



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: May 1 - 2, 2012

LOCATION: Loma Linda University – Centennial Complex
Damazo Amphitheater
4760 Stewart Street
Loma Linda, CA 92354

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Anil Badlani, RPh
Ramón Castellblanch, Public Member, 5/1 only
Roselyn Hackworth, Public Member
Deborah Veale, RPh
Shirley Wheat, Public Member
Tappan Zee, Public Member

BOARD MEMBERS

NOT PRESENT: Ryan Brooks, Public Member
Greg Lippe, Public Member, Treasurer

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joan Coyne, Supervising Inspector, 5/2 only
Janice Dang, Supervising Inspector
Judi Nurse, Supervising Inspector, 5/2 only
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Jan Jamison, Public Information Officer
Tessa Miller, Staff Analyst

NOTE: The webcast for this meeting is available at:

http://www.dca.ca.gov/publications/multimedia/webcast_archive.shtml

I. CLOSED SESSION

Pursuant to Government Code Sections 11126(c)(3) and 11126(a)(1), the board convened in closed session to deliberate on disciplinary matters and to complete the evaluation of the performance of the board's executive officer.

OPEN SESSION

II. GENERAL ANNOUNCEMENTS

Billy Hughes, Dean of the School of Pharmacy at Loma Linda University, welcomed the board and those in attendance.

President Stan Weisser recognized former Board Members Stan Goldenberg, John Jones, and Darlene Fujimoto. President Weisser also recognized former president of the National Association of Boards of Pharmacy, Richard Palombo, and Department of Consumer Affairs Deputy Director, Board and Bureau Relations, Reichel Everhardt,

Executive Officer Virginia Herold introduced Board Inspectors Janice Dang, Robert Kazebee, Josh Lee and Katherine Sill who were in attendance in the audience.

President Stan Weisser called the open session to order at 10:52 a.m.

President Weisser conducted a roll call. Board Members Tappan Zee, Deborah Veale, Rosalyn Hackworth, Shirley Wheat, Anil Badlani, Randy Kajioka, and President Weisser were present.

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JANUARY 31-FEBRUARY 1, 2012

MOTION: Approve the minutes of the January 31-February 1, 2012 Board Meeting.

M/S: Hackworth/Veale

Support: 7 Oppose: 0 Abstain: 0

Board Member Ramón Castellblanch arrived at 10:54 a.m.

IV. SELECTION OF BOARD MEETING DATES FOR 2013

President Weisser reviewed the following rescheduled board meeting dates for 2012:

- July 17 and 18 – Sacramento

- October 25 and 26 – San Diego

The board reviewed proposed board meeting dates for 2013. The following dates were approved by the board:

- February 5 and 6
- April 24 and 25
- July 30 and 31
- October 29 & 30

These dates will be added to the board's Web site.

V. BOARD MEMBER OFFICER ELECTIONS

President

MOTION: Reelect Stan Weisser as president of the Board of Pharmacy.

M/S: Kajioka/Veale

Support: 8 Oppose: 0 Abstain: 0

Vice President

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

M/S: Zee/Hackworth

Support: 8 Oppose: 0 Abstain: 0

Treasurer

MOTION: Reelect Greg Lippe as treasurer of the Board of Pharmacy.

M/S: Zee/Hackworth

Support: 8 Oppose: 0 Abstain: 0

VI. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

VII. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

President Weisser and former board president Stan Goldenberg recognized Warren Newton from Temecula. President Weisser presented Dr. Newton with a 50-year pin. Dr. Newton graduated from USC and was licensed as a pharmacist in 1961. He owned three pharmacies during his career including Temple City Professional Pharmacy, Dow Rx, and Independent Rx L.T.C.

President Weisser recognized John Drum from Corona. President Weisser presented Mr. Drum with a 50-year pin. Mr. Drum graduated from Ohio State University and was licensed as a pharmacist in 1961. Mr. Drum owned D&R Drug and Drum Pharmacy. He shared that he has a son and daughter who are both registered pharmacists and a daughter who is a pharmacy technician.

VIII. DISCUSSION AND POSSIBLE ACTION TO ADOPT THE BOARD'S STRATEGIC PLAN FOR 2012-2017

Discussion

Ms. Herold discussed the process the board has undertaken to update its strategic plan, including soliciting comments from staff and the public. She referenced the new plan provided in the meeting materials and advised that board staff will work with Board President Weisser and Vice President Kajioka to develop an improved reporting method for the quarterly progress and performance report to be reviewed at the July 2012 Board Meeting.

Public Comment

Steve Gray, Kaiser Permanente, commented that the proposed plan is more general than in previous years. He discussed that the board established patient consultation as a priority during the development of the strategic plan and expressed concern that this item is not explicitly included.

MOTION: Approve the board's Strategic Plan for 2012-2017.

M/S: Veale/Hackworth

Support: 8 Oppose: 0 Abstain: 0

IX. LICENSING COMMITTEE REPORT

Report of the Meeting Held April 17, 2012

a. Discussion and Possible Action to Initiate a Rulemaking to Adopt Regulation Requirements to Specify Standards for Agencies that Accredite Licensed Sterile Injectable Compounding Pharmacies (Proposed as 16 California Code of Regulations Section 1751.9)

Relevant Statutes

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. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board

AND

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

Background

In 2003, the Licensing Committee developed general criteria for the evaluation of applications by accrediting entities for board approval. 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. Provided below are the general criteria the board initially established in 2003.

