pharmacy technology
- Completion of a technician training course
- Graduation from a school of pharmacy recognized by the board
- Certification by the Pharmacy Technician Certification Board

Mr. Lippe provided that Business and Professions Code section 139 requires a psychometric assessment description of the occupational analysis serving as the basis for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Mr. Lippe provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT).

Mr. Lippe provided that the results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam, consistent with the requirements in B&PC 139.

Mr. Lippe provided that since that time, board staff has pursued several options to facilitate these evaluations; however, because of contract restrictions including freezes, work could not be initiated. He stated that last year the board was advised that the department's Office of Professional Examination Services would be available to conduct these evaluations for the board.

Mr. Lippe provided that the committee was advised that work is scheduled to begin in January 2011 and should be completed in June 2011. He explained that it was suggested that based on the findings it may be appropriate to recommend a change to the statutory requirements for licensure detailed in B&PC 4202 to allow acceptance of either exam.

Assistant Executive Officer Anne Sodergren indicated that this work has begun.

Dr. Schell left the meeting room at 9:53 a.m.

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

No public comment was provided.

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

Mr. Lippe provided that Business and Professions Code section 4231 requires pharmacists to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Mr. Lippe provided that Business and Professions Code section 4232 establishes the general content of courses.

Mr. Lippe provided that Article 4 of Division 17 of Title 16, California Code of Regulations contains the relevant regulations implementing the statutes.

Mr. Lippe provided that at several prior meetings of the board or its committees, including the last two meetings of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. He stated that to establish such a requirement would take either a legislative or regulation change.

Mr. Lippe provided that prior discussions have included the need to earn CE in emergency response, patient consultation or in maintaining control of a pharmacy's drug inventory.

Dr. Schell returned to the meeting room at 9:54 a.m.

Mr. Lippe provided that at the October 2010 Board Meeting, the board directed that the committee continue its discussion about such a requirement.

Mr. Lippe provided that the committee discussed the challenges in evaluating a course to ensure it is achieving the objective. He stated that the committee also discussed the possibility of breaking the CE requirement into required areas and discretionary subjects and suggested that staff could research providers and possible ways to implement.

President Weisser suspended discussion of agenda item III. c in order to hear public comment for item III. b.

Public Comment

Amy Gutierrez, Director of Pharmacy Affairs with the LA County Department of Health Services, provided comment on pharmacy technician certification. She discussed that many technicians are deficient in simple mathematics. Dr. Gutierrez advised that there is a 40 percent failure rate in math of technicians assessed by LA County. She urged the board to address this issue and the education provided by technician training schools.

Dr. Schell discussed that it is also incumbent on the employer to assess this competency as well.

The board further discussed this issue. President Weisser requested that Dr. Gutierrez forward the data compiled by LA County on this issue.

Steve Gray, representing Kaiser Permanente, discussed that the role of pharmacy technicians should be addressed. He expressed concern regarding the competency and ability of technicians to make compounding calculations. Dr. Gray suggested that a second level of pharmacy technician licensure be established for technicians who will perform compounding calculations. He discussed that Kaiser Permanente is scrutinizing pharmacy technician schools for a variety of reasons including competency and a graduate's likelihood for diversion. Dr. Gray provided that no relationship between the length of the education and the quality of the technician has been determined.

Board Member Ryan Brooks encouraged the board to research this issue and to determine if a problem exists in the area of mathematics. He suggested that this issue be added to the agenda of a future meeting.

The board resumed discussion of agenda item III. c.

Mr. Lippe reviewed the recommendation of the Licensing Committee to pursue specific content areas for continuing education and to authorize board staff to investigate implementation.

Ms. Veale provided that the Licensing Committee discussed that specific content areas will help to better educate licensees for better consumer protection. She discussed that the content areas can change when a need is identified by the board. Ms. Veale discussed that content areas are required by other states.

Dr. Schell provided comment in support of the recommendation. He suggested that the board solicit input regarding content areas from the community, public, and professional organizations.

Public Comment

Dennis McAllister, representing the Accreditation Council for Pharmacy Education (ACPE), cautioned the board from being to prescriptive in this area. He suggested that the board review the current ACPE direction regarding continuous professional development.

Michael Negrete, representing the Pharmacy Foundation of California, reiterated the comments made by Mr. McAllister. He suggested that the board also evaluate whether CE should be earned "live."

Ms. Veale asked Dr. Negrete if he is aware of any studies regarding live education.

Dr. Negrete provided that he is unsure of any specific studies. He expressed concern regarding the educational value of written and online programs.

Dr. Castellblanch provided comment in support of live education. He discussed that certain areas of topics are better addressed during a face to face discussion.

Kristy Shellans, DCA Staff Counsel, discussed first amendment challenges to restricting the delivery of education. She stated that education does not necessarily need to be live if it can be delivered in an interactive manner. Ms. Shellans encouraged the board to focus on the interactive aspect of certain elements of education.

Dr. Gray, representing Kaiser Permanente, suggested that the board address the implementation of CE content areas. He recommended that the board consider drug abuse as a CE subject and the establishment of special requirements for pharmacists-in-charge. Dr. Gray discussed the benefits of live education and stated that the Commissions on Education found that the best way to improve education is to require a test after every educational session.

MOTION: LICENSING COMMITTEE: Recommend that the board pursue specific content areas for continuing education. If the recommendation is approved, authorize staff to investigate implementation.

Support: 11 Oppose: 0 Abstain: 0

d. Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists

Mr. Lippe provided that earlier this year, the board established new requirements for pharmacist renewal that were placed into CCR Section 1702. He stated that this regulation was approved by the Office of Administrative Law and took effect on December 7, 2010.

Mr. Lippe provided that the regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

Mr. Lippe provided that beginning in December 2010, pharmacist renewals will be held if a licensee fails to complete the disclosure section on the renewal form.

Mr. Lippe provided that the board was advised the beginning of November 2010 that due to the on-going fiscal crisis and hiring restrictions within State government, effective Monday, November 8, 2010, the California Department of Justice (DOJ) no longer has the resources to take phone calls or process follow-up inquiries from regulatory entities who have submitted a criminal offender record information search request through the DOJ or the Federal Bureau of Investigation (FBI). He stated that because of this, implementation of the fingerprint requirements was delayed.

Mr. Lippe provided that the committee was advised that the board has been unsuccessful in obtaining the necessary changes to implement this provision because of its dependence on other agencies.

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

Mr. Lippe provided that in late December 2010, the board was successful in achieving the necessary programming changes through the DOJ. He stated that board staff anticipates the revised LiveScan form will be available for download from the board's Web site the beginning of February 2011. Mr. Lippe advised that full implementation of this provision is anticipated in June 2011. He indicated that affected pharmacists will be advised 60-90 days prior to renewal of the requirement.

No public comment was provided.

e. Discussion of the California Hospital Association's Repopulation After Hospital Evacuation Guidelines and Checklist

Mr. Lippe provided that the committee was advised that Executive Officer Herold served on a panel convened by the California Hospital Association to identify the components needing check off following the evacuation of the hospital but before the hospital can be "repopulated." He stated that the committee was provided a brief summary and was advised that with respect to the pharmacy, if called upon by the California Department of Public Health (CDPH), the board will inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs.

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

Public Comment
Steve Gray, representing Kaiser Permanente, suggested that an ad hoc committee including hospital pharmacists be created to help develop the checklist.

Ms. Herold discussed that the board's role in the development of the checklist was relatively minor.

f. Competency Committee Report

Mr. Lippe provided that effective December 1, 2010, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He explained that this process is done periodically to ensure the reliability of the examination. Mr. Lippe stated that during such reviews the board encourages all qualified applicants to continue to schedule and take the CPJE exam. He indicated that the greater the number of applicants who take the exam during this review period, the sooner results can be released.

Mr. Lippe provided that this review was recently completed and results were released January 24, 2011.

Mr. Lippe provided that both Competency Committee workgroups met in the fall of 2010 to work on examination development. He explained 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 did not take action on this report.

Assistant Executive Officer Anne Sodergren provided that the pass rate statistics are not yet available.

Ms. Herold provided that these statistics should be available by the May 2011 Board Meeting.

No public comment was provided.

g. Update on the Conversion to a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists in April 2011

Mr. Lippe provided that Business and Professions Code section 139, requires the board to complete an occupational analysis periodically which serves as the basis for the CPJE examination.

Mr. Lippe provided that consistent with this requirement, in 2010 the competency committee developed a job analysis survey with the board's contracted psychometric firm. He stated that the results of this survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California.

Mr. Lippe provided that under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline, which was presented to the board at the April 2010 Board Meeting. He stated that after the board approved the revised content outline, the Competency Committee worked with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Chair Lippe provided that the new outline and new sample questions will be posted on the board's Web site in early February 2011. He stated that exam applicants will be sent a letter advising them of the change.

Ms. Herold provided that progress with the new content outline is on schedule and will take effect April 1, 2011.

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

No public comment was provided.

h. Licensing Statistics

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

No public comment was provided.

i. Workload and Processing Statistics

Mr. Lippe provided that last year the department established a new unit, Licensing through Job Creation. He stated that one of the products from this unit is workload and processing statistics for each program within the DCA. Mr. Lippe explained that although the board has collected and publicly reported this information for a very long time, not all boards may have historically done so. He indicated that the statistics generated internally vary a bit from those obtained by the department, but generally when looking at the information over a period of time, the statistics end up being pretty consistent.

No public comment was provided.

j. Summary of the Meeting Held December 2, 2010

Mr. Lippe referenced to the summary of the meeting held on December 2, 2010 provided in the board packet.

No public comment was provided.

k. Second Quarterly Report on the Committee's Goals for 2010/11

Mr. Lippe referenced to the second quarterly report on the Licensing Committee's goals contained within the board packet.

No public comment was provided.

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

No pharmacists celebrating 50 years of service were in attendance.

V. Legislation and Regulation Committee.

Part 1 – 2011 LEGISLATION

a. Board-Sponsored Legislation

1. 2011 Omnibus Proposal to Amend Section 4200 – Remove Obsolete Reference to Previous Pharmacist Licensing Requirement

Dr. Schell provided that at the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code section 4200. He stated that staff has submitted language to the Senate Committee on Business, Professions and Economic Development for inclusion in the committee's omnibus bill.

No public comment was provided.

2. Section 4362 – Entry Into Pharmacists Recovery Program

Dr. Schell provided that this item has been withdrawn for clarification. He advised that it will be brought back for discussion at a future meeting.

No public comment was provided.

3. Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine via Reverse Distributors

Dr. Schell provided that 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. He stated that the board voted in January 2010 to pursue sponsorship of such legislation, to include the provisions below, but they were not picked up in the prior session. Dr. Schell indicated that board staff is working to secure an author to carry these provisions.

Dr. Schell referenced to the following amendments.

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.

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.

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.

No public comment was provided.

4. Sections 4104, 4105 and 4112 – Enforcement Enhancements

Dr. Schell provided that in January 2010 the board voted to pursue statutory changes as outlined in Sections 4104 and 4112. He stated that the proposed amendments to §4105 mirror those contained in proposed changes to §4081, related to the production of records, when requested by the board.

Dr. Schell provided that staff is working to secure an author to carry these provisions.

Ms. Herold requested clarification regarding whether it is intended to amend the section to require notification to the board within 14 days or 30 days as two versions have been drafted for the section.

Dr. Schell reviewed the following amendment to §4104.

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.

Dr. Schell referred to the minutes from the October 2010 Board Meeting which indicated that that the section was to be amended to require notification within 14 days.

Ms. Shellans recommended that the board approve a clarifying motion to reaffirm this amendment.

Board Member Rosalyn Hackworth offered a proposal to reaffirm the board's position that the language in §4104 reflect 14 days as opposed to 30.

Board Member Randy Kajioka expressed concern that this requirement will conflict with DEA requirement to report of a loss or shortage within 30 days.

Mr. Room clarified that this amendment will apply to 4104(c).

Ms. Veale provided comment in opposition to the proposal. She discussed that 30 days is a more reasonable amount of time to compile information for the board.

Ms. Herold provided that this provision arose from the department's Consumer Protection Enforcement Initiative (CPEI). She discussed that it is a more aggressive standard than what is currently in law.

Ms. Sodergren discussed that requiring the reporting within 14 days provides the board with the opportunity to take some more immediate action rather than waiting 30 days.

Ms. Veale reiterated her concern that 14 days is not enough time for pharmacies to compile all of the needed information.

Dr. Schell spoke in support of the proposal. He discussed that he reads the language as requiring notification within 14 days and not submission of all of the information.

Ms. Shellans provided that the proposal would require notification and the submission of all of the information listed in subdivision (c) within 14 days. She clarified that the current requirement under law requires that notification be provided within 14 days.

The board discussed this amendment and whether the information required in subdivision (c) should be required with the notification within 14 days.

Ms. Herold provided that a more aggressive timeframe will allow the board to quickly remove an impaired licensee from practice.

Supervising Inspector Robert Ratcliff discussed that the current statute only requires notification. He stated that the board is often required to obtain an investigative subpoena to get the needed information. Dr. Ratcliff explained that this extra step slows down the investigation process. He stated that the amendment to require both the notification and the submission of the information better protects the public and gives the board more timely access to pursue action.

Mr. Lippe suggested that language be amended to require that the pharmacy begin an audit within 14 days.

Ms. Herold suggested that the last sentence in subdivision (c)(4) be removed and added as new subdivision (d). Existing subdivision (d) would be renumbered to (e). New subdivision (d) would read as follows:

> (d) As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board within 30 days of the initial report to the board.

Ms. Hackworth revised her previous proposal to include this modification as suggested by Ms. Herold.

Ms. Veale expressed concern that a pharmacy will have enough time to produce a video and documentary evidence within the 14 days. She discussed that it may be more beneficial to require all information within the same timeframe in one complete package.

Dr. Kajioka suggested that the board seek public comment on this issue. He discussed that organizations may want their legal counsel to review this information prior to submitting it to the board.

Discussion continued regarding a pharmacy's ability to produce video evidence.

Ms. Shellans asked whether it would be problematic to require all information within 14 days with exception to the audit which would be required in 30 days.

Dr. Ratcliff provided that the audit would be supplemental information.

Mr. Room provided that receipt of the video would be sufficient for purposes of obtaining an interim suspension order (ISO) or a PC 23.

Ms. Veale requested that the board hear public comment on this issue.

Public Comment

Darlene Fujimoto, representing UCSD, provided that it is difficult to compile a full package of information in 14 days. She discussed the issue of suspicion of a licensee and asked when a pharmacy is required to notify the board of any suspicion.

Mr. Room provided that the original provisions required reporting based on suspicion. He stated that this version was amended to require concrete elements (items 1-6 in subdivision (c)) to trigger a pharmacy's duty to report to the board.

Steve Gray, representing Kaiser Permanente, provided that Kaiser conducts an audit to conclude that a loss did in fact occur. He encouraged that the 14 day period begin once a conclusion has been made. Dr. Gray indicated that he would prefer a 30 day requirement instead of 14 days. He discussed that there is a process that must be followed when setting up a covert video to catch theft including approval from the National Legal Council, editing of individuals and patients that are not involved, producing an explanation of what is on the video, and giving the possible culprit an opportunity to explain the evidence.

Mr. Room provided that evidence demonstrating theft or impairment is to be judged by an objective standard rather than a subjective standard. He stated that the board must be notified if a reasonable person views a video and concludes that it demonstrates theft or impairment. Mr. Room provided that delaying notification to the board so that an organization can subjectively conclude that theft or impairment has been demonstrated is a violation of the reporting requirement.

Discussion continued regarding the triggering element that requires an organization to report to the board. It was reiterated that the main purpose of the amendment is to facilitate information to the board to aid in the removal of the licensee from practice more quickly.

Dr. Gray asked for clarification regarding certified copies.

Mr. Room clarified that a copy of the audit should be accompanied by a declaration under penalty of perjury from an authorized representative that the copy is a true and correct copy of the audit performed by the organization. He suggested that the word “certified” be struck from the language.

Dr. Kajioka requested clarification regarding the intent of subdivision (d).

Mr. Room provided that that subdivision (d) is intended to provide immunity to the reporting entity against claims that might be brought against that entity by the person that is being reported.

MOTION: Reaffirm that the language in §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure be amended to clarify that a pharmacy shall provide the board within 14 days evidence of a 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 copy of the audit results within 30 days of the initial report to the board.

M/S: Hackworth/Lippe

Support: 10 Oppose: 1 Abstain: 0

MOTION: Approve the amended language to §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure to read as follows:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual or chemical, mental, or physical impairment affecting his or her ability to practice.
(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.
(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A copy of the audit and results shall be provided to the board within 30 days of the initial report to the board.

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

M/S: Hackworth/Lippe

Support: 10 Oppose: 1 Abstain: 0

The board deferred discussion of §4105 and §4112 to a later agenda item.

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

1. SB 41 (Yee) – Disposal of Hypodermic Needles and Syringes

Dr. Schell provided that Senate Bill 41 is a reintroduction of Senator Yee's (prior session) SB 1029. He stated that the Governor vetoed SB 1029 stating the bill would remove the ability of local officials to best determine policies in their jurisdiction. Dr. Schell advised that the board did not take a position on SB 1029.

Dr. Schell provided that as introduced, SB 41 would allow a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 30 years of age or older. He stated that the bill addresses the storage of products to ensure they would be available only to authorized personnel, would require that disposal options are provided to consumers, and would require pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

Dr. Schell provided that the bill has been double-referred to the Senate Committees on Health, and Public Safety.

Dr. Castellblanch provided comment on the importance of this issue. He discussed that there is evidence to support that access to hypodermic needles and syringes reduces the prevalence of HIV, AIDS, and Hepatitis C. Dr. Castellblanch highlighted the history of this policy and indicated that a related policy was signed by former Governor Schwarzenegger with severe restrictions. He encouraged the board to support this bill.

Mr. Room stated that he has one drafting concern that can be addressed if the board chooses to take action on the bill at this meeting.

Dr. Schell suggested that the board refer this item back to the committee to develop and recommend a position to the board. He requested that Dr. Castellblanch send the evidence that he discussed to the committee.

Dr. Kajioka confirmed that the actual legislation specifies that the items can be furnished to a person 18 years of age or older**.**

No public comment was provided.

2. AB 36 (Hill) – Retail Sale of Ephedrine; Transmission of Sale Data to NPLEx

Dr. Schell provided that this bill has been gutted and amended and no longer impacts the board. He stated that the author of the bill will reintroduce the same text in another vehicle. Dr. Schell clarified that NPLEX stands for the National Precursor Log Exchange.

Dr. Schell provided that the board will again follow this bill when it is reintroduced.

Dr. Schell provided that Senate Bill 100 was introduced after the release of the meeting agenda. He provided an overview of the bill and indicated that it would provide for the licensure of surgical clinics owned by physicians by the Department of Public Health.