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.

Over the past few years the board has reviewed and approved several new accreditation agencies. During the course of its discussion and evaluation, the board has expressed some hesitation in the approval of accreditation agencies that do not incorporate the following items:

1. Make a pharmacist as a member of the survey team
2. Perform annual inspections
3. Share information with the board on findings
4. Ensure conformance with California's requirements for LSCs

Regulation language is necessary to facilitate implementation of this process. During the last board meeting, members were advised that the committee continues to discuss the proposal and suggested several changes to the proposed language.

Discussion

Ms. Herold provided background on the issue and reviewed the regulation language that has been drafted to establish standards for accreditation agencies.

Ms. Herold provided that the committee discussed the revised language at its last meeting. She stated that counsel advised the committee members of the need for additional amendments to fully define the appeal process in the event an accreditation agency is denied by the board.

Assistant Executive Officer Anne Sodergren reviewed two areas for discussion by the board. First, she explained that the regulation in its current draft specifies that the board will approve all initial requests for approval. She discussed that this presents a challenge from a due process standpoint in that if the board denies a request, the board cannot resolve or vote on an appeal.

Ms. Sodergren reviewed a staff recommendation to delegate to staff the consideration of such requests, similar to the processing of an application for licensure. She stated that this will allow the board to consider the appeal of any denial.

Ms. Sodergren also asked for the board's consideration as the regulation in its current draft does not specify the process for rescinding an approval and the appeal of such an action.

Ms. Sodergren reviewed a staff recommendation to establish a process that allows board staff to rescind an approval and allow the board or a subcommittee of the board to rule on an appeal submitted in response to such action by board staff.

Ms. Sodergren referenced the two versions of the proposed regulation language provided in the meeting materials. She indicated that Option 1 includes language that would incorporate the staff recommendations. Ms. Sodergren stated that should the board not agree with the recommendation, Option 2 does not incorporate those recommendations.

DCA Staff Counsel Kristy Shellans highlighted the differences between the two versions of the language provided in subdivision c. She stated that Option 1 is consistent with the Administrative Procedure Act guidelines for appeals.

Ms. Veale shared with the board why the committee recommended the basis for the board approving the accreditation agency and spoke in support of Option 2. She indicated that the committee believed that the board needs to have control over the approvals at this point and can consider delegating approval to staff in the future.

Ms. Shellans shared that the board's current process for approval of accreditation agencies has been necessary as there were no standards in this area. She stated that the regulation establishes clear standards for staff to use when considering approval requests. Ms. Shellans explained that this would eliminate the need for the board to consider each case.

No public comment was provided.

MOTION: Licensing Committee: Initiate a formal rulemaking process with the proposed text in Option 2 to add Section 1751.9 to Division 17 of Title 16 of the California Code of Regulations.

Support: 8 Oppose: 0 Abstain: 0

b. Discussion and Possible Action to Initiate Regulation Changes Reviewed by the Licensing Committee

Relevant Statutes

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

Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology
- Biochemistry
- Physiology

- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Background

For some months at meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, substance abuse or in maintaining control of a pharmacy's drug inventory. Any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

During the October 2011 Board Meeting, the board directed the committee to continue its discussion about such a requirement and specified that if the recommendation is approved, to authorize staff to investigate implementation.

1. Discussion and Possible Action to Initiate a Rulemaking to Amend Regulations That Specify Continuing Education Credit for Pharmacists in Specific Content Areas, Amendment to Title 16 California Code of Regulations Section 1732.5

Background

For nearly only one year in meetings of this committee and of the board, there has been discussion about requiring continuing education in certain topics. At the February 2012 Board Meeting, the board determined to proceed with a rulemaking to require six of the 30 units required for pharmacist license renewal every two years to be in:

- Emergency/disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse

Committee Recommendation

Recommend to the board initiation of the rulemaking CCR 1732.5 as amended.

Discussion

Ms. Herold reviewed the following proposed language as recommended by the committee:

1732.5. Renewal Requirements for Pharmacists.

a. Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

b. Effective July 1, 2013, at least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response,
2. Patient Consultation,
3. Maintaining Control of a Pharmacy's Drug Inventory,
4. Ethics,
5. Substance Abuse.

Pharmacists renewing their licenses which expire on or after July 1, 2015 shall be subject to the requirements of this subdivision.

c. All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Ms. Shellans indicated that the committee voted to strike reference to July 1, 2013 in the proposed language to clarify that compliance is required on or after July 1, 2015. (This change is not reflected in the language above.) She stated that the committee also amended that language to replace "drug" with "substance."

Public Comment

Steve Gray, Kaiser Permanente, provided that the proposal does not follow the CE models used by other professions. He stated that he does not believe the proposal will accomplish what the board has intended. Dr. Gray offered an amendment to require a minimum of one hour of CE in each of the identified areas for a total of six hours.

MOTION: Initiate a formal rulemaking process to amend Section 1732.5 of Article 44 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1732.5. Renewal Requirements for Pharmacists.

a. Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

b. Effective July 1, 2013, At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response,
2. Patient Consultation,
3. Maintaining Control of a Pharmacy's Drug Inventory,
4. Ethics,
5. Substance Abuse.