Dr. Schell provided that this bill will be added to a future meeting agenda for discussion. He indicated that copies of the bill have been distributed to the board and are available to the public in the back of the room.

The board resumed discussion of the amendments to §4105 and §4112.

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

Dr. Schell provided that this amendment would specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

No public comment was provided.

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

Dr. Schell provided that this amendment would require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

Dr. Schell reviewed subdivision (c) and the amendment to this section in subdivision (d).

No public comment was provided.

The board recessed for a lunch break at 12:04 p.m.

The board reconvened at 1:15 p.m. Board Members Zee and Kajioka were not present in the meeting room.

Dr. Schell announced that a quorum of the board was present.

Part 2 – REGULATIONS

a. For Board Discussion and Possible Action

1. Staff Recommendations for Modification of Existing Proposed Text and Request for Reconsideration of Prior Board Directive to Modify and Adopt Changes to Title 16 CCR Section 1732.2 – Board Accredited Continuing Education

Dr. Schell provided that 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. He stated that the proposed text was formally noticed for comment on October 8, 2010, and the 45-day comment period concluded on November 22, 2010. Dr. Schell indicated that the board received one comment in support of the proposed amendments.

Dr. Schell provided that during the public comment period, the board learned that the National Association of Boards of Pharmacy (NABP) no longer administers the Pharmacist Self-Assessment Mechanism (PSAM). He indicated that subdivision (f) of the proposed amendments is obsolete. Dr. Schell stated that the NABP is developing a new self-assessment mechanism, the "PARE" – and the NABP anticipates that the PARE will be available in the 4th quarter of 2011.

Dr. Schell provided that as initially noticed, 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) [proposed subdivision (f)]
- Successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy (3 hours of CE)

Dr. Schell provided that board staff recommends modifying the proposed language to strike subdivision (f) from the proposed language (related to the PSAM), and that a 15-day public comment period be issued for the modified text.

No public comment was provided.

MOTION: Direct staff to modify the proposed text of 16 CCR 1732.2, to strike subdivision (f) related to the PSAM, and issue the modified text for a 15-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulations at Section 1732.2 as described in the minutes.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

Ms. Shellans provided that there was a public comment during the rulemaking process requesting clarification regarding whether educational activities are additions to the current CE options. She indicated that this clarification was explained in the initial statement of reasons and will be further explained in the final statement of reasons.

2. Staff Recommendations for Modification of Existing Proposed Text and Request for Reconsideration of Prior Board Directive to Initiate a Rulemaking to Amend Title 16 Section 1793.5 – Amend Pharmacy Technician Application and Require Applicants to Submit a Self-Query From the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

Mr. Zee and Dr. Kajioka returned to the meeting room at 1:20 p.m.

Dr. Schell reviewed the modifications to the Pharmacy Technician Application (Form 17A-5) to reduce the number of deficiencies the board issues for these applicants. He stated that the application will require an applicant to submit documentation to verify that he or she has met the mandatory education requirement as specified in Business and Professions Code section 4202(a).

Dr. Schell provided that action taken by the board today will supersede the action taken at the October 2010 Board Meeting.

No public comment was provided.

MOTION: To modify the Pharmacy Technician Application (Form 17A-5), as proposed, which is incorporated by reference in the proposed language of 16 CCR 1793.5; and direct staff to take all steps necessary to complete the rulemaking process, including noticing the proposed language approved in October 2010 and the proposed Pharmacy Technician Application, as modified, for a 45-day public comment period.

If no negative comments are received during the 45-day public comment period, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1793.5 as described in the minutes.

M/S: Lippe/Weisser

Support: 11 Oppose: 0 Abstain: 0

3. Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self-Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers

Dr. Schell provided that 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.

Dr. Schell provided that board staff has been working to update the board's various self-assessment forms to incorporate changes in pharmacy laws and regulations since the prior revisions. He stated that each self-assessment also includes a proposal to add a signature block of the pharmacy owner, hospital administrator, partner or corporate officer, to acknowledge that they have read and reviewed the self-assessment and understand that failure to correct any deficiency identified therein could result in the revocation of a license issued by the board.

Dr. Schell provided that board staff recommends that the board approve the following modifications to the sections referenced below, and that the self-assessments incorporated by reference be updated with revision dates of 01/11.

- To modify Title 16 section 1715, as proposed, and update the self-assessment forms incorporated by reference (17M-13 and 17M-14), as proposed;

- To modify Title 16 section 1784, as proposed, and update the self-assessment form (17M-26) incorporated by reference, as proposed;
- To modify Title 16 section 1735.2, as proposed, which moves the self-assessment (17M-39) from section 1735.2 to section 1751 (Article 7), and makes that self-assessment specific to sterile injectable compounding;
- To modify Title 16 section 1751, as proposed.

Ms. Herold reviewed additional modifications being suggested by board staff. She provided that the language regarding self assessment in section 1751 is no longer needed and will be struck. Ms. Herold discussed that language will also be added to require that pharmacies complete a self assessment prior to a change in location.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that his organization was unable to submit a sample form including subsection number formatting. He indicated that this sample will be submitted to the board. Dr. Gray encouraged that this sample formatting be considered as a nonsubstantive change.

Dr. Gray expressed concern regarding the signature requirement on the self assessment form. He suggested that clarification be added to allow the signature of any person responsible for a hospital pharmacy license as not all hospitals have a "hospital pharmacy administrator" position.

Mr. Room clarified that the signature is certifying that the administrator has read and reviewed the assessment. He stated that the signature does not certify the contents of the assessment.

Ms. Shellans provided that the intent is to certify that the administrator is aware of the assessment and to acknowledge that failure to correct deficiencies is grounds for discipline.

Dr. Gray discussed the new modification requiring that the intern hour affidavit be signed by the pharmacist under whom the experience was earned. He discussed that this requirement will create a lot of confusion for licensees specifically concerning signature requirements when experience is earned under multiple pharmacists.

Ms. Shellans provided comment regarding Dr. Gray's concern regarding the hospital administrator. She clarified that the pharmacist-in-charge and the owner of the pharmacy are held accountable for misconduct and violations in discipline cases and should be noticed of any deficiencies.

Mr. Room provided that this provision is intended to ensure that the entire burden is not solely placed on the pharmacist-in-charge. He discussed that the pharmacy owner needs to be aware of what is occurring in the pharmacy.

Discussion continued regarding this provision. It was clarified that the intent of this provision is to ensure that the administrator/owner has read and reviewed the assessment and also provides a layer of protection for the pharmacist-in-charge.

Ms. Shellans provided comment regarding Dr. Gray's concern regarding the certification of intern hours. She reviewed Business and Professions Code section 4209 which permits certifications to be completed by the pharmacist under whom the experience was earned or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. She recommended that the intern hour affidavit be consistent with this section.

Ms. Sodergren provided that this change will also need to be made to Self-Assessment form 17M-13.

There was no additional board discussion or public comment.

MOTION: To direct staff to initiate a rulemaking to propose modifications to the text of 16 CCR Sections 1715, 1735.2, 1751, and 1784, and to propose updates to Self-Assessment Forms 17M-13, 17M-14, 17M-26, and 17M-39, as proposed by staff, include language reflecting Business and Professions Code section 4209;and direct staff to take all steps necessary to complete the rulemaking process, including the noticing of modified text and proposed self-assessment forms incorporated by reference for a 45-day public comment period. If no negative comments are received during the 45-day public comment period, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations and forms incorporated by reference before completing the rulemaking process, and adopt the proposed regulations at Sections 1715, 1735.2, 1751, and 1784 as described in the minutes.

M/S: Hackworth/Lippe

Support: 11 Oppose: 0 Abstain: 0

4. Discussion and Possible Action to Initiate a Rulemaking to Add Title 16 Section 1707.6 and to Amend Section 1702 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

Dr. Schell provided that on June 10, 2010, the board adopted its regulation at 16 CCR § 1707.5 to establish requirements for a patient-centered prescription drug container label. He indicated that the regulation was approved by the Office of

Administrative Law on November 17, 2010, and became effective on January 1, 2011. Dr. Schell stated that the regulation requires a pharmacy to provide a consumer with 12-point font for certain components of a prescription label, if requested, and also requires a pharmacy to provide oral interpretive services.

Dr. Schell provided that 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 a 12-point font, as specified in the regulation.

Dr. Schell provided that the board considered possible regulatory language at its July 2010 Board meeting, and thereafter directed staff to develop new language. He stated that the board voted at that time to move the existing consumer notices from 16 CCR § 1702 to a new section that would include any notice(s) regarding language interpretive services and larger font sizes. Dr. Schell indicated that at the October 2010 Board Meeting, the board continued its discussion of the possible regulation text and made modifications to subdivisions (a) and (b) of the draft text.

Ms. Herold suggested that the board view a notice to consumers video produced by Ralphs. She stated that the video includes a vignette of the notice content, rather than just the notice text. Ms. Herold provided that the video does conform to the regulation.

The board viewed the video.

Dr. Castellblanch expressed concern regarding use of the terms “12-point font” and “oral language services.” He discussed that 60 seconds may not be a sufficient amount of time to display the text of the notice on a video screen. Dr. Castellblanch provided that these issues can be discussed as the process moves forward.

Mr. Room provided that the issues discussed by Dr. Castellblanch were all changes made as a result to the board’s previous discussion.

Mr. Brooks discussed the limited space available in pharmacies to post notices. He encouraged the board to consider this limited space when drafting the notice requirement.

Ms. Veale provided that Ralphs has indicated that the video screen option would work as a solution to the limited space option.

Mr. Brooks cautioned the board from being too prescriptive with regards to the requirement that the text of the notice be displayed on the screen for a minimum of 60 seconds.

The board discussed whether the 60 second specification is an appropriate and adequate timeframe. It was clarified that 60 seconds is a minimum as the board has previously discussed that a shorter period of time would not be sufficient.

Ms. Veale discussed that the language regarding a pharmacist's ability to refuse to fill a prescription for ethical, moral or religious reasons has been removed.

Mr. Room provided that there was previous discussion that the consumer is more concerned with their right to have the pharmacy help them obtain their prescription and less concerned regarding the right of the pharmacist to decline to fill the prescription. He clarified that this latter language was removed in the effort to condense and decrease the length of the notice language.

Ms. Veale stated that at the October 2010 Board Meeting counsel was directed to draft alternative language for subdivision (b) regarding conscientious objection to fill a prescription.

Mr. Room apologized that this language was not prepared. He indicated that he will draft the requested language.

Ms. Herold discussed the timeline for the rulemaking process. She indicated that if noticed today, the earliest the process would be completed is a year to a year and a half from now.

Mr. Brooks suggested that the board break up the process and evaluate the language to identify portions that are acceptable and other portions that need to be addressed.

President Weisser suggested that this item be referred back to the committee for discussion at a focused meeting before being brought back to the board.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed the limited space available in pharmacies and stated that the video screen alternative would be a solution so long as the requirements are not too prescriptive. He commended the notice video produced by Ralphs. Dr. Gray encouraged the board to focus on how best to convey the notice information instead of how long the information should be displayed.

Dr. Gray discussed the language services requirement and provided that the board needs to provide pharmacies with references to aid in identifying languages for this requirement.

Dr. Gray expressed concern regarding language that states that the pharmacy will work with the consumer to ensure that they get their medicine or device in a timely manner. He stated that this is only a statutory legal requirement related to

the ability of a pharmacist to conscientiously object. Dr. Gray discussed that the language is beyond what is required by the statute and is beyond the ability of some pharmacies to comply.

Mr. Room provided that he does not agree that the language is beyond the requirements of the statute. He reviewed that current section 1707.2 states that if the pharmacy is unable to fill a prescription, the consumer is entitled to have the prescription returned or transferred to another nearby pharmacy and specifies that a pharmacy will have in place a procedure to help consumers get items that the pharmacy does not have in stock.

Dr. Kajioka discussed that requiring a pharmacy to find another source to provide the consumer with an out of stock medication is time consuming and hinders the care of other patients.

The board further discussed the issue of assisting the consumer with obtaining medication that is out of stock and the requirements of Business and Professions Code section 733. The board was advised by its legal counsel that the requirements of Sections 1707.2 and 733 should apply to a pharmacy regardless of whether a particular item is regularly stocked or not.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that NACDS members have expressed concern regarding subdivision (a) with respect to the 60 second minimum and 5 minute time lapse. She stated that these requirements stifle creativity and should be removed.

Ms. Staples encouraged the board to take as much time as necessary to address subdivision (c) regarding language services. She suggested that most non-English speaking consumers will bring an English speaking caregiver to assist them; and, as such, the point to your language option would suffice. Ms. Staples encouraged the board to require that the text be repeated in the top five languages in the state instead of 14 as drafted in the language.

Ms. Staples asked for clarification regarding the standards or thresholds for languages identified by the Medi-Cal Managed Care Division. She also asked how pharmacies are to identify languages with 10,000 or more limited-English-proficient persons in California as specified in lines 52-54 of the draft language.

Ms. Staples suggested that the board consider handouts as an alternative to the notice posting requirement and discouraged prescriptive requirements (such as cardstock and size) in this area.

Mr. Room provided that based on previous discussions of the board at the July and October 2010 Board Meetings, there was a consensus that the notice provision could be reduced to a handout and that 14 languages would be the maximum number of languages required. He clarified that the language

regarding languages with 10,000 or more Limited-English-proficient persons originated in a bill by Senator Corbett.

Dr. Schell requested that Ms. Staples provide any additional comments in writing.

Ms. Shellans discussed that the draft language is not ready for board action as more clarification should be added to subdivision (c). She stated that this can be accomplished by either listing each required language or by incorporating by reference a document that identifies the specific languages that are required.

Mr. Room recommended that the board incorporate an external reference.

Shirley Wheat encouraged that the committee meet prior to the next board meeting. She asked whether non-committee members can provide a recommendation to the committee chair.

Ms. Shellans provided that the board can convene a working group or refer this matter back to the committee to make a recommendation. She advised that non-committee members can submit comments to the executive officer to provide to the committee in the committee meeting materials.

Dr. Castellblanch provided comment on the regulation process and encouraged the board to move expeditiously. He discussed that the required languages should be based on established criteria and not on an arbitrary number.

Ms. Herold provided that in addition to discussion of the notice language at the next committee meeting, the committee will also need to offer recommendations to the board on legislation. She advised the committee that this will need to be a full day meeting and should be scheduled for the beginning of April 2011 in order to have the workload completed prior to the May 2011 Board Meeting.

It was the consensus of the board to refer this item back to the Legislation and Regulation Committee.

b. Board Adopted Regulations – Approved by OAL and Now in Effect

Dr. Schell provided on January 1, 2011, Title 16 California Code of Regulations Section 1707.5 – Patient-Centered Labels for Prescription Drug Containers; Requirements became effective.

Dr. Castellblanch shared that he recently received a prescription with the new label. He discussed that this label was placed on a smaller bottle than what was previously dispensed.

No public comment was provided.

c. Board Approved – Awaiting Notice

Dr. Schell referenced to the following regulations awaiting notice:

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination - Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

There was no board discussion or public comment.

d. Board Approved – Under Development

1. Proposed Amendments to §1746 – Emergency Contraception Protocol

Dr. Schell provided that in 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. He advised that the regulation became operative on December 2, 2004. Dr. Schell indicated that the board has discussed the need to update the regulation at its January and July 2010 Board Meetings. He stated that the board has begun working with the Medical Board to update the emergency contraceptive protocol. Dr. Schell explained that the Medical Board will need to approve any update to the protocol before the Board of Pharmacy can adopt any proposed changes and initiate a rulemaking.

No public comment was provided.

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

Dr. Schell provided that Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. He stated that staff is continuing to work 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) [referred to subcommittee]

Dr. Schell provided that Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. He indicated that this regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. Dr. Schell advised that USP Standards are updated and published annually. He reviewed that 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.

Dr. Schell provided that 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 that the board established a subcommittee for this purpose 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. He recommended that the board president appoint a new member.

No public comment was provided.

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

Dr. Schell provided that 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.

Dr. Schell provided that 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. He stated that board staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

No public comment was provided.

Part 3 – General

a. Second Quarterly Report on the Committee's Goals for 2010/11

Dr. Schell referenced to the staff recommendations to the Strategic Plan to reflect actions of the board in previous quarters.

No public comment was provided.

MOTION: Approve the following staff recommendations to the Strategic Plan.

Objective 3.1. Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.

Objective 3.2. Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.

- Task 17 - Update Protocol for Pharmacists Furnishing Emergency Contraception (ED) (§1746)

Staff recommendation to move 3.2 – Task 17 to Objective 3.3., as the board is participating with the Medical Board in a full review of the EC protocol, and modifications will need to first be approved by the Medical Board prior to consideration and possible adoption by the board.

Objective 3.3 Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.

- Task 1 – Initiate review of PIC Requirement
- Task 2 – Staff recommendation to include Task 17 from Objective 3.2.
- Task 3 – Staff recommendation to add "Review of Continuing Education for Pharmacists in Specific Areas"

M/S: Brooks/Hackworth

Support: 11 Oppose: 0 Abstain: 0

The board recessed for a break at 3:12 p.m.

The board reconvened at 3:23 p.m. Board Members Brooks, Zee, Badlani, and Kajioka were not present.

VI. Organizational Development Committee

a. Presentation on the BreEZe Project and an Interim Solution to Allowing Online Renewals of Licenses by Sean O'Connor, BreEZe Business Project Manager, Department of Consumer Affairs

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. This new project will build upon components of the initial I-Licensing system and will ultimately allow for improved services for applicants and licensees, and 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, board staff is working with the department to ensure the new solution can fulfill business requirements necessary to carry out the board's functions.

Presentation to the Board

Mr. Badlani returned to the meeting room at 3:26 p.m.

Sean O'Connor, BreEZe Business Project manager, provided an overview of the functionality of the new BreEZe system. He discussed beneficial functions and components of the system including:

- Document image storage
- Board member access to aid in enforcement decisions
- Individual board controlled configuration
- System will interface with current interfaces
- Online status checks for applicants

- Electronic applications, renewals and payments
- Electronic workflow routing

Mr. Brooks returned to the meeting room at 3:31 p.m.

Mr. O'Connor provided that there is an anticipated $3 fee for each transaction fee assessed to the board for new initial applications and renewals for the first five years. He clarified that the $3 fee will be deducted from the application or renewal fee and is not an additional service fee to the applicant or licensee. Mr. O'Connor advised that the fee will be offset as the board will no longer be paying fees for the current legacy licensing and enforcement systems. He emphasized that the vendor will not receive payment from the board until the board approves the successfully implemented system.

Dr. Kajioka and Mr. Zee returned to the meeting room at 3:35 p.m.