Pharmacists renewing their licenses which expire on or after July 1, 2015 shall be subject to the requirements of this subdivision.

c. All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

M/S: Veale/Hackworth

Support: 8 Oppose: 0 Abstain: 0

2. Discussion and Possible Action to Pursue Regulations to Amend Provisions for the Award of Continuing Education at Title 16 California Code of Regulations, Section 1732.2

Discussion

Ms. Herold provided that at the February 2012 Board Meeting, the board reviewed a pending regulation change that would have awarded six units of continuing education per renewal period to a pharmacist or pharmacy technician who attends a full day of a board meeting, and two units of continuing education per renewal period to a pharmacist or pharmacy technician who attends a committee meeting. She advised that during this meeting, the board withdrew its proposed amendment to CCR 1732.2 as it wished to modify the CE to be awarded for such attendance. (The rulemaking was at that time undergoing review by the Office of Administrative Law, the final step in the regulation adoption process.)

Ms. Herold referenced the amended language provided in the meeting materials which incorporates this modification and recommendations by the committee.

No public comment was provided.

MOTION: Initiate a formal rulemaking process to amend 16 California Code of Regulations section 1732.2 as indicated.

1732.2 Board Accredited Continuing Education Courses

- a. Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.
- b. Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.
- c. A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and

Professions Code may annually be awarded up to six hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

- (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.
- (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.
- (f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

M/S: Veale/Wheat

Support: 8 Oppose: 0 Abstain: 0

3. Discussion and Possible Action to Pursue Changes to Update a Reference to Accreditation Agencies for Continuing Education, Amendment to Title 16 California Code of Regulations Section 1732.05

Discussion

Ms. Herold provided that the board received a request from the California Pharmacists Association requesting a modification to CCR section 1732.05 to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

No public comment was provided.

MOTION: Initiate a formal rulemaking process to amend 16 California Code of Regulations section 1732.05 as proposed.

1732.05. Accreditation Agencies for Continuing Education.

- (a) The following organizations are approved as accreditation agencies:
 - (1) The Accreditation Council for Pharmacy Education.
 - (2) ~~The Pharmacy Foundation of California.~~ The California Pharmacists Association.
- (b) Accreditation agencies shall:
 - (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
 - (2) Maintain a list of the name and address of person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
 - (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
 - (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
 - (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
 - (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board; and
 - (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.
- (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

M/S: Veale/Hackworth

Support: 8 Oppose: 0 Abstain: 0

c. Discussion and Possible Action to Sponsor a Statutory Provision to Authorize the Board to Issue a Public Reprimand for Violations That Would Not Warrant License Denial or Issuance of a Probationary License

Discussion

Ms. Sodergren provided that before issuing a license, the board does a background review of all applicants for licensure. She stated that sometimes the information gained from these background reviews shows serious violations in an applicant's past. In such cases, when the matters are substantially related to the duties of the license, the board denies the license or may issue a probationary license. Ms. Sodergren advised that currently, these are the only two options open to the board when making a licensing decision about an application.

Ms. Sodergren provided that when making a licensing decision, board staff recognizes that some violations, while serious, are not sufficient or are so old that the board would have difficulty in denying the license or issuing a probationary license based on the violation.

Ms. Sodergren provided that the Medical Board has a provision in its statutes that provides another alternative – issuance of the license, but with a public reproof. She stated that the committee discussed this issue and reviewed proposed statutory language that could be used to facilitate implementation of a similar provision.

Ms. Sodergren advised that the public reprimand would constitute discipline and would remain on the licensee's record for three years. She stated that the public reprimand would be disclosed to the public and posted on the board's Web site.

Ms. Sodergren provided that board staff and counsel modified the language after the committee's meeting to provide a more structured statutory framework. A copy of this modified language is provided in the meeting materials.

Ms. Shellans provided comment on the legal effect of the proposed provision. She explained that a letter of reprimand would be issued concurrently with a license and would be purged three years from the date of issuance if no other action (e.g., letter of admonishment, citation, notice of correction, disciplinary action, etc.) is initiated by the board against the license during the three-year period. Ms. Shellans discussed that the reprimand can be used as a factor for any unprofessional conduct during the three-year period.

Ms. Veale provided that the committee spoke in support of the proposal as an additional option for the board and as an extra level of consumer protection.

President Weisser discussed that this option would allow the board to document a licensee's history regarding an event that may have happened many years ago when considering disciplinary action for misconduct during the first three years of licensure.

Dr. Kajioka spoke in support of the proposal and encouraged the board to continue to set high standards for its licensees.

The board discussed whether a longer time period would be appropriate for maintaining a public letter of reprimand on record. It was the consensus of the board to maintain the three-year period as proposed.

Public Comment

Steve Gray, Kaiser Permanente, asked whether the letter of public reprimand would be reported to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB).

Ms. Sodergren indicated that it would be reported.

MOTION: Sponsor a statutory provision to authorize the board to issue a public reprimand for violations that would not warrant license denial or issuance of a probationary license.

M/S: Veale/Hackworth

Support: 8 Oppose: 0 Abstain: 0

d. Evaluation of the Impact of Changes Incorporated on the Pharmacy Technician Application Form

Report

Ms. Sodergren provided that amendments to California Code of Regulations section 1793.5 and changes to the pharmacy technician application took effect on October 1, 2011. She stated that the revised application more clearly specifies the requirements for licensure as well as the information necessary to confirm compliance. In addition, changes were made to reduce the likelihood of applicants providing false information to the board. Ms. Sodergren explained that the revised application now requires an applicant to submit an official high school transcript or GED test scores as well as a sealed original Self-Query Report from the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB).

Ms. Sodergren provided that since implementation, the number of deficient applications the board receives is reducing each month. She stated that in October 2011, 79 percent of applications received were deficient compared to February 2012 where 49 percent of the applications were deficient. Ms. Sodergren provided that it is expected that application deficiencies will continue to decrease as board staff continue to provide outreach efforts to pharmacy technician training programs. She advised that receiving complete applications allows the board to process applications and issue licenses to qualified applicants more quickly.

There was no board discussion or public comment.

e. Review of the Education and Experience Requirements for Pharmacist Licensure in California and Other US States

Report

Ms. Sodergren provided that over the past several years the committee and board have discussed the requirements for pharmacist licensure, especially in the area of intern hour experience. She highlighted the following comparison of California requirements with several other states.

Examination

All states require pharmacist examination applicants to pass the North American Pharmacist Licensure Examination (NAPLEX) and all but seven states require the Multistate Pharmacy Jurisprudence Examination (MPJE). California is one of the seven that does not require the MPJE as it has its own California Practice Standards and Jurisprudence Examination for pharmacists (CPJE).

Education

Although states vary in the method by which they confirm education, all states require similar education requirements for domestic graduates including graduation from a school of pharmacy by the Accreditation Council for Pharmacy Education (ACPE).

Experience

One area where states vary is in the number of intern hours experience as well as the method by which such experience is verified. The majority of the states require a minimum of 1,500 hours of practice experience. Some state accept hours in conjunction with academic credit and some states accept hours earned and verified by another state board of pharmacy.

Ms. Sodergren provided that the committee discussed the comparison of licensure requirements as well as the intern requirements. She advised that the board is pursuing a statutory change to allow the board to accept intern hours earned in another state for purposes of licensure in California.

There was no discussion or public comment.

f. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)
Ms. Sodergren provided that the committee was advised that board instituted a quality assurance review of the CPJE effective April 2, 2012. She stated that this process is done periodically to ensure the reliability of the examination. Ms. Sodergren advised that the quality assurance review is still underway. She indicated that based on historical patterns, the board anticipates results being released before August 2012.

Examination Development

Ms. Sodergren provided that the Competency Committee workgroup will continue to meet in the spring of 2012 for examination development.

There was no board discussion or public comment.

g. Licensing Statistics

President Weisser referenced the licensing statistics for the second quarter of 2011/12 provided in the meeting materials.

h. Meeting Minutes of the Meeting Held April 17, 2012

President Weisser referenced the meeting minutes provided in the meeting materials.

i. Third Quarterly Report on the Committee's Goals for 2011/12

President Weisser referenced the third quarterly report on the Licensing Committee's goals provided in the meeting materials.

The board recessed for a lunch break at 11:53 a.m. and reconvened at 1:37 p.m.

X. BOARD DISCUSSION AND POSSIBLE ACTION ON PROPOSED REGULATIONS

a. Regulation Hearing to Amend Title 16 California Code of Regulations Sections 1735.1, 1735.2, 1735.3 and 1751.2, Related to Compounding Drug Products

President Weisser called the regulation hearing to order at 1:37 p.m.

Oral Testimony

Steve Gray, California Society of Health-System Pharmacists (CSHP), thanked the board for its efforts to address the issues raised by the hospital pharmacists during the rulemaking process. He highlighted written comments submitted to the board and stated that, in general, CHSP supports all of the regulation changes as proposed with the exception of the proposal to add the expiration date of each component in the compounded drug product. Dr. Gray discussed that this requirement will not improve patient safety, and if implemented, will add to the cost of healthcare.

Dr. Gray recommended that the language specify that sterile injectable drugs must be stored in accordance with United States Pharmacopeia Standards, and adding the following words after standards: **“for redispensed CSPs in Chapter 797.”**

Katy Marconi, Director of Pharmacy and Clinical Quality, Doctors Hospital of Manteca, expressed concern regarding the direction and the progression of the rulemaking. Dr. Marconi reviewed her written comments submitted to the board and stated that she does not support addressing compounding globally. She recommended that sterile to sterile compounding be conducted according to USP 797 and stated that the new requirements should only pertain to non-sterile to sterile compounding. Dr. Marconi discussed that the recall process should be separated from issues regarding the compounding process. She also discussed that the proposed requirements regarding expiration dates are not economical. Dr. Marconi encouraged the board to address these concerns and to focus on promoting quality product.

Kent Martyn, Director of Pharmacy Services, CVMC, provided comment on “reasonable quantity” and stated that a distinction is needed regarding the judgments that are made in a hospital setting versus a prescriber’s intent in this area. He discussed that the 72-hour supply requirement conflicts with the requirement that the “beyond use date” of the compounded drug product shall not exceed 180 days from preparation. Dr. Martyn stated that the requirements will have a significant financial impact on labor and the cost of materials.