Mr. O'Connor reviewed the project timeline and implementation schedule. He stated that implementation for the board is scheduled for Phase 2 beginning in March 2013.

Ms. Herold provided that the board currently does not provide status checks over the phone for applications pending less than 60 days. She discussed the significant benefit that online status checks will have for the board.

Mr. O'Connor discussed a DCA pilot project providing an interim solution to accept credit card payments for renewals prior to the implementation of the BreEZe system. He indicated that if the board is interested, Ms. Herold can contact the DCA's pilot project to participate. Mr. O'Connor reviewed the costs for this project which includes two percent of the transaction per board in addition to a $1 service charge per licensee. He indicated that this process will allow the licensee to answer conviction related questions on the renewal form.

Dr. Schell and Ms. Wheat left the meeting at 3:50 p.m.

Mr. Badlani requested that Mr. O'Connor seek clarification from the pilot project to clarify who receives the 2 percent transaction fee.

President Weisser requested that Ms. Herold present relevant data regarding this interim option at a future meeting in order to consider participation in the pilot project.

No public comment was provided.

b. Budget Update/Report

1. Budget Report for 2010/11

Ms. Herold provided that the 2010/11 budget change approval (BCP) was approved. She discussed that despite this approval, the board has been unable to fill the 22.5 new positions in the board's enforcement unit and 2 new positions in the licensing unit due to the current hiring freeze. Ms. Herold advised that the board has submitted two exceptions requests; however, both have been denied by the State and Consumer Services Agency.

Ms. Herold provided an overview of the board's fund condition including authorized expenditures of $13,470,000 and total revenue of approximately $11,000,000.

No public comment was provided.

2. Budget Constraints and Reductions to Reduce the State Budget Deficit

Ms. Herold discussed that over the last several years, the board has been directed to reduce several budget areas. She stated that the board's operating expenses were reduced by 15 percent in 2009/10 and more recently the board's personnel budget was reduced by 5 percent in 2010/11 and ongoing years. Ms. Herold stated that the board will continue to evaluate its business operations and identify ways to further reduce expenditures.

No public comment was provided.

3. Fund Condition Report

Ms. Herold reviewed the following fund conditions assessed for the end of the identified fiscal years:

2009/10	$12,411,000	11.6 months in reserve (actual)
2010/11	$9,954,000	8.4 months in reserve
2011/12	$6,005,000	5 months in reserve
2012/13	$2,806,000	2.3 months in reserve

Ms. Herold discussed 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. She stated that the board will continue to closely monitor its fund condition before increasing any additional fees. Ms. Herold advised that with the new fee structure established under AB 1071, the board does have the ability to raise fees via the regulation process to address the funds projected for 2011/12 and 2012/13.

Ms. Brooks expressed concern regarding fees and a possible surplus. He requested that board staff evaluate this issue.

Ms. Sodergren provided that all fees are currently at their statutory minimums. She advised that legislation would be needed to modify the existing fee structure.

No public comment was provided.

4. Budget Change Proposals for the 2011/12 Budget

Ms. Herold provided that the board did not receive approval for the 2011/12 Budget Change Proposal (BCP) submitted. She advised that no additional information is available at this time.

No public comment was provided.

5. Reimbursement to Board Members

Ms. Herold referenced to the expenses and per diem payments to board members provided in the board packet.

No public comment was provided.

6. Board of Pharmacy Committee Membership Roster

Ms. Herold referenced to the current committee membership roster provided in the board packet.

No public comment was provided.

c. Selection of a Board Meeting Date for One Day in April

Ms. Herold provided that the Administrative Procedures Act details the rules the board must follow when seeking to discipline a licensee. She explained that because of the specified time frames the board must adhere to, a special one day meeting is necessary to allow the board to convene in closed session to consider a disciplinary matter. Ms. Herold advised that this meeting needs to be scheduled between February 23, 2011 and the end of March 2011 to allow sufficient time for written argument to be submitted prior to the meeting, while also allowing counsel sufficient time to write the decision.

The board discussed possible meeting dates to convene a one day board meeting as well as committee meetings. The following meeting dates were scheduled:

March 29, 2011: Legislation and Regulation Committee Meeting; and Enforcement Committee Meeting

March 30, 2011: Board Meeting

April 7, 2011: Communication and Public Education Committee Meeting

Mr. Brooks offered to find a meeting room location in San Francisco for the April 7, 2011 Communication and Public Education Committee Meeting.

No public comment was provided.

d. Future Development of a Strategic Plan for 2011/12 to 2016/17

Ms. Herold provided that about every five years the board develops a new strategic plan that will guide the board for the following five years.

Mr. Herold provided that the current plan was developed in 2006 with the assistance of a consultant who specialized in the development of such plans. She advised that it is time once again to complete this process. Ms. Herold stated that staff is currently soliciting bids for a consultant to guide the board and staff through the process. She indicated that staff is aiming to execute a contract in advance of the one day board meeting in April.

No public comment was provided.

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

Ms. Herold provided that no pharmacists reached this milestone between November 2010 and January 2011.

No public comment was provided.

f. Transition Issues of Governor Brown's Administration

Ms. Herold provided that the governor issued an executive order requiring the state to reduce the number of cell phones by 50 percent. She explained that in order to facilitate this, the department is requiring all DCA programs to reduce the number of cell phones by 50 percent. Ms. Herold indicated that after much advocacy, the board was successful in maintaining the cell phones for all field staff, however all of the managers turned in their blackberries.

Ms. Herold provided that the governor also issued an executive order requiring the state to reduce its fleet of vehicles by 50 percent. She discussed that at one time all board inspectors and supervising inspectors were given vehicles as part of their equipment. However, these board staff are gradually surrendering the state vehicles and receives the current mileage reimbursement rate of 51.0 cents per mile for use of a personal vehicle.

Ms. Herold stated that there are currently 30 vacancies at the board that will be hard to fill due to the hiring freeze.

No public comment was provided.

g. Personnel Update

President Weisser provided that prior to leaving office, Governor Schwarzenegger appointed Anil "Neil" Hiro Badlani and reappointed Shirley Wheat.

No public comment was provided.

h. Second Quarterly Report on the Committee's Goals for 2010/11

President Weisser referenced to the second quarterly report on the Organizational Development Committee's goals provided in the board packet.

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

No public comment was provided.

Mr. Brooks suggested that the DCA develop a training program for non-pharmacist members appointed to the board to better serve the public.

Recess for Day

The board meeting was recessed at 4:24 p.m.

Wednesday, February 2, 2011

The board reconvened at 8:33 a.m. on February 2, 2011. Mr. Badlani and Dr. Castellblanch were not present at the call to order.

President Weisser recognized former board member Stan Goldenberg, who was in the audience.

Board members and board staff present introduced themselves to the members of the public.

VIII. Communication and Public Education Committee Report and Action

a. Report of the Meeting Held January 10, 2011

1. Update of the State's Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746.) and Consumer Fact Sheet

Mr. Brooks provided that the Board of Pharmacy needs to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 California Code of Regulations section 1746. He stated that the current state protocol was developed in 2004 and adopted by this board as a regulation.

Mr. Brooks provided that since the last board meeting, the executive officer has met with the Medical Board's executive officer, and spoken with a women's health specialist pharmacist representative from the California Pharmacists Association (CPhA), and a representative of the American College of Obstetricians and Gynecologists.

Ms. Herold advised that an updated manuscript is being prepared, and will be shared with all entities and brought to the board at the May 2011 Board Meeting. She explained that once both boards have an opportunity to review and approve the protocol, the board will need to adopt the protocol as a revision to regulation section 1746.

Mr. Brooks provided that as part of the rulemaking, the board will need to develop a patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception.

No public comment was provided.

2. Discussion of the 39th Annual Report of the Research Advisory Panel of California

Mr. Brooks provided that at the last meeting of the Communication and Public Education Committee, the committee asked that a representative of the

Research Advisory Panel of California come to a future meeting to explain the role and activities of this group. He stated that this representative will be invited to a future meeting of this committee, and a full report will be shared with the board at a future meeting.

No public comment was provided.

3. Public Education Campaign for Patient-Centered Prescription Drug Container Labels

Mr. Brooks provided that at the January 2011 Committee Meeting, Kim Brown of the department's Press Office attended the meeting to work with the committee on refining a public outreach campaign to educate patients about the redesigned prescription drug container labels and the ability to obtain oral interpretive services for those with limited English skills. He stated that an initial public education campaign was discussed by the committee at its last meeting in July 2010.

Mr. Brooks provided that one date the board could consider to begin publicizing more widely the requirements could be March 2011, in conjunction with National Consumer Protection Week (March 6-12, 2011).

Ms. Brown provided copies of the press release and a draft article for public publications. She reviewed the press release and advised that it will be revised to emphasize information regarding interpretive services.

Dr. Castellblanch arrived at 8:42 a.m.

Mr. Brooks suggested that a general press release be issued. He stated that a detailed press release can be issued at a later date after pharmacies have had time to implement the requirements and after more work has been done on the language for the notice to consumers.

President Weisser offered support to this suggestion.

Mr. Badlani arrived at 8:44 a.m.

Dr. Castellblanch cautioned the board from delaying the release for too long. He discussed that informing the public may encourage faster implementation.

Ms. Veale sought clarification on the status of implementation.

Mr. Ratcliff indicated that pharmacies are in various stages of implementation. He discussed that some larger chains are already compliant; whereas independents may face greater challenges because of the older technology and

may not be aware of the current regulations. He advised that board staff is exercising enforcement discretion and is offering education to assist the pharmacies with implementation.

Ms. Herold discussed that pharmacies have received frequent notification regarding the new requirements. She advised that pharmacies that are not aware of the requirements at all will be addressed by enforcement staff.

Dr. Castellblanch discussed the current inspector vacancies. He suggested that it may be better to notify the public so that they can assist in identifying non-compliant pharmacies. He encouraged the board to move forward with public outreach in this area.

Mr. Brooks requested that the executive officer work with the Press Office to refine the press release for a March 2011 release date.

No public comment was provided.

4. Development of Consumer Education Videos for the Board's Web Site

Mr. Brooks provided background on this issue. He shared that 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. Mr. Brooks advised that this video is available on the board's Web site.

Mr. Brooks commended staff on their efforts to develop the video.

Mr. Brooks provided that after production of this video, the board's staff expressed an interest to the Department of Consumer Affairs in developing additional videos. He stated that a draft video on the dangers of purchasing drugs on the Internet (and how to do so wisely) was prepared in July 2010, but reviewers did not believe the completed video was adequate, so a new script was developed. Mr. Brooks indicated that planned completion of this video is by July 1, 2011. He indicated that the video will be shown at the May 2011 Board Meeting if it is completed earlier.

Mr. Brooks advised that one part of the public education campaign for patient-centered labels also includes development of a video.

No public comment was provided.

5. Update on Consumer Fact Sheet Series with California Schools of Pharmacy Interns

Mr. Brooks provided that the board has advocated a proposal by the committee to integrate pharmacy students into public outreach activities.

Mr. Brooks spoke in support of this effort as an innovative way to provide information and to engage students.

Mr. Brooks provided that the board previously provided a fact sheet template, guidelines, and potential topics to all schools of pharmacy. He indicated that five schools confirmed their interest in the project, and materials from two schools have been submitted to the board for review. Mr. Brooks stated that the committee reviewed the unedited copies of the materials sent to the board during the meeting.

Mr. Brooks provided that the committee discussed whether the content provided in the unedited fact sheets was getting the right message across to consumers. He shared that the committee expressed appreciation for the efforts and imagination of the students.

Mr. Brooks provided that staff will need to work on refining the fact sheets, and fully research the facts stated in them before they can be released to the public.

Mr. Herold provided that the fact sheets will be released sequentially. She advised that a former board member has been enlisted to assist with this process.

No public comment was provided.

6. Discussion: Balancing Providing Important Consumer Information Versus Consumer Indifference to Reading Extensive Important Warnings in Public Education Materials

Mr. Brooks discussed an October 2010 article entitled, “Supreme Court Chief Justice Admits He Doesn’t Read Online EULAs or Other Fine Print.” He reviewed that in the article, Richard Posner admitted to not reading boilerplate legalese on his mortgage agreement, the fine print on websites or on medicines.

Mr. Brooks underscored that “less” is “more” in terms of communications. He indicated that sometimes too much information gets lost and asked the board to remain cognizant of this fact as it moves forwards with several notice items.

No public comment was provided.

7. Suggestions from Pharmacists Planning Service on a Redesigned Notice to Consumers

Mr. Brooks provided that Pharmacists Planning Services, Inc. recently sent two posters for consideration by the board. He reviewed that one poster was designed with the intent of placement in pharmacies, and the other was designed to post in prescribers' offices.

Mr. Brooks provided that the committee discussed these posters during its meeting. He discussed that while the posters were simple and straightforward, neither complied with the legal requirements for information that must be provided to patients by Business and Professions Code sections 4122 and 733(f).

Mr. Brooks provided that additionally the board has decided to develop two consumer advisements for posting in a pharmacy -- one notice will relate to the right of patients to request a 12-point font printed on their prescription labels, the other will relate to the right of patients to have access to interpretative services.

No public comment was provided.

8. Update on the Committee's Assessment of the Board's Public Education Materials

Mr. Brooks provided that at a prior meeting, Board Members Debbie Veale and Ramón Castellblanch agreed to work as a subcommittee to assess the board's public education materials. He stated that to assist in that effort, board staff subsequently prepared a list of all 50 State Boards of Pharmacy and their corresponding consumer information.

Mr. Brooks provided that the list clearly displays the board's dominance in this area with its extensive list of consumer and licensee educational materials.

Mr. Brooks provided that the subcommittee will continue their review, and report back to the next Communication and Public Education Committee meeting.

Dr. Castellblanch provided that he hopes to have graduate students evaluating these materials beginning in fall 2011.
No public comment was provided.

9. Public Education Materials Under Development and Proposed for the Future

Mr. Brooks provided that the committee intends to work on refining the new fact sheets under development by school of pharmacy interns.

Mr. Brooks referenced to the following publications that are currently being developed by staff:

- Questions and answers relating to the board's compounding regulations. The questions and answers relate to a discussion held at the June 2010 Enforcement Committee, and an ongoing number of questions being asked of the board regarding the compounding regulations. A subcommittee of board members worked with board senior staff to refine the responses which will be considered at this board meeting under the Enforcement Committee Report.
- The Pharmacists Recovery Program brochure (update)
- Becoming a Licensed Pharmacist in California
- Guidance to Pharmacies on the E-Prescribing of Controlled Substances

Mr. Brooks reviewed other developments including revisions of the self-assessment forms for community pharmacies, hospital pharmacies, and wholesalers. He stated that these self assessments are being updated by staff, and must be promulgated as regulations.

No public comment was provided.

10. Update on *The Script*

Mr. Brooks provided that the February 2011 issue of *The Script* is being finalized and will be submitted to DCA's Legal Office for review in the very near future. He discussed that the February 2011 issue will focus on new pharmacy law and regulations for 2011. Mr. Brooks indicated that the issue will also include an update for licensees about the requirements for patient-centered prescription labels, an article about medication errors reported to the board during 2009/10, and the board's citation and fines issued for those errors.

No public comment was provided.

11. Update on Public Outreach Activities

Mr. Brooks referenced the following public and licensee outreach activities performed during the second quarter of Fiscal Year 10/11 include:

- September 27, 2010 – Inspector Wong provided information about Board of Pharmacy enforcement activities to students at California Northstate School of Pharmacy
- October 22, 2010 – Executive Officer Herold presented information about the 2010 legislative year at Seminar 2010, the annual meeting of the California Society of Health System Pharmacists (CSHP) in San Francisco
- October 22-23, 2010 – Executive Officer Herold and Inspector Hokana staffed the board's public information booth at CSHP's Seminar 2010
- November 9, 2010 – Executive Officer Herold presented information on e-prescribing and e-prescribing of controlled drugs to attendees of a CalERx Conference in Oakland
- December 15, 2010 – Executive Officer Herold provided a presentation on California's patient-centered prescription container label requirements at a quarterly meeting of the California Hospital Association's Medication Safety Committee

No public comment was provided.

12. Minutes of the January 10, 2011 Committee Meeting Summary

Mr. Brooks referenced to the minutes of the meeting held January 10, 2011 provided in the board packet.

No public comment was provided.

b. Second Quarterly Report on the Committee's Goals for 2010/11

Mr. Brooks provided that the second quarter's Committee Goals were discussed yesterday and are moving forward.

No public comment was provided.

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

Kim Kirchmeyer, Deputy Director, Board and Bureau Relations, provided an update on projects and matters of interest on behalf of Director Brian Stiger. She thanked the board and board staff for showing great leadership in several areas including consumer education videos and going paperless for board packet materials. Ms. Kirchmeyer also thanked Ms. Sodergren for her involvement in the BreEZe project and the Forms Workgroup.

Ms. Kirchmeyer discussed the transition to the new administration. She indicated that there have not been many appointments at the department level resulting in a delay in

reviewing regulation packages. She stated that Director Stiger has been asked to continue at the department and will continue to pursue the Consumer Protection Enforcement Initiative (CPEI) and the implementation of any executive orders. Ms. Kirchmeyer provided that the department will continue to adhere to the current hiring freeze and will only allow interdepartmental transfers. She advised that the department will continue to seek freeze exemptions for critical positions.

Ms. Kirchmeyer discussed the executive order to reduce state issued cell phones. She indicated that the department is working to finalize implementation of this order. Ms. Kirchmeyer advised that the department is striving to maintain phones for field staff.

Mr. Lippe asked why the board is subject to the hiring freeze despite being special funded and allocation for new positions in the 2010/11 budget change proposal.

Ms. Kirchmeyer discussed that there has been no differentiation between general fund and special fund organizations within the executive order. She stated that more information regarding the hiring freeze is anticipated next month.

Dr. Castellblanch sought clarification regarding the delay in regulation packages.

Ms. Kirchmeyer indicated that the delay is due to vacancies in the agency secretary and undersecretary positions.

Ms. Kirchmeyer provided notice that the department is changing the way expert consultants are paid and classified. She stated that all boards are being asked to move forward with contract requests for consultants which is a laborious process. Ms. Kirchmeyer shared that the department is willing to lend assistance with this process. She advised that the Senate and Business Professions Committee has indicated interest in carrying some type of legislative fix for this issue.

Ms. Kirchmeyer encouraged the board to move forward with program proposal changes from the CPEI. She indicated that the second set of enforcement performance measurements will be posted on the department's Web site in February 2011. Ms. Kirchmeyer encouraged the board members to review these statistics.

Ms. Kirchmeyer also encouraged the board to implement the SB 1441 standards and to incorporate the necessary language into regulation. She advised that this implementation will be addressed during the board's sunset review hearing.