President Weisser closed the regulation hearing at 1:50 p.m.

b. Review and Discussion of Comments for Noticed Rulemaking to Amend Title 16 California Code of Regulations Sections 1735.1, 1735.2, 1735.3 and 1751.2, Related to Compounding Drug Products

Ms. Shellans requested direction from the board regarding whether to accept or reject the written comments that were submitted to the board during the 45-day comment period.

Carolyn Klein, Legislation and Regulation Manager, provided an overview of the comments that were submitted. She advised that comments that discuss compounding

in general or that discuss sections of compounding regulations that are not part of the rulemaking do not need to be considered as part of this rulemaking.

Ms. Shellans provided that comments that are outside the scope of the regulation can be rejected or the rulemaking can be modified and renoticed to incorporate such comments for a 45-day comment period.

Ms. Shellans recommended that the board consider a suggestion by Steve Gray, Kaiser Permanente, to amend the current modified text in Section 1735.3(a) to specify references within USP 797 related to “Redispensed CSPs.” She stated that the appropriate reference will need to be confirmed. Ms. Shellans advised that this modification will require a 15-day comment period.

Ms. Shellans responded to a question by Ms. Veale and indicated that the board will need to update the regulation if the USP reference is revised.

Ms. Veale sought clarification regarding the addition of the expiration dating requirements in the modified text.

Dr. Kajioka discussed that the regulation applies to both community and hospital settings. He stated that the board continues to find expired products on pharmacy shelves and indicated that the committee supports this addition as an additional check to ensure that expired products are not being used.

Joshua Room, Deputy Attorney General, shared that he has seen enforcement cases where drugs were compounded using expired products. He also suggested that the board request that staff confirm the appropriate USP reference if the board votes to incorporate it in the language.

Ms. Herold provided that the lot number alone does not provide information regarding the expiration date.

The board discussed a comment in support of an alternate label that can be used for cytotoxic agents. Consideration was given to the information listed on labels that are currently in use (i.e. “Cytotoxic Product – Dispose of Properly”).

Mr. Room advised that the label can simply state “Cytotoxic – Dispose of Properly.” He stated that specifying “product” or “agent” is not necessary but would be acceptable.

It was the consensus of the board to remove the word “product” from the language. All other comments received by the board were rejected and not incorporated into the language.

Mr. Zee left the meeting room at 2:10 p.m.

c. Board Discussion and Possible Action to Adopt Title 16 California Code of Regulations Sections 1735.1, 1735.2, 1735.3 and 1751.2, Related to Compounding Drug Products

MOTION: Direct staff to take all steps necessary to amend Section 1735.3(a)(6) to refer to the appropriate section of the United States Pharmacopeia Standards as confirmed by staff, and amend 1751.2(d) of the proposed language to read as follows:

(d) All cytotoxic agents shall bear a special label which states “Chemotherapy - Dispose of Properly-” or “Cytotoxic Product – Dispose of Properly.”

Authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide the modified language for a 15-day public comment period. If no negative comments are received during the public comment period, 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 and adopt the regulations at Title 16 Sections 1735.1, 1735.2, 1735.3 and 1751.2 – as well as the Self-Assessment Form incorporated by reference at Section 1735.3 as described in the minutes.

M/S: Castellblanch/Hackworth
Support: 7 Oppose: 0 Abstain: 0

XI. LEGISLATION AND REGULATION COMMITTEE REPORT

Summary of the Meeting Held April 24, 2012

PART I – REGULATIONS

a. Board Approved – Undergoing Review by the Administration

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)
[45-day comment period: May 6-June 20, 2011]

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) [45-day comment period: May 6-June 20, 2011]

Report

Ms. Wheat provided an update on the status of the proposed changes to Sections 1727.2 and 1728. She stated that on May 6, 2011, the board initiated a rulemaking to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728. The proposal would require a Pharmacist Intern applicant to submit with his or her application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDBHIPDB). This proposal would also require an applicant seeking board authority to take the pharmacist licensure examination to submit with his or her application a Self-Query Report from the NPDB-HIPDB.

Ms. Wheat stated that board staff has been advised that the DCA and the State and Consumer Services Agency have completed their review. She advised that the file has been at the Department of Finance awaiting review/approval since January 9, 2012, but as of April 25, 2012, the Department of Finance had not completed its review. Ms. Wheat indicated that once all administrative approvals are received, the board will file the rulemaking with the Office of Administrative Law for final approval.

Ms. Wheat provided that the one-year notice period for this rulemaking will expire on May 5, 2012, unless extended by the director of the Department of Consumer Affairs.

Ms. Herold advised the board that staff will request that the department request a 90-day extension to allow for the Department of Finance's approval.

There was no board discussion or public comment.

b. Discussion and Possible Action – Board Approved Regulations Recently Noticed

1. Proposed Amendments to Title 16 California Code of Regulations Section 1760 – Board of Pharmacy Disciplinary Guidelines, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008) [45-day comment period: October 24 –November 28, 2011]

Relevant Sections

California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The

committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (Business and Professions Code sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking such discipline.

Background

Last year the board directed staff to a restructuring and updating of its Disciplinary Guidelines last year. Subsequent to this, in April 2011, the SACC finalized the uniform standards required in B&PC section 315. Many of these standards need to be incorporated into the guidelines to facilitate implementation.