Ms. Kirchmeyer encouraged the board to move forward with the Web casting of its meetings.
Dr. Castellblanch sought clarification regarding the Web casting process.

Ms. Kirchmeyer provided that the department has the necessary equipment to provide this service to the board and can travel to offsite meeting locations if necessary.

Ms. Brown provided that the meeting room will need to be equipped with a DSL line.

Mr. Zee sought clarification regarding the travel restriction imposed on the board's legal counsel.

Ms. Shellans reviewed that she has been advised that she is not permitted to travel to committee meetings that are not in conjunction with a board meeting.

Ms. Kirchmeyer discussed that this is required as part of the mandated 5 percent reduction in operating costs for the Legal Office. She confirmed that it will only impact travel for committee meetings that do not coincide with a board meeting.

No public comment was provided.

X. Enforcement Committee Report and Action

a. Report of the Meeting Held December 6, 2010

1. Discussion of Requests for Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010) for Infusion Pharmacies and Skilled Nursing

Dr. Kajioka provided that effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5.

Dr. Kajioka provided that also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. He stated that the exemptions are provided as subdivisions (d) and (e) below.

> 4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.
> (b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.
> (c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.
(2) Improved directions for use.
(3) Improved font types and sizes.
(4) Placement of information that is patient-centered.
(5) The needs of patients with limited English proficiency.
(6) The needs of senior citizens.
(7) Technology requirements necessary to implement the standards.
(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code. if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.
(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.
(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

Mr. Brooks left the meeting room at 9:18 a.m.

Dr. Kajioka provided that this law directs that the board "may exempt," so to allow such an exemption, the board will need to promulgate regulations.

Dr. Kajioka provided that at the December 2010 meeting, the Enforcement Committee heard presentations from two groups seeking an exemption from the labeling requirements for their specialized patient populations. He stated that one was from an infusion pharmacy and the other represented skilled nursing facilities. Dr. Kajioka discussed that neither presentation provided the committee with sufficient information to act to recommend a waiver to the board. He indicated that the committee asked that companies interested in seeking an exemption provide data or samples to support their request and that the request contains at least (1) an explanation as to why the company cannot comply with the new requirements and (2) information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

Dr. Kajioka provided that since the December 2010 Enforcement Committee Meeting, the board's executive officer has received two more exemption requests (to exempt radiologic pharmacies and to exempt parenteral nutrition labeling). He stated that these requests also will be scheduled for the next Enforcement Committee Meeting.

Ms. Veale suggested that the committee continue its work on this issue and bring it back to the full board for discussion when more information is available.

Public Comment

Stan Goldenberg, prior board member and president, discussed challenges facing pharmacies providing services to long term care facilities. He introduced Scott Huhn, representing the California Pharmacists Association Long Term Care Council and OmniCare, and Art Whitney, representing City West Pharmacy Long Term Care.

Mr. Goldenberg requested an exemption to the 12-point font labeling requirement for long term care facilities. He discussed that it will be difficult to relabel medication with a 12-point font prior to the discharge of a patient. Mr. Goldenberg stated that the exemption will benefit the patient and will eliminate the retraining of nursing staff.

President Weisser discussed that bubble packs are typically used in long term care facilities. Given this, he asked why these facilities cannot implement a 12-point font on the label.

Mr. Goldenberg discussed physical limitations with ensuring that all information required by both state and federal regulations can fit on the label. He indicated that there will be a new regulation to take effect in October 2012 that will require a seven-day bubble pack versus the current 30 day supply. Mr. Goldenberg

offered to bring sample bubble pack cards to the next Enforcement Committee Meeting.

Mr. Huhn and Mr. Whitney provided comment on the logistics involved with the relabeling of medication and stated that providing all of the required label information in a 12-point font can require three labels. Clarification was sought regarding whether the 12-point requirement applies to initial dispensing and repackaging.

Mr. Brooks returned to the meeting room at 9:38 a.m.

Mr. Goldenberg clarified that he is requesting a complete exemption from the labeling requirements. He stated that if this is not permissible, he would request an exemption to the 12-point font requirement.

The board discussed this request. Mr. Goldenberg, Mr. Huhn, and Mr. Whitney were asked to prepare a presentation for the next Enforcement Committee Meeting.

Dr. Kajioka provided that the board will seek input from legal counsel regarding whether these requirements are applicable to relabeling.

President Weisser requested that Mr. Goldenberg submit sample bubble pack cards in advance of the next committee meeting.

2. Discussion Regarding Reporting Financial Settlements to the Board Under Sections 801-804 of the California Business and Professions Code

Dr. Kajioka reviewed the relevant statues for this item. He stated that Business and Professions Code sections 801-802 establishes reporting requirements by professional liability insurers and by licensees without professional liability insurance, of any settlement or arbitration award over $3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

Dr. Kajioka provided that section 803 of the Business and Professions Code requires that the clerk of a court that renders a judgment that a licensee has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount over $30,000.00 caused by the licensee's negligence, error or omission in practice, or his or her rendering of unauthorized professional services, report that judgment to the board within 10 days after the judgment is entered.

Dr. Kajioka provided that the board recently undertook efforts to ensure that licensees and insurance companies are aware of their responsibilities to report to the board pursuant to sections 801 to 804 of the California Business and Professions Code.

Dr. Kajioka provided that the board provided a notice of these reporting requirements in the September 2010 *The Script*.
President Weisser sought clarification regarding section 803 with regards to the crime committed. He asked whether this crime needs to be related to the profession or is required for any crime.

Mr. Room clarified that this section applies to any crime. He discussed that the duty to disclose is broad to allow the board to exercise discretion based on the crime committed.

Dr. Kajioka provided that in 2009, there were approximately 360 million prescriptions filled and dispensed in California by pharmacies. He stated that the board received notice from patients and from other sources of 307 medication errors during 2009/10. Dr. Kajioka discussed that this further indicates the high degree of under-reporting under these statutory sections.

Dr. Kajioka provided that the committee suggested that the board work with the Department of Insurance and the Department of Managed Health Care to achieve better compliance. He advised that the committee did not take action on this item.

Ms. Herold provided that the board has received more reports this year than in prior years. She advised that the board will issue citations and fines for failure to notify the board.

Mr. Room stated that there are more direct obligations on licensees to report for other professions. He discussed that these models can be used if the board is interested in requiring licensees to report directly to the board.

No public comment was provided.

3. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Dr. Kajioka provided that beginning in July 2009, the Department of Consumer Affairs has been working with health care boards to improve 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. Kajioka explained that the CPEI was comprised of a three-pronged

solution designed to ensure that investigations were completed and final action taken against licensees within 12 – 18 months. Dr. Kajioka indicated that the solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the board's needs to collect information and monitor performance, and additional staff resources.

Dr. Kajioka provided that many of the legislative changes identified by the department were incorporated into SB 1111 (Negrete McLeod, 2010). He advised that this bill failed passage early in the session 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 the provisions requested by the department. He stated that the board expressed concern about some of the provisions and with one exception, did not take action on the items.

Dr. Kajioka provided that during the October 2010 Board Meeting, board members were advised that the department continues to encourage boards to pursue regulations changes that were previously incorporated into SB 1111. He stated that consistent with the department's request, the board considered the following proposed regulation changes:

1. Amendments to section 1760 regarding standardized disciplinary guidelines for violations dealing with sexual contact. As drafted, the change would provide 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.

   Board Action: The board rejected this proposal.

2. Amendments to section 1762 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. 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.

   Board Action: The board voted to 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. (Additional information on this item will be provided under the next agenda item.)

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.

   Board Action: The board voted to 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 and directed staff to take all necessary steps to initiate the formal rulemaking process.

No public comment was provided.

4. Proposed Amendment to 16 California Code of Regulations Section 1762, Regarding Submission of Records to the Board

Dr. Kajioka stated that under the previous item is general background on this proposal. He clarified that under consideration for the board is the addition to Title 16 CCR Section 1762 which would define activities that constitute unprofessional conduct.

Dr. Kajioka provided that the proposed language would establish the following:

- Section 1762(a) would specify that that gag clauses in a civil suit settlement would constitute unprofessional conduct.
- Section 1762(b) would specify that failure without lawful excuse to provide information as requested by the board within 15 days of the receipt of the request or as specified would constitute unprofessional conduct.
- Section 1762(c) would specify that failure to comply with a court order or subpoena for records would constitute unprofessional conduct.
- Section 1762(d) would specify that failure to notify the board about an arrest, indictment, conviction or discipline as specified would constitute unprofessional conduct.
- Section 1762(e) 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.

Dr. Kajioka reviewed the recommendation from the committee to begin the rulemaking process to adopt the proposed text for section 1762(a), (b), (c), and (e). He indicated that the committee requested that subdivision (d)(4) be revised. Mr. Brooks expressed concern regarding subdivision (e) related to action against an individual who is required to register as a sex offender.

Ms. Shellans reviewed the proposal for subdivision (e) and clarified that it is not as stringent as a prior proposal that was struck by the board that would require that a license be revoked. She clarified that this provision authorizes grounds for board action without having to analyze whether this conviction is substantially related to the practice of pharmacy.

The board discussed various crimes and whether they should be deemed substantially related. It was clarified that this provision derived from the CPEI and will streamline enforcement policies.

Mr. Brooks requested that the Enforcement Committee evaluate other convictions that may be appropriate to also be included in a list of convictions that should also be included as substantially related.

Dr. Kajioka asked if there was any statistical analysis that identified this crime as an area to be addressed.

Ms. Kirchmeyer provided some background on this provision. She discussed that this provision was identified during the enforcement review of another board and was incorporated into the CPEI by the department as it was identified as good policy for consumer protection for all boards.

Mr. Room provided comment in support of development of the list suggested by Mr. Brooks.

Discussion - §1762(a)
Dr. Kajioka reviewed the following proposed language for §1762(a):

> 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 licensee's 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 contracting, 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.

No public comment was provided.

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(a).

Support: 9 Oppose: 0 Abstain: 0

Discussion - §1762(b)
Dr. Kajioka reviewed the following proposed language for §1762(b):

> (b) Failure without lawful excuse 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.

Mr. Brooks provided that there should be a clause allowing for a licensee to petition for more time if records are not readily available.

Ms. Shellans provided that similar language has already been struck.

Mr. Room provided that he does not believe that this exception is needed within the regulation.

No public comment was provided.

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(b).

Support: 6 Oppose: 1 Abstain: 2

Discussion - §1762(c)
Dr. Kajioka reviewed the following proposed language for §1762(c):

> (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.

Mr. Zee asked whether this subdivision is needed considering the requirements under (b).

Mr. Room indicated that subdivision (c) can encompass additional information that the board could not otherwise request under subsection (b). He explained that there may be some records that are subject to a subpoena that are not subject to the board inspector's authority to inspect. Mr. Room discussed that unlike subdivision (b), subdivision (c) would allow the board access to records of undisclosed ownership that are not kept in the pharmacy.

No public comment was provided.

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(c).

Support: 9 Oppose: 0 Abstain: 0

Discussion - §1762(d)(4)
President Weisser provided that §1762(d)(4) will be further evaluated by staff and the committee.

No public comment was provided.

The board took no action on this item.

Discussion - §1762(e)
Dr. Kajioka reviewed the following proposed language for §1762(e):

> (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 discussed that this subdivision is drafted in an inconsistent matter. He stated that be believes the language should read as follows:

> (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 the suggested language to be struck is superfluous in a section that is just defining something as unprofessional conduct. He clarified that this redundancy is solely a drafting issue and has no legal impact. Mr. Room indicated that this issue can be addressed during the rulemaking process.

No public comment was provided.

MOTION: ENFORCEMENT COMMITTEE Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(e).

Support: 5 Oppose: 4 Abstain: 0

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

Dr. Kajioka provided that 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.

Dr. Kajioka provided that 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 SACC consideration during public meetings.

Dr. Kajioka referenced the 16 standards as provided in the board packet.

Dr. Kajioka provided that the most recent version of the standards was approved in April 2010. He stated that during the April 2010 committee, the director established a subcommittee of executive officers to re-evaluate the provisions contained within Uniform Standard 4.

Dr. Kajioka provided that the subcommittee met on August 4, 2010 but did not complete its work. He indicated that a subsequent meeting was scheduled for September 24, 2010, however that meeting was cancelled.

Dr. Castellblanch left the meeting room at 11:07 a.m.

Dr. Kajioka provided that the committee discussed in general the uniform standards as well as the process used to develop them. He stated that the committee was advised that some of the proposed changes to the Disciplinary Guidelines would facilitate implementation of portions of these standards.

President Weisser suggested that the board establish a subcommittee to facilitate timely implementation of this issue.

Mr. Room provided that many of the standards are being considered currently for purposes of the ongoing revision of the disciplinary guidelines.

Dr. Castellblanch returned to the meeting room at 11:09 a.m.

No public comment was provided.

6. Discussion Regarding Proposed Modifications to the Board's Disciplinary Guidelines

Dr. Kajioka provided that California Code of Regulations section 1760 requires the board to consider its disciplinary guidelines when reaching a decision on a disciplinary action. He stated that this regulation section was last amended in May 2009.

Dr. Kajioka provided that during the October 2010 Board Meeting, the board voted to direct staff to work on updating the Disciplinary Guidelines for the board. He stated that staff has initiated work on identification of proposed changes, many of which have been developed by counsel, but there is still additional work that needs to be done. Dr. Kajioka advised that in addition to identifying changes to the language, the board will be asked to consider a reorganization of the guidelines to facilitate better understanding and remove duplication.

Dr. Kajioka provided that the committee was provided with draft proposals and was advised that work on the guidelines will continue over the next several months and will be discussed during the next committee meeting for possible action. He stated that the committee considered if a subcommittee should be established to assist in this process and discussed the Pharmacists Recovery Program.

Mr. Brooks left the meeting room at 11:12 a.m.

No public comment was provided.

7. Questions and Answers on 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 reviewed relevant statutes for this issue. He stated that sections 1735 – 1735.8 establish requirements for pharmacies that compound medicine. Dr. Kajioka provided that sections 1751 - 1751.8 establish requirements for pharmacies that compound sterile injectable medications.

Dr. Kajioka provided that effective July 7, 2010, new and amended regulations took effect regarding pharmacies that compound medications as well as pharmacies that compound sterile injectable medications.

Dr. Kajioka provided that since the approval of these regulations, board staff has been educating licensees on the requirements. He stated that during enforcement committee meetings, Supervising Inspector Robert Ratcliff has been providing a question and answer session on the new compounding regulations.

Dr. Kajioka reviewed that during the October 2010 Board Meeting, the board voted to create a subcommittee to further review the questions and answers received thus far, as well as to respond to any new questions.

Dr. Kajioka provided that the subcommittee, comprised of Dr. Kajioka, Dr. Schell, Dr. Dang, Dr. Ratcliff and Ms. Herold, met on January 5, 2011.

Dr. Kajioka provided that the Q&A's are posted on the board's Web site.

Dr. Kajioka provided that the committee discussed the Q&A's and requested that future questions be submitted in writing and forwarded to the subcommittee to evaluate. He advised that the committee did not take action on this item.

Mr. Brooks returned to the meeting room at 11:15 a.m.

Mr. Badlani encouraged staff to update the Q&A's on the Web site as new questions are submitted. He discussed that there is still a lot of confusion among the profession, especially regarding master formulas.

No public comment was provided.

8. Discussion Regarding Whether Patients Should Be Allowed to Take Their Multi-Dose Medications Home Upon Discharge From a Hospital

Dr. Kajioka provided that several weeks ago, the executive officer met with representatives of drug manufacturer Sanofi-Aventis regarding the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use.

Dr. Kajioka provided that during the committee meeting, the committee heard a presentation by Deanne Calvert, JD, representing Sanofi Aventis. He stated that Ms. Calvert discussed the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use.

Dr. Kajioka provided that Ms. Calvert discussed a project by Spectrum Health, a hospital system in Michigan, which evaluated whether it was feasible to implement a system that would allow patients to take home these medications. He explained that Ms. Calvert indicated that this project was successful in identifying a generic preprinted label to be added to the patient barcode label that would meet all federal and Michigan state regulations regarding properly labeling medication for dispensing at discharge.

Dr. Kajioka provided that Ms. Calvert discussed outreach efforts for this process in other states and sought input regarding any California laws that would prohibit this process.

Dr. Kajioka provided that the committee did not take action on this item.

Ms. Veale sought clarification regarding the intent for this discussion.

Dr. Kajioka provided that this discussion is being used to shine light on this problem.
President Weisser clarified that although this issue is similar to the previously discussed item regarding long term care facilities, this issue involves acute hospitals.

Ms. Herold discussed that this does also deal with medications that are not originally dispensed for patient use.

Discussion continued regarding this issue. It was suggested that out patient hospital pharmacies may provide assistance with the relabeling of medications upon discharge.

Public Comment
Darlene Fujimoto, representing UCSD, discussed that there are varied practices and policies in California on this issue. She suggested that the board seek input on this issue from the pharmacy associations.

9. Provision of the First Ethics Course Pursuant to 16 California Code of Regulations Section 1773.5

Dr. Kajioka provided that California Code of Regulations Section 1773.5 establishes the criteria for an ethics course that may be required as a term and condition of probation, license reinstatement or as abatement for a citation and fine. He indicated that this regulation section took effect September 3, 2009.

Dr. Kajioka provided that in mid-November, the Institute for Medical Quality provided the first ethics course for pharmacists under the requirements specified in 16 California Code of Regulations sections 1773 and 1773.5. He indicated that 12 pharmacists (ordered to complete this course as a condition of their probation) have enrolled. Dr. Kajioka stated that the course will follow these individuals over the next 12 months. He advised that periodic reports of the progress of this course will be provided to the committee and board in the future.

Dr. Kajioka provided that there is a second course provider interested in providing a course that meets the parameters of section 1773.5; however, the

board is not aware that this course has actually been provided or scheduled at this time.

Dr. Kajioka provided that whereas the board is not specifically involved in the course provided, and because it is a new program, the board will be kept updated as probationers take and complete these courses.

Dr. Kajioka provided that the committee did not take action on this item.

Public Comment

Darlene Fujimoto, representing UCSD, asked whether it would be possible to obtain information regarding course content or outline.

Ms. Sodergren directed Dr. Fujimoto to the course providers for this information.

10. Review and Discussion of Enforcement Statistics and Performance Standards of the Board

Ms. Herold provided an overview of the board's current activities. She discussed that the board's current enforcement processing is solid considering current staffing.

Ms. Sodergren provided that the second quarterly performance measures have not yet been posted.

No public comment was provided.

11. Summary of Meeting of December 6, 2010

Dr. Kajioka referenced to the meeting summary of the December 6, 2010 Enforcement Committee Meeting provided in the board packet.

No public comment was provided.