During the July 2011 board meeting, staff was directed to incorporate the uniform standards into the disciplinary guidelines for consideration by the board at a future meeting. Most recently, during the September 2011 board meeting, the board voted to initiate a rulemaking to amend Section 1760 and the Disciplinary Guidelines that are incorporated by reference in this section.

On October 14, 2012, the board released the rulemaking, initiating the 45-day comment period on the proposed changes. The board held a regulation hearing during the January 2012 board meeting.

Report

Ms. Wheat provided that during the January 2012 board meeting, the board discussed the proposed change and the comments received in response to the rulemaking consistent with the administrative procedures process established in the government code. She stated that at the conclusion of this discussion the board voted to make several changes to the proposed language and requested that the proposed changes be brought back to the board prior to staff releasing the changes as part of a 15-day comment. Specifically the board requested the following changes.

- Modify term 24 of the proposed amendments to the Disciplinary Guidelines to strike the testing frequency and replace with more general language consistent with the board's discussion and to strike the section regarding specimen collectors.
- Modify term 30 to strike all language regarding the minimum requirements for facilitators or evaluators within the proposed language.

Ms. Wheat provided that prior to staff preparing the changes for consideration, staff received correspondence from the DCA legal office regarding SB 1441 implementation.

Discussion

Ms. Shellans provided background on the issue and the varying opinions regarding whether or not the board had discretion on the implementation of the standards. She stated that the department sought advice from the Government Law Section of the Attorney General's Office and Senator Price also requested a legal opinion from the Legislative Counsel Bureau. Ms. Shellans stated that based on these opinions, the department's memorandum clarifies that the board has no discretion on how to implement the standards.

Ms. Shellans provided that the board has two options in this area. First, the board can move forward with the changes it made at the January 2012 board meeting. She cautioned that this option will most likely result in a rejection of the rulemaking package. Ms. Shellans stated that the second option is to rescind the current rulemaking package and develop a new proposal that is consistent with the department's memo.

Ms. Shellans stated that the two areas where the board has discretion are: (1) whether the Uniform Standards should be placed in a regulation separate from the Disciplinary Guidelines; and (2) if the regulation should include a definition of (or criteria by which to determine) what constitutes a "substance-abusing licensee."

Ms. Shellans recommended that the board rescind its current rulemaking package. She offered to develop language regarding what constitutes a "substance-abusing licensee" for review by the board at a future meeting. She also recommended that standards be implemented as part of a separate regulation and not as part of the board's Disciplinary Guidelines.

Mr. Room provided that the board also has the option to request a formal opinion from the Attorney General's Office or to litigate this issue.

Ms. Shellans indicated that seeking a formal opinion may help the board decide what course of action to take. She stated that if the opinion from the Attorney General's Office is consistent with the other opinions, the board will have something to rely upon for purpose of litigation.

President Weisser sought clarification on the implementation for these options.

Ms. Shellans indicated that it may be most prudent for the board to pursue the changes as recommended by the department while also seeking a legal opinion.

Dr. Castellblanch asked why the board would not request a formal opinion by the AG's office and was advised that such an opinion could take as long as two years to receive. He commented that the board should make the political decision in this area.

Ms. Herold provided comment in support of the board pursuing modifications to the Disciplinary Guidelines while also seeking an opinion from the Attorney General's Office.

She recommended that the board rescind the rulemaking rather than letting it expire.

Mr. Room offered to help Ms. Herold draft a letter to request an opinion from the Attorney General's Office.

The board discussed work on this issue can be referred back to the committee for final review and approval by the board.

No public comment was provided.

MOTION: Rescind the current rulemaking and request that counsel craft language that would place the Uniform Standards outside of the Disciplinary Guidelines, propose updates to the guidelines, and develop language regarding what constitutes a "substance-abusing licensee." Direct the executive officer to send a formal request to the AG's Office for a formal opinion regarding the implementation of the Uniform Standards.

M/S: Hackworth/Veale

Support: 7 Oppose: 0 Abstain: 1

2. Proposed Amendments to Title 16, Section 1746 -- Emergency Contraception Protocol
Review and Discussion of Comments Submitted During 45-day Comment Period
[45-day comment period: January 6 – February 20, 2012]

Background

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, as specified; and (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified.

The current state protocol was developed by the Medical Board in 2004 and was adopted by the Board of Pharmacy that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication. The protocol also has a typographical error that requires correction (mcg instead of mg).

In October 2011, the board voted to initiate a proposed rulemaking to update the board's Emergency Contraception Protocol at Title 16 Section 1746, to reflect the language and protocol approved by the Medical Board of California in July 2011.

The board noticed the proposed regulation on January 6, 2012, and the 45-day public comment period concluded on February 20, 2012. The board received one comment during that period.

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee.

Discussion

Ms. Wheat provided an overview of this item.

Ms. Herold highlighted the comment received during the 45-day public comment period. She introduced women's health specialist designated by the California Pharmacists Association, Kathleen Hill-Besinque, to respond to the comment.

Dr. Besinque recommended that the board not make any changes to the protocol as suggested in the written comment. She stated that the proposed protocol is consistent with medical guidelines for the use of emergency contraception. Dr. Besinque discussed that the protocol is intended to be used as a guidance to be implemented by pharmacists who have received specialized training in this area.