Ms. Herold stated that the following agenda items were not discussed by the Enforcement Committee as they were brought to the attention of the executive officer after December 2010 meeting.

b. Request from University Specialty Pharmacy to Renew its Board Waiver From 16 California Code of Regulations Section 1713(b) to Provide Synagis Prescription Medicine to Home Health Patients

Dr. Kajioka provided that the University Specialty Pharmacy has requested that the board renew its waiver of 16 California Code of Regulations Section 1713(a) under the waiver authority specified in section 1713(b).

Ms. Shellans clarified that University Specialty Pharmacy will need to request approval for a new waiver as the previous waiver has already expired.

Glen Truitt, General Counsel for University Specialty Pharmacy, reviewed the specific request to allow University Specialty Pharmacy to deliver "dispensed" Synagis medication to a licensed home health agency for administration to the patient by the home health agency at the patient's home. He advised that failure to approve the waiver would result in alarming waste of expensive medication.

Mr. Brooks offered a proposal to approve the waiver for three years.

Mr. Brooks asked why the law is not changed to eliminate the need for the waiver.

Ms. Herold provided that this process was established by the board to provide opportunity to periodically review this issue. She discussed that at the time the original waiver was initiated, counsel had advised the board not to grant permanent waivers.

Mr. Brooks suggested that, due to the nature of the medications, the board readdress this policy.

Mr. Truitt indicated that there is no risk of diversion for this drug.

President Weisser asked whether it is a difficult to appear before the board to obtain this waiver.

Mr. Truitt indicated that there is no difficulty.

Mr. Room clarified that the waiver process is in place so that any problems during the three year period can be addressed prior to the next waiver approval.

Ms. Herold provided that the board can direct staff to inspect these facilities.

Mr. Brooks suggested that staff inspect these facilities to determine if there are any problems and report back to the board with a recommendation on how to proceed with this waiver process.

Ms. Shellans advised that this would require amendments to current regulations.

Dr. Ratcliff suggested that the board grant a shorter waiver period pending the results of the inspection.

Mr. Zee suggested that prior to the next extension of the waiver, the applicant can schedule an inspection to request a longer period of time for the waiver. He offered an amendment to the proposal made by Mr. Brooks to make the waiver retroactive as it has already expired.

Ms. Shellans advised that the board does not have the authority to grant a retroactive waiver.

Mr. Truitt provided that there were attempts to appear before the board prior to the expiration of the waiver.

Ms. Herold confirmed that the agenda for the October 2010 Board Meeting was full. She discussed that the board has enforcement discretion in this area.

No public comment was provided.

MOTION: Approve waiver from 16 California Code of Regulations Section 1713(b) for University Specialty Pharmacy to provide synagis prescription medicine to home health patients for three years.

M/S: Brooks/Veale

Support: 9 Oppose: 0 Abstain: 0

c. Discussion and Review of Proposed Written Guidance to Pharmacies and Prescribers on the Transmission and Receipt of Electronic Controlled Substances Prescriptions Pursuant to the Drug Enforcement Administration's Interim Final Rule

Background

Early in 2010, the Drug Enforcement Administration released its Interim Final Rule on that agency's requirements for the electronic transmission of prescriptions for controlled drugs. This interim rule took effect in June 2010.

Mr. Room provided that the draft of the document included in the board packet has been revised slightly. He directed the board to a handout of the revised version. Mr. Room advised that the differences between the draft and the revised version are nonmaterial.

President Weisser provided that the DEA's requirements for e-prescribing of controlled drugs are laid out in a 330 page document that is both detailed and highly technical. He

commended Mr. Room for his work on condensing this document in order to provide information to board licensees about the requirements.

Dr. Kajioka provided that before starting this process, the executive officer also approached the executive officer of the Medical Board to see if they would be interested in a similar guidance document for their licensees. He stated that they were interested, and Mr. Room worked in conjunction with an attorney from the Medical Board to produce the draft document.

Mr. Room asked if the board would like this document to be disseminated.

President Weisser encouraged that the document be distributed to the other entities involved.

Dr. Kajioka discussed that it is important for the board to have an active role in this process and to solicit input from the other boards involved in this issue.

Ms. Herold discussed that the document should be edited to be more reader friendly. She stated that the layout can be modified so that the condensed text is not overwhelming to readers.

Mr. Room provided that the document was developed to limit the number of pages.

Mr. Brooks and Ms. Hackworth left the meeting room at 11:48 a.m.

The board discussed the next step for this process. It was suggested that the board receive input from the Medical Board and possibly consider the establishment of a taskforce.

Mr. Lippe offered a proposal to adopt and distribute the California State Board of Pharmacy and Medical Board of California's Transmission and Receipt of Electronic Controlled Substance Prescriptions, authored by Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel.

Ms. Hackworth and Mr. Brooks returned to the meeting room at 11:51 a.m.

Public Comment

Darlene Fujimoto sought clarification regarding the Medical Board's role with this document.

Mr. Room reviewed that the Medical Board's participation in this process included preparation of the guidance document. He discussed that it is anticipated that the Board of Pharmacy will take the lead on this process and the Medical Board will follow.

Dr. Fujimoto asked if the board will be providing additional guidance regarding the expectations of the board in this area. She discussed that additional guidance would be beneficial to help pharmacist's understand their responsibilities in this area.

Mr. Room clarified that the document was developed to assist organizations with their continuing compliance with the federal regulations when engaging in electronic prescriptions for controlled substances.

Ms. Herold provided that the document can be used as a general guide to cross-reference with the actual requirements.

Mr. Room discussed that entities interested in electronic prescribing should choose a vendor that provides software platforms that have been certified as compliant with the DEA Interim Final Rule (IFR).

There was no additional board discussion or public comment.

Dr. Castellblanch and Ms. Veale left the meeting room at 11:58 a.m.

Ms. Hackworth left for the day at 11:58 a.m. A quorum of the board was not present.

The board postponed action on this item until a quorum of the board was present.

d. Review and Comments on CalRecycle's Report to the Legislature on the Evaluation of Home-Genereated Pharmaceutical Programs in California, Revised January 19, 2011

Dr. Kajioka provided that in 2007, the Legislature enacted SB 966 (Simitian, Chapter 542). He stated that among other things, this law directed that until January 1, 2013, the California Integrated Waste Management Board (now CalReycle) shall develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste.

Dr. Kajioka provided that this law required a report to the Legislature in December 2010. He reviewed that the legislative report must:

> . . . include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

Ms. Veale returned to the meeting room at 12:00 p.m. A quorum of the board was established.

Dr. Kajioka provided that CalRecycle's report is now complete. He stated that the board provided draft comments to an initial version of this report in August 2010.

Dr. Kajioka asked the board to consider any additional comments in response to this CalRecycle report.

Ms. Herold provided an overview of the report. She stated that only five percent of the programs are compliant with the model guidelines in this area.

Mr. Herold discussed four options proposed for further state action including (1) continue current use of model guidelines, (2) establish clear state agency roles and responsibilities, improve model guidelines and enforcement, and convert guidelines to regulation, (3) implement product stewardship, and (4) create a state collection program funded by advanced disposal fee.

The board discussed this report and the board's role in this issue.

Mr. Brooks suggested that the board seek a legislative remedy to require that medicine be destroyed prior to being placed in the collection receptacle.

Dr. Castellblanch returned to the meeting room at 12:06 p.m.

Ms. Veale expressed concern regarding pharmacy involvement in take-back programs.

It was the consensus of the board to not issue comments to the Legislature regarding the report.

No public comment was provided.

The board resumed action on the previous agenda item as a quorum of the board was present.

MOTION: Adopt and distribute the California State Board of Pharmacy and Medical Board of California's Transmission and Receipt of Electronic Controlled Substance Prescriptions, authored by Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel.

M/S: Lippe/Kajioka

Support: 8 Abstain: 0 Oppose: 0

e. Possible Board Comments to the DEA on Parameters for the Take Back of Unwanted Prescription Medication From Patients for Destruction

Dr. Kajioka provided that late in December 2010, board staff learned that the Drug Enforcement Administration (DEA) would be conducting a public meeting on January 19 and 20, 2011 to discuss procedures for the surrender of unwanted controlled substances by ultimate users and long-term care facilities. He stated that this hearing would be a step toward the development of regulations to implement the Secure and Responsible Drug Disposal Act of 2010. Dr. Kajioka indicated that at that time, the DEA announced that they were seeking oral and written comment at the meeting; written comments were due January 12. He advised that the DEA stated that a transcript from this public meeting would be made available at the DEA Diversion Control Program Web site, http://www.deadiversion.usdoj.gov.

Dr. Kajioka provided that due to the short notice period, which coincided with the holidays, no written comments were submitted from the Board of Pharmacy.

Dr. Kajioka referenced the following comments requested by the DEA :

- The process of the disposal of unwanted controlled substances could create new and unwanted avenues for diversion. What is the safest manner, in your opinion, to dispose of unwanted controlled substances while preventing diversion?
- Please explain why you believe the solution you propose would protect the public health and safety and would curtail diversion.
- Do you foresee any specific obstacles to the disposal of controlled substances in your community or geographical area? If so, what are they?
- How is the disposal of controlled substances affected by State and local laws and regulations?

Dr. Castellblanch encouraged the board to consider pharmacies as a venue for take back programs as they are a logical and convenient resource for the consumer.

Mr. Brooks provided comment on the costs associated with these programs and whether this should be the responsibility of the pharmacies. He discussed that the board should do a better job at educating consumers on how to properly dispose of drugs at home.

Mr. Room advised that controlled substances can only be surrendered to a law enforcement officer.

Dr. Kajioka provided that the DEA sponsored a national Drug Take-back Day in the fall of 2010 and will be scheduling a new date for 2011. He advised that pharmacies are not permitted to take back controlled substances.

Dr. Castellblanch provided comment in support of the DEA's Drug Take-back Day.

Mr. Zee left the meeting room at 12:19 p.m.

The board discussed whether a response is needed. The confusion and lack of information regarding this issue was emphasized.

MOTION: Delegate authority to the executive officer to provide comments on behalf of the board to be ratified at the next board meeting after the comments have been released.

M/S: Veale/Castellblanch

Support: 7 Oppose: 0 Abstain: 0

f. Transition Issues Surrounding the New Vendor for California's CURES Program

Dr. Kajioka provided that in mid-December, the California Department of Justice (DOJ) advised California pharmacies that effective January 1, 2011, all pharmacies were to electronically submit their data regarding controlled substances dispensed to a new vendor. He advised that this was very short notice.

Dr. Kajioka provided that the board has received a few complaints regarding transmission of data to the new vendor. He stated that these complaints typically are referred to the DOJ.

Dr. Kajioka stated that the board needs to request that the DOJ provide more advanced notice to allow time for pharmacies to make the necessary changes.

Mr. Zee returned to the meeting room at 12:27 p.m.

No public comment was provided.

g. Second Quarterly Report on the Committee's Goals for 2010/11

The second quarter's report on the committee's strategic plan is provided in the board packet.

XI. Executive Officer's Report

Ms. Herold reviewed the significant impact and challenges posed by the current hiring freeze. She indicated that there is currently over a 35 percent vacancy rate of staff positions.

Ms. Sodergren provided that the internal hiring process where one DCA employee can transfer to another DCA agency is not applicable to filling vacant inspector positions because the Board of Pharmacy is the only DCA entity to employ pharmacists.

Ms. Herold discussed the executive order requiring fleet reduction and the possibility of "pooling" cars. She provided that this will pose challenges for board inspectors who are stationed throughout the state.

Ms. Herold discussed the development of a new strategic plan. She stated that staff is seeking a consultant contract to facilitate this process.

Ms. Herold indicated that it is time to begin discussion on electronic pedigree requirements to work out some of the implementation issues. She stated that this will be discussed later in the year in July or October 2011.

Ms. Herold solicited input from the board regarding the preferred location for the next board meeting. She discussed that previous meetings have been held in Sacramento as a cost savings measure.

Dr. Castellblanch stated preference to meeting near public transportation.

Mr. Zee stated preference to relocating some meetings to Southern California.

Ms. Brooks agreed with Mr. Zee and discussed that the board should travel to Southern California to accommodate these constituents.

President Weisser discussed that the board should continue the tradition of meeting throughout the state. He encouraged the board to also consider the cost savings when meeting in Sacramento.

Ms. Herold commended the board staff for their work and commitment.

Mr. Brooks requested that board counsel evaluate guidelines with regards to a nonprofit program to solicit industry and public advocacy groups to donate funds for staff development, trips, or other activities that the board deems appropriate. He discussed other organizations that have model programs in this area. Mr. Brooks suggested that the donations be anonymous.

Mr. Zee provided that he believes that internal revenue code 501(c) would allow for this.

Mr. Brooks requested that this item be added as a future agenda item for board discussion and input from industry and advocacy groups.

No public comment was provided.

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

No public comment was provided.
The board recessed for a lunch break at 12:39 p.m.

The board reconvened at 1:18 p.m.

XIII. Petition for Reinstatement

- Mary French, RPH 35330

ADJOURNMENT

The meeting was adjourned at 3:05 p.m.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

APPLICATION FOR A PHARMACY TECHNICIAN LICENSE

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets of paper if necessary.

Applicant Information - Please Type or Print

Full Legal Name-Last Name First Name Middle Name

Previous Names (AKA, Maiden Name, Alias, etc)

*Official Mailing/Public Address of Record (Street Address, PO Box #, etc)

City State Zip Code

Residence Address (if different from above)

City State Zip Code

Home# Cell# Work# Email Address

Date of Birth (Month/Day/Year) **Social Security No Driver's License # State

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

☐ High school graduate or foreign equivalent.

Attach a certified copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

☐ Completed a General Education Development (GED)

Attach an official transcript of your GED test results.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION

NO POLAROID OR SCANNED IMAGES

PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(1)(2)(3)(4) of the Business and Professions Code.

☐ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

☐ Attached is a certified copy of PTCB certificate - Date certified: _____

☐ Attached is a certified copy of your military training DD214

Self-Query Report by the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)

☐ Attached is the sealed envelope containing my Self-Query Report from the NPDB-HIPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

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SENATE BILL No. 100

Introduced by Senator Price

January 11, 2011

An act to amend Sections 651 and 2023.5 of, and to add Section 2027.5 to, the Business and Professions Code, and to amend Sections 1204, 1248, 1248.15, 1248.2, 1248.25, 1248.35, 1248.5, 1248.55, and 1279 of, and to add Sections 1204.6, 1204.7, and 1204.8 to, the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 100, as introduced, Price. Healing arts.

(1) Existing law provides for the licensure and regulation of various healing arts practitioners and requires certain of those practitioners to use particular designations following their names in specified instances. Existing law provides that it is unlawful for healing arts licensees to disseminate or cause to be disseminated any form of public communication, as defined, containing a false, fraudulent, misleading, or deceptive statement, claim, or image to induce the rendering of services or the furnishing of products relating to a professional practice or business for which they are licensed. Existing law authorizes advertising by these healing arts licensees to include certain general information. A violation of these provisions is a misdemeanor.

This bill would require certain healing arts licensees to include in advertisements, as defined, certain words or designations following their names indicating the particular educational degree they hold or healing art they practice, as specified. By changing the definition of a crime, this bill would impose a state-mandated local program.

(2) Existing law requires the Medical Board of California, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field,

to review issues and problems relating to the use of laser or intense light pulse devices for elective cosmetic procedures by their respective licensees.

This bill would require the board to adopt regulations by January 1, 2013, regarding the appropriate level of physician availability needed within clinics or other settings using certain laser or intense pulse light devices for elective cosmetic procedures.

(3) Existing law requires the Medical Board of California to post on the Internet specified information regarding licensed physicians and surgeons.

This bill would require the board to post on its Internet Web site an easy-to-understand factsheet to educate the public about cosmetic surgery and procedures, as specified.

(4) Under existing law, the State Department of Public Health licenses and regulates clinics, including surgical clinics, as defined.

This bill would expand the definition of surgical clinics to include a surgical clinic owned in whole or in part by a physician and would require, until the department promulgates regulations for the licensing of surgical clinics, the department to use specified federal conditions of coverage.

(5) Existing law requires the Medical Board of California, as successor to the Division of Licensing of the Medical Board of California, to adopt standards for accreditation of outpatient settings, as defined, and, in approving accreditation agencies to perform this accreditation, to ensure that the certification program shall, at a minimum, include standards for specified aspects of the settings' operations. Existing law makes a willful violation of these and other provisions relating to outpatient settings a crime.

This bill would include, among those specified aspects, the submission for approval by an accreditation agency at the time of accreditation, a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery. The bill would also modify the definition of "outpatient setting" to include facilities that offer in vitro fertilization, as defined. By changing the definition of a crime, this bill would impose a state-mandated local program.

Existing law also requires the Medical Board of California to obtain and maintain a list of all accredited, certified, and licensed outpatient settings, and to notify the public, upon inquiry, whether a setting is

accredited, certified, or licensed, or whether the setting's accreditation, certification, or license has been revoked.

This bill would require the board, absent inquiry, to notify the public whether a setting is accredited, certified, or licensed, or the setting's accreditation, certification, or license has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency. The bill would also require the board to give the department notice of all accredited, certified, and licensed outpatient settings and to notify the department of accreditation standards, changes in the accreditation of an outpatient setting, or any disciplinary actions and corrective actions.

Existing law requires accreditation of an outpatient setting to be denied if the setting does not meet specified standards. Existing law authorizes an outpatient setting to reapply for accreditation at any time after receiving notification of the denial.

This bill would require the accreditation agency to immediately report to the Medical Board of California if the outpatient setting's certificate for accreditation has been denied. Because a willful violation of this requirement would be a crime, the bill would impose a state-mandated local program. The bill would also apply the denial of accreditation, or the revocation or suspension of accreditation by one accrediting agency to all other accrediting agencies.

Existing law authorizes the Medical Board of California, as successor to the Division of Medical Quality of the Medical Board of California, or an accreditation agency to, upon reasonable prior notice and presentation of proper identification, enter and inspect any accredited outpatient setting to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of the specified law.

This bill would delete the notice and identification requirements. The bill would require that every outpatient setting that is accredited be inspected by the accreditation agency, as specified, and would specify that it may also be inspected by the board and the department, as specified. The bill would require the board to ensure that accreditation agencies inspect outpatient settings.

Existing law authorizes the Medical Board of California to terminate approval of an accreditation agency if the agency is not meeting the criteria set by the board.

This bill would also authorize the board to issue a citation to the agency, including an administrative fine, in accordance with a specified system established by the board.

Existing law authorizes the Medical Board of California to evaluate the performance of an approved accreditation agency no less than every 3 years, or in response to complaints against an agency, or complaints against one or more outpatient settings accreditation by an agency that indicates noncompliance by the agency with the standards approved by the board.

This bill would make that evaluation mandatory.

(5) Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health and requires the department to periodically inspect those facilities, as specified.

This bill would state the intent of the Legislature that the department, as part of its periodic inspections of acute care hospitals, inspect the peer review process utilized by those hospitals.

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. (a) It is the intent of the Legislature to clarify Capen v. Shewry (2007) 147.Cal.App.4th 680 and give surgical clinics that are owned in whole or in part by physicians the option to be licensed by the State Department of Public Health. It is further the intent of the Legislature that this clarification shall not be construed to permit the practice of medicine in prohibition of the corporate practice of medicine pursuant to Section 2400 of the Business and Professions Code.

(b) It is the further intent of the Legislature to continue to give physicians and surgeons the option to obtain licensure from the State Department of Public Health if they are operating surgical clinics, or an accreditation through an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3

(commencing with Section 1248) of Division 2 of the Health and Safety Code.

(c) It is the further intent of the Legislature, in order to ensure patient protection, to provide appropriate oversight by the State Department of Public Health, and to allow corrective action to be taken against an outpatient setting if there is reason to believe that there may be risk to patient safety, health, or welfare, that an outpatient setting shall be deemed licensed by the State Department of Public Health.

SEC. 2. Section 651 of the Business and Professions Code is amended to read:

651. (a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.

(3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

(B) Use of any photograph or other image of a model without clearly stating in a prominent location in easily readable type the fact that the photograph or image is of a model is a violation of subdivision (a). For purposes of this paragraph, a model is anyone other than an actual patient, who has undergone the procedure

being advertised, of the licensee who is advertising for his or her services.

(C) Use of any photograph or other image of an actual patient that depicts or purports to depict the results of any procedure, or presents "before" and "after" views of a patient, without specifying in a prominent location in easily readable type size what procedures were performed on that patient is a violation of subdivision (a). Any "before" and "after" views (i) shall be comparable in presentation so that the results are not distorted by favorable poses, lighting, or other features of presentation, and (ii) shall contain a statement that the same "before" and "after" results may not occur for all patients.

(4) Relates to fees, other than a standard consultation fee or a range of fees for specific types of services, without fully and specifically disclosing all variables and other material factors.

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, "as low as," "and up," "lowest prices," or words or phrases of similar import. Any advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges for any related professional

services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5) (A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(i) For the purposes of this section, a dentist licensed under Chapter 4 (commencing with Section 1600) may not hold himself or herself out as a specialist, or advertise membership in or specialty recognition by an accrediting organization, unless the practitioner has completed a specialty education program approved by the American Dental Association and the Commission on Dental Accreditation, is eligible for examination by a national specialty board recognized by the American Dental Association, or is a

diplomate of a national specialty board recognized by the American Dental Association.

(ii) A dentist licensed under Chapter 4 (commencing with Section 1600) shall not represent to the public or advertise accreditation either in a specialty area of practice or by a board not meeting the requirements of clause (i) unless the dentist has attained membership in or otherwise been credentialed by an accrediting organization that is recognized by the board as a bona fide organization for that area of dental practice. In order to be recognized by the board as a bona fide accrediting organization for a specific area of dental practice other than a specialty area of dentistry authorized under clause (i), the organization shall condition membership or credentialing of its members upon all of the following:

(I) Successful completion of a formal, full-time advanced education program that is affiliated with or sponsored by a university based dental school and is beyond the dental degree at a graduate or postgraduate level.

(II) Prior didactic training and clinical experience in the specific area of dentistry that is greater than that of other dentists.

(III) Successful completion of oral and written examinations based on psychometric principles.

(iii) Notwithstanding the requirements of clauses (i) and (ii), a dentist who lacks membership in or certification, diplomate status, other similar credentials, or completed advanced training approved as bona fide either by an American Dental Association recognized accrediting organization or by the board, may announce a practice emphasis in any other area of dental practice only if the dentist incorporates in capital letters or some other manner clearly distinguishable from the rest of the announcement, solicitation, or advertisement that he or she is a general dentist.

(iv) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

(B) A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she limits his or her practice to specific fields, but shall not include a statement that he

or she is certified or eligible for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, unless that board or association is (i) an American Board of Medical Specialties member board, (ii) a board or association with equivalent requirements approved by that physician and surgeon's licensing board, or (iii) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty. A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification, unless the physician and surgeon is also licensed under Chapter 4 (commencing with Section 1600) and the use of the term "board certified" in reference to that.certification is in accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the Medical Board of California, for certifying medical doctors and other health care professionals that is based on the applicant's education, training, and experience.

For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is an American Board of Medical Specialties member board, an organization with equivalent requirements approved by a physician and surgeon's licensing board, or an organization with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in a specialty or subspecialty.

The Medical Board of California shall adopt regulations to establish and collect a reasonable fee from each board or

association applying for recognition pursuant to this subparagraph. The fee shall not exceed the cost of administering this subparagraph. Notwithstanding Section 2 of Chapter 1660 of the Statutes of 1990, this subparagraph shall become operative July 1, 1993. However, an administrative agency or accrediting organization may take any action contemplated by this subparagraph relating to the establishment or approval of specialist requirements on and after January 1, 1991.

(C) A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she is certified or eligible or qualified for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, if that board or association meets one of the following requirements: (i) is approved by the Council on Podiatric Medical Education, (ii) is a board or association with equivalent requirements approved by the California Board of Podiatric Medicine, or (iii) is a board or association with the Council on Podiatric Medical Education approved postgraduate training programs that provide training in podiatric medicine and podiatric surgery. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the California Board of Podiatric Medicine, for certifying doctors of podiatric medicine that is based on the applicant's education, training, and experience. For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is a Council on Podiatric Medical

Education approved board, an organization with equivalent requirements approved by the California Board of Podiatric Medicine, or an organization with a Council on Podiatric Medical Education approved postgraduate training program that provides training in podiatric medicine and podiatric surgery.

The California Board of Podiatric Medicine shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph, to be deposited in the State Treasury in the Podiatry Fund, pursuant to Section 2499. The fee shall not exceed the cost of administering this subparagraph.

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

(7) A statement of names of schools and postgraduate clinical training programs from which the practitioner has graduated, together with the degrees received.

(8) A statement of publications authored by the practitioner.

(9) A statement of teaching positions currently or formerly held by the practitioner, together with pertinent dates.

(10) A statement of his or her affiliations with hospitals or clinics.

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

(15) An advertisement of a registered dispensing optician may include statements in addition to those specified in paragraphs (1) to (14), inclusive, provided that any statement shall not violate subdivision (a), (b), (c), or (e) or any other section of this code.

(16) A statement, or statements, providing public health information encouraging preventative or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) (1) Advertising by the following licensees shall include the designations as follows:

(A) Advertising by a chiropractor licensed under Chapter 2 (commencing with Section 1000) shall include the designation "DC" or the word "chiropractor" immediately following the chiropractor's name.

(B) Advertising by a dentist licensed under Chapter 4 (commencing with Section 1600) shall include the designation "DDS" or "DMD" immediately following the dentist's name.

(C) Advertising by a physician and surgeon licensed under Chapter 5 (commencing with Section 2000) shall include the designation "MD" immediately following the physician and surgeon's name.

(D) Advertising by an osteopathic physician and surgeon certified under Article 21 (commencing with Section 2450) shall include the designation "DO" immediately following the osteopathic physician and surgeon's name.

(E) Advertising by a podiatrist certified under Article 22 (commencing with Section 2460) of Chapter 5 shall include the designation "DPM" immediately following the podiatrist's name.

(F) Advertising by a registered nurse licensed under Chapter 6 (commencing with Section 2700) shall include the designation "RN" immediately following the registered nurse's name.

(G) Advertising by a licensed vocational nurse under Chapter 6.5 (commencing with Section 2840) shall include the designation "LVN" immediately following the licensed vocational nurse's name.

(H) Advertising by a psychologist licensed under Chapter 6.6 (commencing with Section 2900) shall include the designation "Ph.D." immediately following the psychologist's name.

(I) Advertising by an optometrist licensed under Chapter 7 (commencing with Section 3000) shall include the applicable designation or word described in Section 3098 immediately following the optometrist's name.

(J) Advertising by a physician assistant licensed under Chapter 7.7 (commencing with Section 3500) shall include the designation "PA" immediately following the physician assistant's name.

(K) Advertising by a naturopathic doctor licensed under Chapter 8.2 (commencing with Section 3610) shall include the designation "ND" immediately following the naturopathic doctor's name. However, if the naturopathic doctor uses the term or designation

"Dr." in an advertisement, he or she shall further identify himself by any of the terms listed in Section 3661.

(2) For purposes of this subdivision, "advertisement" includes communication by means of mail, television, radio, motion picture, newspaper, book, directory, Internet, or other electronic communication.

(3) Advertisements do not include any of the following:

(A) A medical directory released by a health care service plan or a health insurer.

(B) A billing statement from a health care practitioner to a patient.

(C) An appointment reminder from a health care practitioner to a patient.

(4) This subdivision shall not apply until January 1, 2013, to any advertisement that is published annually and prior to July 1, 2012.

(5) This subdivision shall not apply to any advertisement or business card disseminated by a health care service plan that is subject to the requirements of Section 1367.26 of the Health and Safety Code.

~~(i)~~

(j) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of health services or commodities. A board or committee shall not,

by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

~~(j)~~

(k) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

~~(k)~~

(l) A physician and surgeon or doctor of podiatric medicine licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars ($10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

SEC. 3. Section 2023.5 of the Business and Professions Code is amended to read:

2023.5. (a) The board, in conjunction with the Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:

(1) The appropriate level of physician supervision needed.

(2) The appropriate level of training to ensure competency.

(3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:

(A) Patient selection.

(B) Patient education, instruction, and informed consent.

(C) Use of topical agents.

(D) Procedures to be followed in the event of complications or side effects from the treatment.

(E) Procedures governing emergency and urgent care situations.

(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.

(c) On or before January 1, 2013, the board shall adopt regulations regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures. However, these regulations shall not apply to laser or intense pulse light devices approved by the federal Food and Drug Administration for over-the-counter use by a health care practitioner or by an unlicensed person on himself or herself.

(d) Nothing in this section shall be construed to modify the prohibition against the unlicensed practice of medicine.

SEC. 4. Section 2027.5 is added to the Business and Professions Code, to read:

2027.5. The board shall post on its Internet Web site an easy-to-understand factsheet to educate the public about cosmetic surgery and procedures, including their risks. Included with the factsheet shall be a comprehensive list of questions for patients to ask their physician and surgeon regarding cosmetic surgery.

SEC. 5. Section 1204 of the Health and Safety Code is amended to read:

1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics and specialty clinics.

(a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:

(A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods,

or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.

(B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

(2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.

(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:

(1) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain

less than 24 hours, *including a surgical clinic that is owned in whole or in part by a physician.* A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.

(2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.

(3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

(4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

SEC. 6. Section 1204.6 is added to the Health and Safety Code, to read:

1204.6. Until the department promulgates regulations for the licensing of surgical clinics, the department shall use the federal conditions of coverage, as set forth in Subpart C of Part 416 of Title 42 of the Code of Federal Regulations, as those conditions existed on May 18, 2009, as the basis for licensure for facilities licensed pursuant to paragraph (1) of subdivision (b) of Section 1204.

SEC. 7. Section 1204.7 is added to the Health and Safety Code, to read:

1204.7. (a) An outpatient setting, as defined in subdivision (a) of Section 1248, that is accredited by an accrediting agency approved by the Medical Board of California, shall be deemed licensed by the department and shall be required to pay an annual licensing fee as established pursuant to Section 1266.

(b) The department shall have only that authority over outpatient settings specified in Chapter 3.1 (commencing with Section 1248).

(c) The department shall notify the Medical Board of California of any action taken against an outpatient setting and, if licensure of an outpatient setting is revoked or suspended by the department for any reason, then accreditation shall be void by operation of law. Notwithstanding Sections 1241 and 131071, proceedings shall not be required to void the accreditation of an outpatient setting under these circumstances.

SEC. 8. Section 1204.8 is added to the Health and Safety Code, to read:

1204.8. A clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 or an outpatient setting, as defined in Section 1248, shall be subject to the reporting requirements in Section 1279.1 and the penalties for failure to report specified in Section 1280.4.

SEC. 9. Section 1248 of the Health and Safety Code is amended to read:

1248. For purposes of this chapter, the following definitions shall apply:

(a) "Division" means the *Medical Board of California. All references in this chapter to the division, the* Division of Licensing of the Medical Board of ~~California.~~ *California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.*

~~(b) "Division of Medical Quality" means the Division of Medical Quality of the Medical Board of California.~~

~~(c)~~

(b) (1) "Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.

(2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.

(3) "Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of

practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

~~(d)~~

(c) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the ~~division~~ *board* pursuant to Sections 1248.15 and 1248.4.

SEC. 10. Section 1248.15 of the Health and Safety Code is amended to read:

1248.15. (a) The ~~division~~ *board* shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.

(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.

(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:

(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.

(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.

~~(iii) Submit~~

(D) The outpatient setting shall submit for approval by an accrediting agency a detailed procedural plan for handling medical

emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.

(E) The outpatient setting shall submit for approval by an accreditation agency at the time accreditation of a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations.

~~(D)~~

(F) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body, the Health Care Financing Administration, the State Department of ~~Health Services,~~ *Public Health,* and the appropriate licensing authority.

(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of *Division 2 of* the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of *Division 2 of* the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of *Division 2 of* the Business and Professions Code.

(4) Outpatient settings shall have a system for maintaining clinical records.

(5) Outpatient settings shall have a system for patient care and monitoring procedures.

(6) (A) Outpatient settings shall have a system for quality assessment and improvement.

(B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and

appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.

(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.

(7) Outpatient settings regulated by this chapter that have multiple service locations governed by the same standards may elect to have all service sites surveyed on any accreditation survey. Organizations that do not elect to have all sites surveyed shall have a sample, not to exceed 20 percent of all service sites, surveyed. The actual sample size shall be determined by the ~~division.~~ *board.* The accreditation agency shall determine the location of the sites to be surveyed. Outpatient settings that have five or fewer sites shall have at least one site surveyed. When an organization that elects to have a sample of sites surveyed is approved for accreditation, all of the organizations' sites shall be automatically accredited.

(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.

(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.

(10) Outpatient settings shall have a written discharge criteria.

(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.

(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the ~~division~~ *board* to protect the public health and safety.

(d) No accreditation standard adopted or approved by the ~~division,~~ *board,* and no standard included in any certification

program of any accreditation agency approved by the ~~division,~~ *board,* shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.

(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.

SEC. 11. Section 1248.2 of the Health and Safety Code is amended to read:

1248.2. (a) Any outpatient setting may apply to an accreditation agency for a certificate of accreditation. Accreditation shall be issued by the accreditation agency solely on the basis of compliance with its standards as approved by the ~~division~~ *board* under this chapter.

(b) The board shall submit to the State Department of Public Health the information required pursuant to paragraph (3) of subdivision (d) within 10 days of the accreditation of an outpatient setting.

~~(b)~~

(c) The ~~division~~ *board* shall obtain and maintain a list of all accredited, certified, and licensed outpatient settings from the information provided by the accreditation, certification, and licensing agencies approved by the ~~division,~~ *board,* and shall notify the ~~public, upon inquiry,~~ *public* whether a setting is accredited, certified, or licensed, or ~~whether~~ the setting's accreditation, certification, or license has been ~~revoked.~~ *revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency. The board shall provide notice to the department within 10 days when an outpatient setting's accreditation has been revoked, suspended, or placed on probation. The department shall notify the board within 10 days if the license of a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204, has been revoked.*

(d) (1) The board shall, on or before February 1, 2012, provide the department with a list of all outpatient settings that are accredited as of January 1, 2012.

(2) Beginning April 1, 2012, the board shall provide the department with an updated list of outpatient settings every three months.

(3) The list of outpatient settings shall include all of the following:

(A) Name, address, and telephone number of the owner.

(B) Name and address of the facility.

(C) The name and telephone number of the accreditation agency.

(D) The effective and expiration dates of the accreditation.

(e) The board shall provide the department with all accreditation standards approved by the board, free of charge. Accreditation standards provided to the department by the board shall not be subject to public disclosure provisions of the California Public Records Act (Chapter 3.5 commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

SEC. 12. Section 1248.25 of the Health and Safety Code is amended to read:

1248.25. If an outpatient setting does not meet the standards approved by the ~~division,~~ *board,* accreditation shall be denied by the accreditation agency, which shall provide the outpatient setting notification of the reasons for the denial. An outpatient setting may reapply for accreditation at any time after receiving notification of the denial. *The accreditation agency shall immediately report to the board if the outpatient setting's certificate for accreditation has been denied.*

SEC. 13. Section 1248.35 of the Health and Safety Code is amended to read:

1248.35. *(a) Every outpatient setting which is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.*

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided.

~~(a)~~

(3) The ~~Division of~~ Medical ~~Quality~~ *Board of California* or ~~an~~ *the* accreditation agency ~~may, upon reasonable prior notice and presentation of proper identification,~~ *may* enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

~~(b)~~

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Issue a reprimand.

(2) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the ~~division~~ *board* or the accreditation agency, to correct the deficiencies.

(3) Suspend or revoke the outpatient setting's certification of accreditation.

~~(c)~~

(d) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and *the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting* reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient center. *During that allotted time, a list of deficiencies and the plan of correction shall be conspicuously posted in a clinic location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to both the board and the department.* The accreditation agency may

immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

~~(d) If the division determines that deficiencies found during an inspection suggests that the accreditation agency does not comply with the standards approved by the division, the division may conduct inspections, as described in this section, of other settings accredited by the accreditation agency to determine if the agency is accrediting settings in accordance with Section 1248.15.~~

(e) The department may enter and inspect an outpatient setting upon receipt of a notice of corrective action or if it has reason to believe that there may be risk to patient safety, health, or welfare.

(f) An outpatient setting that does not comply with a corrective action may be required by the department to pay similar penalties assessed against a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204, and may have its license suspended or revoked pursuant to Article 5 (commencing with Section 1240) of Chapter 1.

(g) If the licensee disputes a determination by the department regarding the alleged deficiency, the alleged failure to correct a deficiency, the reasonableness of the proposed deadline for correction, or the amount of the penalty, the licensee may, within 10 days, request a hearing pursuant to Section 130171. Penalties shall be paid when appeals have been exhausted and the department's position has been upheld.

(h) Moneys collected by the department as a result of administrative penalties imposed under this section shall be deposited into the Internal Departmental Quality Improvement Account established pursuant to Section 1280.15. These moneys shall be tracked and available for expenditure, upon appropriation by the Legislature, to support internal departmental quality improvement activities.