Dr. Castellblanch questioned Dr. Besinque's background and was advised that she is a faculty member at the University of Southern California School of Pharmacy, an author and lecturer on emergency contraception and women's health, and serves on the Board of Directors for the Association of Reproductive Health Professionals.

Ms. Shellans recommended that the board reject the comment if the board does not want to make changes to the proposal. She advised that the Medical Board will also have to reject this comment before the board can finalize the rulemaking process.

No public comment was provided.

MOTION: Reject the comment submitted during the 45-day comment period.

M/S: Wheat/Veale

Support: 7 Oppose: 0 Abstain: 1

MOTION: If the Medical Board of California agrees to reject the comment submitted during the 45-day comment period, direct staff to take all steps necessary to finalize the rulemaking package and authorize the executive office to make any non-substantive changes to the rulemaking package before adopting the regulation to amend section

1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations as noticed.

M/S: Wheat/Veale

Support: 8 Oppose: 0 Abstain: 0

c. Discussion and Possible Action – Board Approved Regulations Recently Noticed

1. Proposed Amendments to Section 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]

Background

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

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

Report

Ms. Wheat 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.

President Weisser encouraged that the board begin work in this area soon.

There was no board discussion or public comment.

2. Proposed Amendments to Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

Background

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

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

Discussion

Ms. Wheat provided that the Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. She stated that staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

Mr. Badlani sought clarification regarding this program.

Ms. Herold stated that the board issues Veterinary Food-Animal Drug Retailer licenses to wholesalers that dispense veterinary drugs for food-processing animals pursuant to a prescription from a licensed veterinarian. This specialized wholesaler is permitted to label drugs -- in accordance with prescribed directions -- for animals that will produce or become food.

No public comment was provided.

3. Proposed Addition of Section 1762 – Additional Grounds for Unprofessional Conduct

Report

Ms. Wheat provided that in October 2010, the board began discussions to add 16 CCR § 1762 to implement components of the DCA's Consumer Protection Enforcement Initiative relative to unprofessional conduct. She stated that in February 2011 the board addressed draft language and moved to initiate the rulemaking process to amend Section 1762 to 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 authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Ms. Wheat provided that board staff is working to prepare a rulemaking package for a 45-day public comment period.

There was no board discussion or public comment.

4. Proposed Addition of Section 1769 – Addition of Application Review to Criteria for Rehabilitation.

Report

Ms. Wheat provided that the Protection Enforcement Initiative with regarding to 16 CCR § 1769 – a proposal that would authorize the board to request that an applicant for licensure undergo an examination, as specified, to determine if the applicant is safe to practice. She stated that the board directed that staff initiate the rulemaking process to amend 16 CCR § 1769, specifying that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

Ms. Wheat provided that staff is working to prepare a rulemaking package for a 45-day public comment period.

There was no board discussion or public comment.

5. Proposed Amendments to Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions

Report

Ms. Wheat provided that at the October 2010 Board Meeting, the board voted to initiate a rulemaking to amend Section 1745(c)(2) to allow pharmacies to maintain electronic records or document on the original prescription when partially filling a Schedule II controlled substance. The reviewed that following language approved by the board:

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

Ms. Wheat provided that staff is working to prepare a rulemaking package for a 45-day public comment period.

There was no board discussion or public comment.

6. Proposed Amendments to Section 1751.2 and 1751.9 – Sterile Injectable Compounding, Sterile Injectable Labeling Requirements, and Accreditation Agencies

Background

The board voted to amend Section 1751.2 related to the labeling of cytotoxic agents at its Board Meeting held January 31, 2012. The proposed amendments were included in the board's noticed rulemaking to also amend Title 16 Sections 1735.1, 1735.2, and 1735.3.

The board's proposal related to Section 1751.9 requirements for accreditation agencies, was referred to the Licensing Committee, and will be brought back to the board for future consideration.

Report

Ms. Wheat provided that this item was discussed under Agenda Item X.

There was no board discussion or public comment.

7. Proposed Amendments to Section 1732.2 – Board Accredited Continuing Education

Background

At the board meeting held January 31, 2012, the board considered amendments to the board's continuing education regulation. At that time, a rulemaking to amend Section 1732.2 related to continuing education was pending final review at the Office of Administrative Law. The board voted to withdraw from OAL its rulemaking to amend Title 16 of the California Code of Regulations Section 1732.2 and refer the matter to the Licensing Committee for further review.

Report

Ms. Wheat provided that this item was discussed under Agenda Item IX(b).

There was no board discussion or public comment.

The board recessed for a break at 3:03 p.m. and resumed at 3:20 p.m.

PART II – LEGISLATION

a. Board-Sponsored Legislation for 2012

Ms. Wheat provided a summary of each of the following measures and reviewed recommendations from the committee.

Board votes on the committee recommendations are provided below.

1. SB 1575 (Senate Committee on Business, Professions and Economic Development, Price, Chair)

Last Amended: April 16, 2012

Location: Senate Appropriations

Status: No hearing set as of 4/24/12

Each year the Senate Committee on Business, Professions and Economic Development sponsors omnibus measures.