(i) If, after an inspection authorized pursuant to this section, the department finds a violation of a standard of the facility's accrediting agency or any provision of this chapter or the regulations promulgated thereunder, or if the facility fails to pay a licensing fee or an administrative penalty assessed under this chapter, the department may take any action pursuant to Article

5 (commencing with Section 1240) of Chapter 1 and shall report the violation to the board and may recommend that accreditation be revoked, canceled, or not renewed.

(j) Reports on the results of any inspection conducted pursuant to subdivision (a) shall be kept on file with the board or the accreditation agency along with the plan of correction and the outpatient setting comments. The inspection report may include a recommendation for reinspection. All inspection reports, lists of deficiencies, and plans of correction shall be public records open to public inspection.

(k) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation.

(l) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies.

SEC. 14. Section 1248.5 of the Health and Safety Code is amended to read:

1248.5. The ~~division may~~ *board shall* evaluate the performance of an approved accreditation agency no less than every three years, or in response to complaints against an agency, or complaints against one or more outpatient settings accreditation by an agency that indicates noncompliance by the agency with the standards approved by the ~~division.~~ *board.*

SEC. 15. Section 1248.55 of the Health and Safety Code is amended to read:

1248.55. (a) If the accreditation agency is not meeting the criteria set by the ~~division,~~ *board,* the ~~division~~ *board* may terminate approval of the ~~agency.~~ *agency or may issue a citation to the agency in accordance with the system established under subdivision (b).*

(b) The board may establish, by regulation, a system for the issuance of a citation to an accreditation agency that is not meeting the criteria set by the board. This system shall meet the requirements of Section 125.9 of the Business and Professions Code, as applicable, except that both of the following shall apply:

(1) Failure of an agency to pay an administrative fine assessed pursuant to a citation within 30 days of the date of the assessment,

unless the citation is being appealed, may result in the board's termination of approval of the agency. Where a citation is not contested and a fine is not paid, the full amount of the assessed fine shall be added to the renewal fee established under Section 1248.6. Approval of an agency shall not be renewed without payment of the renewal fee and fine.

(2) Administrative fines collected pursuant to the system shall be deposited in the Outpatient Setting Fund of the Medical Board of California established under Section 1248.6.

~~(b)~~

(c) Before terminating approval of an accreditation agency, the ~~division~~ *board* shall provide the accreditation agency with notice of any deficiencies and reasonable time to supply information demonstrating compliance with the requirements of this chapter, as well as the opportunity for a hearing on the matter in compliance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

~~(c)~~

(d) (1) If approval of the accreditation agency is terminated by the ~~division,~~ *board,* outpatient settings accredited by that agency shall be notified by the ~~division~~ *board* and, except as provided in paragraph (2), shall be authorized to continue to operate for a period of 12 months in order to seek accreditation through an approved accreditation agency, unless the time is extended by the ~~division~~ *board* for good cause.

(2) The ~~division~~ *board* may require that an outpatient setting, that has been accredited by an accreditation agency whose approval has been terminated by the ~~division,~~ *board,* cease operations immediately ~~in~~ *if* the ~~event that the division~~ *board* is in possession of information indicating that continued operation poses an imminent risk of harm to the health of an individual. In such cases, the ~~division~~ *board* shall provide the outpatient setting with notice of its action, the reason underlying it, and a subsequent opportunity for a hearing on the matter. An outpatient setting that is ordered to cease operations under this paragraph may reapply for a certificate of accreditation after six months and shall notify the ~~division~~ *board* promptly of its reapplication. *The board shall notify the department of any action taken pursuant to this section for an outpatient setting. Upon cancellation, revocation, nonrenewal, or any other loss of accreditation, an outpatient setting's license shall*

be void by operation of law. Notwithstanding Sections 1241 and 131071, no proceedings shall be required to void the license of an outpatient setting.

SEC. 16. Section 1279 of the Health and Safety Code is amended to read:

1279. (a) Every health facility for which a license or special permit has been issued shall be periodically inspected by the department, or by another governmental entity under contract with the department. The frequency of inspections shall vary, depending upon the type and complexity of the health facility or special service to be inspected, unless otherwise specified by state or federal law or regulation. The inspection shall include participation by the California Medical Association consistent with the manner in which it participated in inspections, as provided in Section 1282 prior to September 15, 1992.

(b) Except as provided in subdivision (c), inspections shall be conducted no less than once every two years and as often as necessary to ensure the quality of care being provided.

(c) For a health facility specified in subdivision (a), (b), or (f) of Section 1250, inspections shall be conducted no less than once every three years, and as often as necessary to ensure the quality of care being provided.

(d) During the inspection, the representative or representatives shall offer such advice and assistance to the health facility as they deem appropriate.

(e) For acute care hospitals of 100 beds or more, the inspection team shall include at least a physician, registered nurse, and persons experienced in hospital administration and sanitary inspections. During the inspection, the team shall offer advice and assistance to the hospital as it deems appropriate.

(f) The department shall ensure that a periodic inspection conducted pursuant to this section is not announced in advance of the date of inspection. An inspection may be conducted jointly with inspections by entities specified in Section 1282. However, if the department conducts an inspection jointly with an entity specified in Section 1282 that provides notice in advance of the periodic inspection, the department shall conduct an additional periodic inspection that is not announced or noticed to the health facility.

(g) Notwithstanding any other ~~provision~~ of law, the department shall inspect for compliance with provisions of state law and regulations during a state periodic inspection or at the same time as a federal periodic inspection, including, but not limited to, an inspection required under this section. If the department inspects for compliance with state law and regulations at the same time as a federal periodic inspection, the inspection shall be done consistent with the guidance of the federal Centers for Medicare and Medicaid Services for the federal portion of the inspection.

(h) The department shall emphasize consistency across the state and *in* its district offices when conducting licensing and certification surveys and complaint investigations, including the selection of state or federal enforcement remedies in accordance with Section 1423. The department may issue federal deficiencies and recommend federal enforcement actions in those circumstances where they provide more rigorous enforcement action.

(i) It is the intent of the Legislature that the department, pursuant to its existing regulations, inspect the peer review process utilized by acute care hospitals as part of its periodic inspection of those hospitals pursuant to this section.

SEC. 17. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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California State Board of Pharmacy and Medical Board of California

Transmission and Receipt of Electronic Controlled Substance Prescriptions

Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances
21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010))
Effective June 1, 2010

Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel

The following is merely a summary and/or paraphrasing of the law as reflected in the IFR, and/or a compilation of opinion(s) on the interpretation of the IFR. It does not constitute an official opinion of, nor is it sanctioned by, the Attorney General, the California State Board of Pharmacy, or the Medical Board of California. This is not a binding statement of pertinent law. It is a summary, and is not intended to be comprehensive. It is offered as a guideline and a compilation of references to the appropriate sections of the IFR. Any person(s) wishing to understand the IFR are encouraged to review the regulation(s) themselves, and/or to consult an attorney.

California State Board of Pharmacy and Medical Board of California
Transmission and Receipt of Electronic Controlled Substance Prescriptions
Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances
21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010)) – **effective June 1, 2010**

Who is affected: Prescribers; pharmacies; application providers. To participate, each category must:

Prescribers	Pharmacies	Application Providers
Select application and ensure it meets DEA requirements	Select application and ensure it meets DEA requirements	Evaluate application(s) and/or reprogram as necessary
Apply for identity proofing	Set access controls	Undergo third-party audit or certification of software
Set access controls	Process prescriptions	Make audit/certification report available to users/possible users
Sign (and archive) prescriptions	Archive prescriptions	

Participation is voluntary.[1] The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions.[2] Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. If used, electronic prescriptions for Schedule II-V controlled substances must meet DEA regulatory requirements.

Audit and Selection of Software Application(s)
Before being used to create, sign, transmit, or process controlled substance prescriptions, electronic prescribing applications or pharmacy applications (stand-alone or integrated Electronic Medical Record (EMR) types) must have a third-party audit of the application certifying that it meets the requirements of the DEA regulations. The **application provider** must secure an audit from (1) a person/entity qualified to conduct a SysTrust, WebTrust, or SAS 70 audit; (2) a Certified Information System Auditor that performs compliance audits; or (3) a certifying organization whose certification process has been approved by the DEA.[3] (21 CFR § 1311.300.)

The auditor issues a report and/or certification to the application provider. The application provider must keep that report and/or certification for two years, and make it available to any prescriber or pharmacy that uses the application or is considering using the application. (21 CFR § 1311.300(f).) May be on provider's website.

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully. (21 CFR §§ 1311.102(d), (e), 1311.200(a), (b).) A prescription created using an application that does not meet requirements is invalid. (21 CFR § 1311.100(d).)

[1] There are various incentives for electronic prescribing and use of electronic medical records (EMR), most notably those contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act of 2009 (ARRA). These federal laws include incentive payments under Medicare for prescribers who reach certain e-prescribing and/or EMR thresholds. Prescribers may receive incentive payments on their billings of up to 2% in 2009 and 2010, 1% in 2011 and 2012, and 0.5% in 2013; they may be hit with penalties of 1% in 2012, 1.5% in 2013, and 2% in 2014 and beyond, for failure to meet these e-prescribing/EMR thresholds.

[2] Beginning January 1, 2012, Medicare Part D prescriptions can no longer be sent to a pharmacy by computer-generated fax. As of this date, prescriptions must be (a) transmitted electronically, (b) handed to the patient in hardcopy form, or (c) manually faxed to the pharmacy. As of October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) required all written Medicaid prescriptions be written on a tamper-resistant prescription blank. Electronic prescriptions are excluded from this requirement (and are acceptable).

[3] A follow-up audit/certification must be conducted whenever functionality related to controlled substance prescription requirements is altered, or every two years, whichever comes first. (21 CFR § 1311.300(a)(2), (e)(2).)

Furthermore, both prescribers and pharmacies have an **ongoing responsibility** to immediately cease using an application (and ensure that any designated agents also cease using the application) if: any required function of the application is disabled or appears to be functioning improperly; the application provider notifies them that a third-party audit or certification report indicates that the application no longer meets DEA requirements; or the application provider reports that the application is non-compliant. (21 CFR §§ 1311.102, 1311.200, 1311.300.)

The requirements for an electronic prescription application are quite specific. (21 CFR § 1311.120.)

Identity Proofing of Prescribers (Practitioners)[4]

Identity proofing is the process by which a prescriber is uniquely identified, so that only that prescriber has the access necessary to authorize and sign electronic prescriptions using a software application. Identity proofing of prescriber must be done by an approved credential service provider (CSP) or certification authority (CA) [for digital certificates]. Remote identity proofing is permissible. (21 CFR § 1311.105.) Prescribers should consult with their selected application provider to determine which identity proofing organization to work with.

Institutional prescribers can undergo identity proofing using the third-party method described above, or identity proofing can be conducted in-house by their institution(s). (21 CFR § 1311.110.)

Once identity is verified, the prescriber is issued a two-factor authentication credential. (21 CFR § 1311.105.) The two factors must be two of the following: (1) Something the prescriber knows, such as a password or PIN; (2) A hard token separate from the computer being accessed (meeting at least FIPS 140-2 Security Level 1); or (3) A biometric, such as a fingerprint or iris scan, meeting DEA criteria. (21 CFR. §§ 1311.115, 1311.116.)

Two-factor credentials will be used for (1) approving access controls, and (2) signing electronic prescriptions. (21 CFR § 1311.120.) They must always be in the exclusive control of the prescriber. (21 CFR § 1311.102.)

Access Controls – For Both Prescribers and Pharmacies

Access controls relate to software-based specifications and restrictions that ensure that only those individuals authorized to sign prescriptions are allowed to do so, and only those persons authorized to enter information regarding dispensing, or to annotate or alter or delete prescription information, are allowed to do so.

At the prescriber level, in each registered location there must be at least two individuals designated to manage access control to the application. One of these has to be the registered prescriber who has obtained two-factor authentication credentials. (21 CFR § 1311.125.) These access controls are required to limit the permission to sign controlled substance prescriptions to persons whose DEA registration is current and in good standing, and whose state authorization(s) to prescribe are current and in good standing,. (21 CFR § 1311.125(b).) There is also a two-person management requirement in an institutional setting. (21 CFR § 1311.130.)

Prescriber software application must be capable of setting logical access controls to limit permissions for both the indication that a prescription is ready for signing, and the electronic signature on the prescription, as well as for changes to the access controls themselves. (21 CFR § 1311.120(b).) The software must revoke permission to sign controlled substance prescriptions on the date that any of the following is discovered: A hard token or any other authentication factor is lost, stolen or compromised; DEA registration expires without renewal; DEA registration is terminated, revoked, or suspended; or the prescriber is no longer authorized to use the software (e.g., when the prescriber leaves the practice or institution). (21 CFR §§ 1311.125(d), 1311.130(d).)

At the pharmacy level, logical access controls in the pharmacy application must be set so that only the person(s) authorized to enter information regarding dispensing of controlled substance prescriptions and/or to annotate or alter or delete records of prescriptions, are permitted to do so. (21 CFR §§ 1311.200(e), 1311.205(b)(1), (2).)

[4] "Practitioner" is used throughout the regulations where we might use "prescriber." We use prescriber exclusively in this document.

Signature and Transmission of Prescription(s) by Prescribers

A prescriber or prescriber's agent may prepare one or more prescriptions for review and signature by prescriber. (21 CFR § 1311.135(a).) A prescriber may access a list of prescriptions for a single patient, and sign one, some, or all of them at once. (21 CFR § 1311.140(a)(1).) The screen must display, for each prescription: the date of issuance; full patient name; drug name; dosage strength and form; quantity prescribed; directions for use; refills authorized (for Schedule III-V drugs); earliest fill date, if applicable (see 21 CFR § 1306.12(b)); and the name, address, and DEA registration number of the prescriber. (21 CFR § 1311.140(a)(1), 1311.120(b)(9).) The same screen must also display the following statement: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." (21 CFR § 1311.140(a)(3).)

Only the prescriber may indicate those prescriptions that are ready to be signed and, while the screen displays the prescription information and the warning statement, only the prescriber may be prompted to complete, and may complete, the two-factor authentication protocol. Completion of the two-factor authentication protocol by the prescriber is a legal signature pursuant to 21 CFR § 1306.05. (21 CFR § 1311.140(a)(2), (4), (5).) Multiple prescriptions for the same patient can be signed by one application of the two-factor authentication protocol; no separate keystroke is required to acknowledge the warning or to sign the prescription. (21 CFR § 1311.140.)

Upon completion of the two-step authentication protocol, one of two things must happen: either the application digitally signs (i.e., locks) and electronically archives the required information (21 CFR § 1311.140(a)(6)), and designates the prescription eligible for transmission; or, if the prescriber has a digital certificate (see 21 CFR § 1311.105), the application applies the prescriber's private key to digitally sign and electronically archive the required data (21 CFR § 1311.145) before designating the prescription for transmission. If the latter, digital certificate methodology is applied, the prescription may be transmitted to a pharmacy without digital signature, and a digital signature is not required, so long as the application first checks the certificate revocation list of the prescriber's issuing certificate authority (CA) prior to transmission. (21 CFR § 1311.145(e), (f), (g).)

The prescription must be transmitted as soon as possible after signature. (21 CFR § 1311.170(a).) It must stay in electronic form all the way from the prescriber to the pharmacy (including through intermediaries); at no time may it be converted to another form (e.g., facsimile). (21 CFR § 1311.170(f).) Likewise, the application must restrict printing of electronic prescriptions for controlled substances. The application must not allow electronic transmission of a prescription that has already been printed. (21 CFR § 1311.170(d).) A prescription may be printed **after** its electronic transmission only under two circumstances: (a) where the prescriber is notified by an intermediary or pharmacy that an electronic prescription was not delivered, in which case the prescriber must be sure that any paper (or oral) prescription issued as a replacement indicates that the prescription was previously transmitted electronically, to a particular pharmacy, and that transmission failed; or (b) where a prescriber prints a copy of an electronically-transmitted prescription (or a list of a patient's prescriptions), and the copy or list is clearly labeled "Copy only – not valid for dispensing." (21 CFR § 1311.170(c).) Data from prescription(s) may also be electronically transferred to (electronic) medical records. (21 CFR § 1311.170(c).)

It is no longer required that the prescription be transmitted immediately. The DEA has expressly acknowledged that prescribers "may prefer to sign prescriptions before office staff add pharmacy or insurance information." (General Questions and Answers [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm.) In other words, a (reasonable) delay between signature and transmission is permissible, and it is also acceptable for additions or changes to be made to items in the information being electronically transmitted that are not part of the prescription information required by DEA regulations under 21 CFR Part 1306. However, the contents of the prescription required by Part 1306 must not be altered either following signature or during transmission, not by the prescriber, prescriber's staff, or intermediaries. (21 CFR § 1311.170(e).) The data may be converted to be readable in or by different softwares and so forth, but Part 1306 data may not be changed. (*Ibid.*)

Receipt and Processing of Prescription(s) by Pharmacies

The pharmacy application must be certified by the third-party auditor to, among other things: import, store, and display the information required for prescriptions; import, store, and display an indication of signing transmitted by the prescriber; import, store, and display the number of refills; and import, store, and verify the prescriber's digital signature, where applicable. (21 CFR § 1311.200(a)(1), (2), (3), (4).) The second and the fourth of these listed requirements are particularly important to a pharmacy's proper verification of transmitted prescriptions.

Namely, when a pharmacy receives a transmitted electronic prescription, it must either: (a) have been digitally signed by the last intermediary that sends the prescription record to the pharmacy, in which case the digitally signed record must be archived upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(b)(1)); (b) have been signed digitally using the prescriber's digital certificate, in which case the pharmacy application must verify the digital signature as provided in FIPS 186-3, check the validity of the digital certificate against the certificate revocation list of the issuing certificate authority (CA), and archive the digitally signed record as well as an indication that it was verified upon receipt (21 CFR § 1311.210(c)); or (c) be digitally signed (as per 21 CFR § 1311.205(b)(4)) and archived by the pharmacy upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(a)(2).) Pharmacists are (still) permitted to annotate an electronic prescription in the same way they would a paper prescription, except that the annotations must be made and retained electronically. (21 CFR § 1311.200(f).) The IFR also permits transfers between pharmacies of electronic prescription information for Schedule III-V controlled substances for refill(s) on a "one-time basis only," so long as the transfer is communicated directly between two licensed pharmacists, and appropriate notations are added to the prescription record at both the transferring and receiving pharmacy. Pharmacies that electronically share a real-time, online database may (also) transfer up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR § 1306.25(a), (b).)

When a pharmacist receives a paper or oral prescription that indicates that it was previously transmitted to that pharmacy electronically, the pharmacist must check the pharmacy's records to ensure that the electronic version of the prescription was not received and (already) dispensed. If both versions were received, the pharmacist must mark one as void. (21 CFR § 1311.200(g).) When a pharmacist receives a paper or oral prescription that indicates that it was previously electronically transmitted to a different pharmacy, the pharmacist must check with the other pharmacy to determine whether the prescription was (already) received and dispensed. If the electronic transmission version was already received and dispensed, the subsequent paper (or oral) prescription must be marked as void. If the electronic transmission version has not yet been dispensed, that version must be marked as void and the paper (or oral) prescription may be dispensed. (21 CFR § 1311.200(h).)

Archiving of Prescription(s) Recordkeeping by Prescribers and Pharmacies

As has been indicated above, the prescribing application is required to archive the prescription at the time that it is signed, and the pharmacy application is required to archive the prescription at the time it is received (so that the two archived versions can later be compared to ensure there has been no alteration of prescription contents required by Part 1306). (21 CFR §§ 1311.140(a)(6), 1311.145, 1311.205(b).) In addition to storing the data required by Part 1306 and by 21 CFR § 1311.205, pharmacy applications must be capable of sorting/retrieving controlled substance prescriptions by prescriber name, patient name, drug name, and date dispensed. (21 CFR § 1311.205(b)(11), (12).) The records must be secure, maintained electronically, backed up daily, and able to be read or downloaded into human-readable format. (21 CFR §§ 1311.205(b)(17), (18), 1311.305.)

The prescriber's electronic prescription application must generate a log of all controlled substance prescriptions issued by the prescriber during the previous calendar month and must provide that log to the prescriber no later than seven calendar days after month's end. (21 CFR § 1311.120(b)(27)(i).) In addition, the application must be capable of generating a log of all controlled substance prescriptions issued by the prescriber during a time period specified by the prescriber, upon request; it must be able to search back for at least the previous two years. (21 CFR § 1311.120(b)(27)(ii).) Any logs that are generated must be archived, human-readable, and sortable by patient name, drug name, and issuance date. (21 CFR § 1311.120(b)(27)(iii), (iv), (v).)

Audit Trails and Other Requirements

The regulations specify various events and incidents for which both prescriber and pharmacy applications must maintain an audit trail (i.e., a secure activity log that can be used to retrace those events/incidents). An "audit trail" is defined as "a record showing who has accessed an information technology application and what operations the user performed during a given period." (21 CFR § 1300.03.)

For prescribers, the application must track, among other things, the creation, alteration, indication of readiness for signing, signing, transmission, or deletion of an electronic controlled substance prescription, as well as any notification of a failed transmission. (21 CFR § 1311.120(b)(23).) For pharmacies, the application must track, among other things, all receipts, annotations, alterations, and deletions of controlled substance prescriptions. (21 CFR § 1311.205(b)(13)(i).) For both prescribers and pharmacies, the application(s) must track: the setting of, or changes to, access controls (21 CFR §§ 1311.120(b)(23)(ii), 1311.205(b)(13)(ii)); as well as other events that the application provider establishes as "auditable events," which are typically security incidents (21 CFR §§ 1311.120(b)(23)(iv), 1311.205(b)(13)(iii), 1311.150(a), 1311.215(a).)

In addition, both types of applications must conduct daily internal audits to determine whether any "auditable events" (security incidents) have occurred on that day. (21 CFR §§ 1311.150, 1311.215.) This may be an automated function that generates a report for the prescriber or pharmacist to review. If the prescriber or pharmacist reviewing the report determines that a security incident has in fact occurred, that incident must be reported to the application provider and to the DEA within one day. (21 CFR §§ 1311.150(c), 1311.215(c).)

Relationship Between DEA Regulation(s) and California Law

The IFR packet issued by the DEA contains the following statement: "This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws." (VII. Required Analyses, G. Executive Order 13132, Fed Reg. 16304.) The DEA has also been explicit in the FAQs on its website that "electronic prescriptions for controlled substances may be subject to state laws and regulations," and that "[i]f state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision." (Interim Final Rule with Request for Comment, Questions and Answers for Pharmacies [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm.) Thus, any conflicting state laws (e.g., about five states prohibit controlled substance electronic prescriptions altogether, and a further twenty or so do not permit electronic prescribing of Schedule II drugs) are apparently permitted to control. The IFR is also explicit that the two-year retention period prescribed by the IFR does not preempt any longer retention period required by state (or other federal) law or regulation. (21 CFR § 1311.205(b).)

As to this last point, because the requirement in California is that all records of manufacture, sale, acquisition, or disposition, and/or all prescription records, be maintained and kept available for inspection for three years (Bus. & Prof. Code, §§ 4081, 4333; Cal. Code Regs., tit. 16, § 1717), the three-year retention period applies. (See also Health & Saf. Code, §§ 11159, 11159.1 [seven year retention for chart orders].) California standards for transfers of electronic prescriptions between pharmacies also control. (Cal. Code Regs., tit. 16, § 1717.)

In general, however, California is one of the most "e-prescribing-friendly" states, and state law does not set up any obstacles to electronic prescribing of controlled substances (or dangerous drugs). California law (Bus. & Prof. Code, § 4040, Health & Saf. Code, § 11027) defines "prescription" to include "electronic transmission." And California requirements for electronic transmission of prescriptions (Cal. Code Regs., tit. 16, §1717.4) do not materially increase the burden for electronic prescribing over the DEA requirements.[5] California law even specifically permits electronically transmitted prescriptions to be stored only in electronic form (i.e., they do not have to be printed/reduced to writing) so long as that storage is tamper-proof. (Bus. & Prof. Code, §4070.)

[5] Under California law, an electronically transmitted prescription shall include, in addition to the name and address of the prescriber, a prescriber telephone number, the date of transmission, and the identity of the recipient. (Cal. Code Regs., tit. 16, § 1717.4(c), (d).)

Project Overview

California Board of Pharmacy

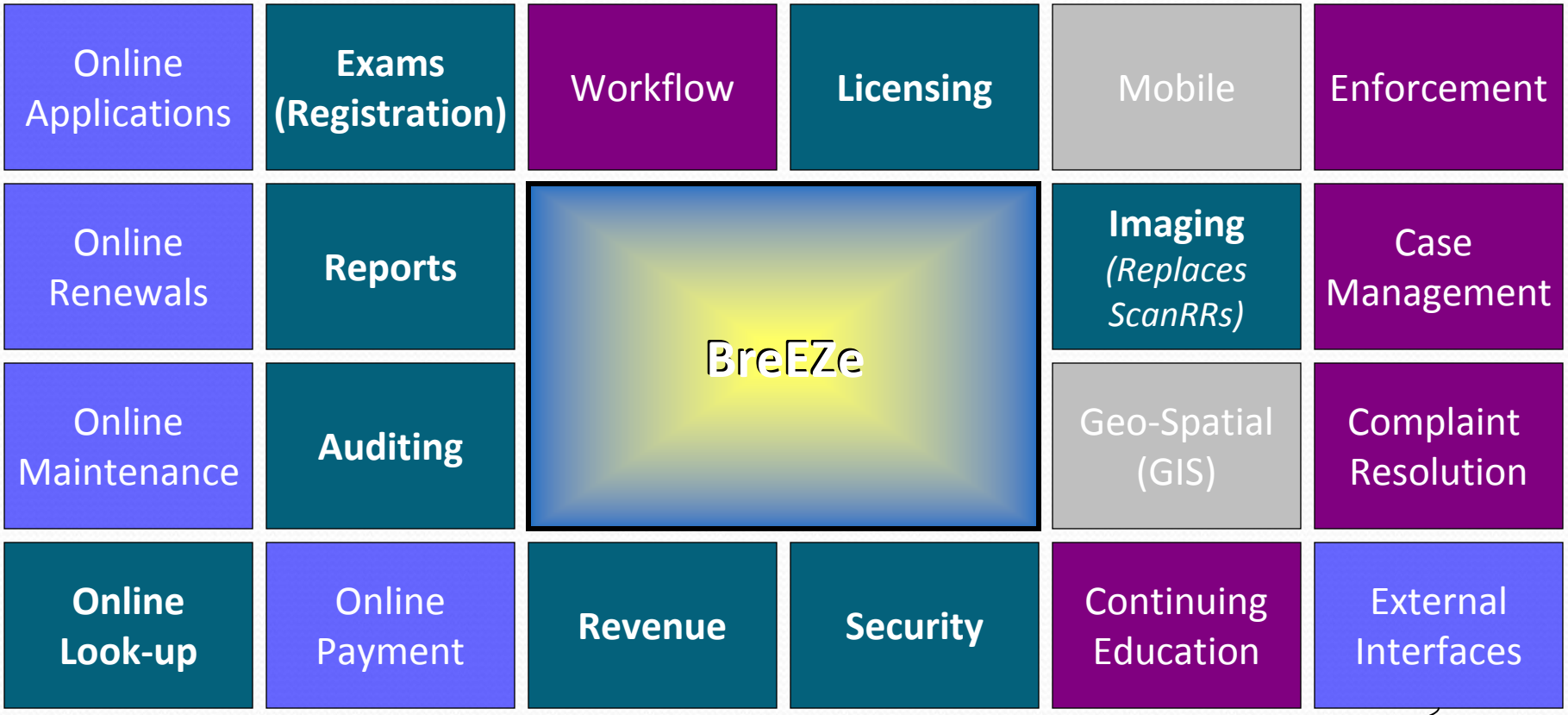
Today's Topics

- Brief Project Summary
- Project Concept & Benefits
- Transaction Fee
- Key Success Factors
- Project Leadership
- Recent Activities & Next Steps
- Tentative Implementation Schedule

Project Summary

- Integrated Licensing & Enforcement solution
- Completely replaces legacy licensing and enforcement systems (CAS, ATS, & Others)
- Replaces the iLicensing & CRIMS projects
- Incorporates document image storage

Project Concept

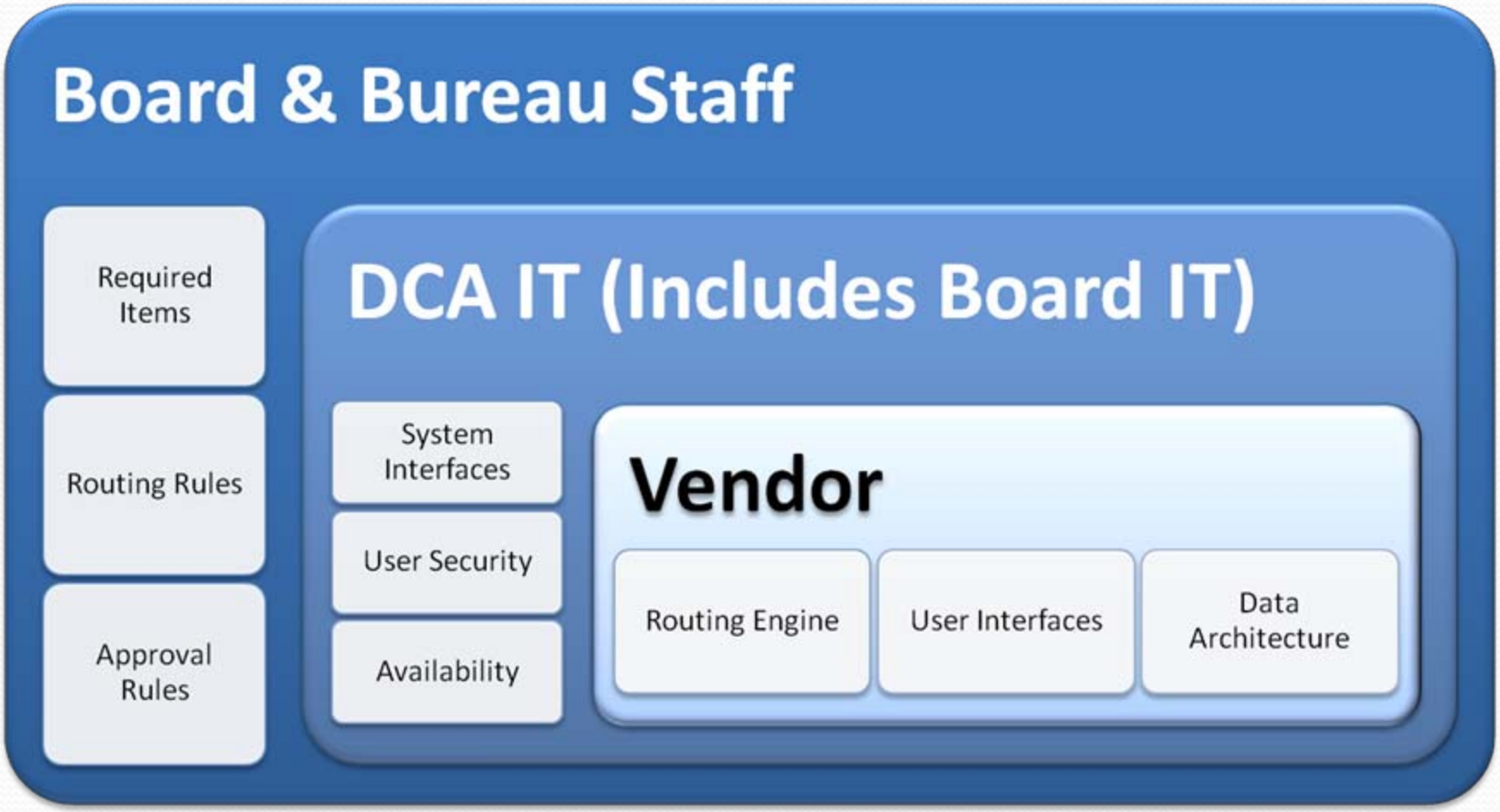


One System…..Many Boards

Question: How will one system work for 40+ unique entities?

Answer: Individual Board controlled configuration…

Conceptual Design



What's in it for Us?

- Customers
  - Self-Service and single point of entry
  - Electronic Applications and Renewals
  - Electronic Payments
  - Expedited processing
- Staff
  - Pre-screened applications
  - Automated routing
  - Single system with DCA-wide view

Transaction Fee

- Initial Vendor payment for software and Detail Design only
- After Deployment, transaction fee assessed to Board for new initial applications and renewals

Keys to Success

Procure solution with proven success

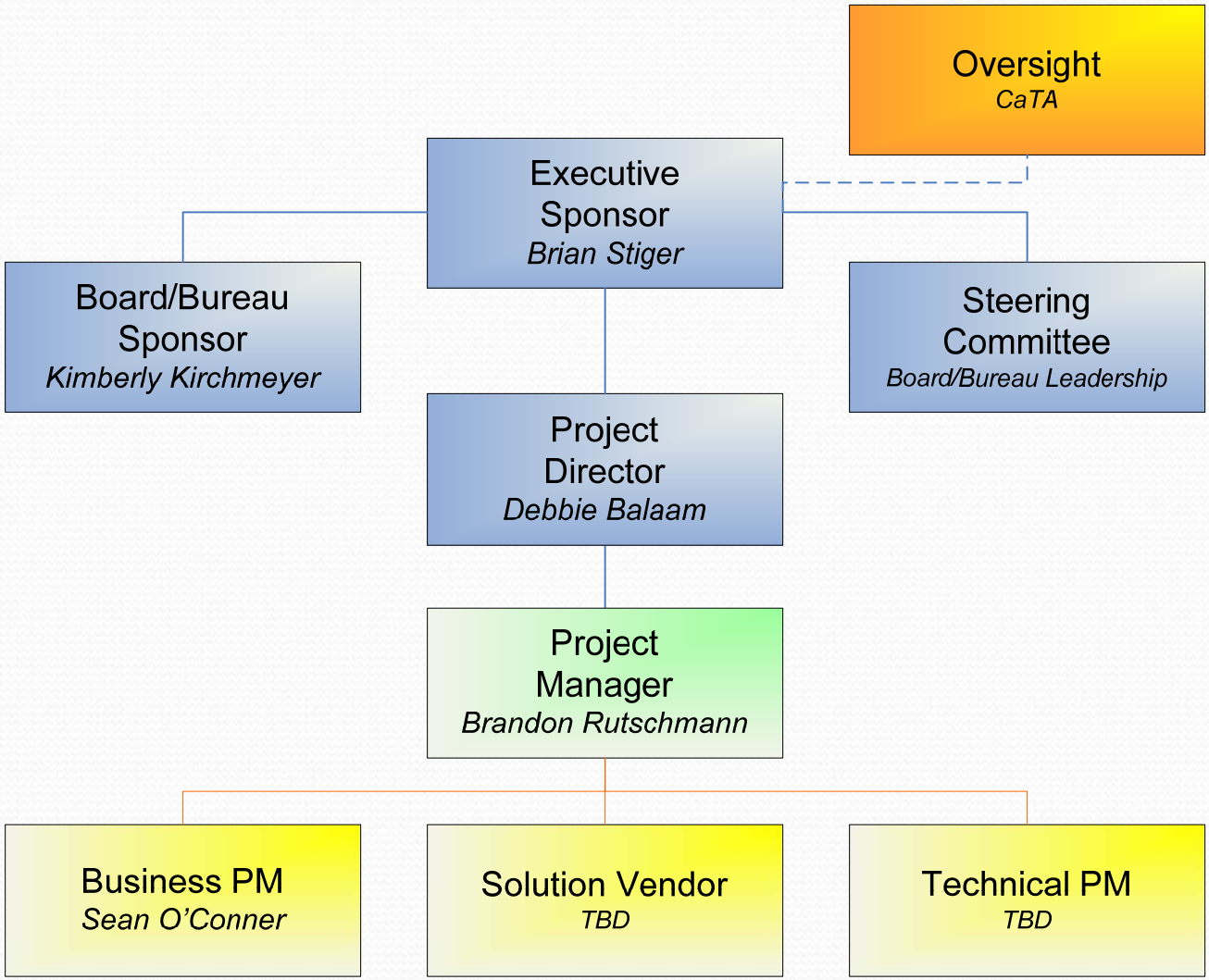
Joint review of business requirements

Active executive support

Active business ownership (Not IT driven)

Strong Project Leadership

Project Leadership



Business Activities To-Date

- Legislative Budget Committee approval
- Business project manager selected
- Data Conversion, Forms Consolidation, & Reports workgroups initiated
- On-going outreach and communication

Procurement Activities To-Date

- Initial Request For Proposal (RFP) released
- Pre-qualified bidders selected
  - Accenture & Verizon
- Working Sessions completed
- Final system requirements acceptance in process
- Final RFP released

Next Steps

- Continue business preparation activities
- Respond to final bidder questions
- Receive & evaluate final proposals
- Submit Special Project Report (SPR)
- Project approved to move forward

Implementation Schedule

Key Action (Activity)	Dates
First Phase Implementation (Healing Arts)	December 2012
Phase 2 Implementation (Healing Arts)	**March 2013**
Phase 3 Implementation (Healing Arts)	June 2013
Phase 4 Implementation (Business Svcs.)	October 2013
Phase 5 Implementation (Design/Construction)	February 2014