SB 1575 contains two omnibus proposals sponsored by the board:

- Section 4209 of the Business and Professions Code would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants. This language was approved by the board in October 2011.
- Section 4300.1 of the Business and Professions Code would ensure the board can put discipline on record even if the license is cancelled. This language was approved by the board in January 2012

In addition, SB 1575 contains a department-sponsored proposal to add Section 144.5 to the Business and Professions Code to authorize a board to request – and require a local or state agency to provide – certified records, such as arrests, convictions, and other documents required to complete an applicant or licensee investigation.

The bill was introduced on March 12, 2012, containing multiple omnibus provisions for various boards, bureaus and entities and, on April 16, was amended to include the boards sponsored provisions. The bill passed out of the Senate Business, Professions and Economic Development on consent on April 23, and was referred to Senate Appropriations.

COMMITTEE RECOMMENDATION: Support

MOTION: Legislation and Regulation Committee: Establish a position of Support on SB 1575.

Support: 8 Oppose: 0 Abstain: 0

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

Sunset Review and Legislative Oversight

1. SB 1237 (Price) – Sunset Extension to 2017

Last Amended: April 16, 2012
Location: Senate Appropriations

Summary: In November 2011, the Board provided its "Sunset Review Report 2011" to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board's public website. The board last underwent sunset review in 2002. Board President Stan Weisser and Executive Officer Giny Herold testified before the Senate Committee on Business, Professions and Economic Development on March 19, 2012, and responded to the committee's questions and comments.

The committee passed the measure (on consent) on April 23, 2012, and the bill was referred to Appropriations.

COMMITTEE RECOMMENDATION: Affirm Board Support

There was no board discussion or public comment.

MOTION: Legislation and Regulation Committee: Affirm the board's position of Support on SB 1237.

Support: 8 Oppose: 0 Abstain: 0

Regulation of Dangerous Drugs and Devices

2. SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program

Last Amend: March 29, 2012 (Introduced Feb. 23, 2012)
Location: SEN Com. on Business, Professions and Economic Development
Hearing: May 7, 2012 in SEN BP&ED

Summary: Under current law a county may establish a repository and distribution program under which a pharmacy may distribute donated/surplus medications to medically indigent persons. Currently, skilled nursing facilities, manufacturers, and pharmacy wholesalers may donate medications to a program. Those who donate medications to these programs are not subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program. SB 1329 would expand repository and drug distribution programs by allowing a county health officer to establish a program, and would expand the pool of defined entities that can donate drugs to the program. SB 1329 would also allow donated drugs to be transferred from one program to another. The bill would require certain information to be reported to the county, and would allow the board to request this information. The bill specifies entities, including the Board of Pharmacy, that may prohibit a pharmacy or clinic from participating in a program, as specified.

Senator Simitian addressed the Legislation and Regulation Committee on April 24, 2012, and asked for the board's support of this legislation. He stated that SB 1329 is designed to make these programs more effective, and allow more people to donate drugs. Senator Simitian said he shares the board's concern to maintain the integrity of the drug supply chain, and that he would be happy to work with the board to address its concerns.

COMMITTEE RECOMMENDATION: Support if Amended

There was no board discussion or public comment.

MOTION: Legislation and Regulation Committee: Establish a position of Support if Amended on SB 1329.

Support: 8 Oppose: 0 Abstain: 0

3. SB 419 (Simitian) Solid Waste: Home Generated Sharps

Introduced: February 16, 2011

Location: In ASM. Ordered to Inactive File on Request of Assembly Member Allen (1/9/12)

Summary: Existing law permits hospitals and other entities to accept for disposal home-generated sharps. Currently a pharmaceutical manufacturer that sells or distributes a medication in California that is self-injected, as specified, is required to submit to the Department of Resource Recovery and Recycling a plan that describes what actions, if any, the manufacturer supports for the safe management of sharps. This bill would require that the manufacturers provide their reports to DRRR electronically and also make them readily accessible on the manufacturers' websites.

Ms. Wheat provided that the committee did not take a position on this measure.

There was no board discussion or public comment.

4. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply

Last Amend: April 16, 2012

Location: Senate Appropriations

Status: On April 23, the bill passed out of the SEN Committee on Business Professions and Economic Development.
Do-pass to Appropriations (Fiscal: yes)

This measure would specify conditions under which a pharmacist may dispense a 90-day supply of a dangerous drug, as specified, without first receiving authorization from the prescriber. The board's regulation at 16 CCR 1716 precludes a pharmacist from deviating from the requirements of a prescription, except as specified.

COMMITTEE RECOMMENDATION: Support

Discussion

The board expressed concern that this provision may lack consideration for the patient's desire and ability to pay for a 90-day supply.

Dr. Kajjoka provided comment on mail order pharmacy incentives for 3-month supplies that can be used for consumers to maximize their benefit. He discussed that physicians often write a prescription for a 30-day supply to monitor utilization of medication and to allow for physician oversight.

Mr. Veale stated that under current practice, a prescriber is not consulted until all refills are depleted. She indicated that she does not believe that this provision would present a problem for physicians.

Ms. Shellans indicated that this provision could be in conflict with current pharmacy law that requires prescriber authorization for refills. She stated that additional clarification in this area may be needed.

Mr. Room indicated that if this provision were to be implemented, the board would need to amend Section 1716 to specify the circumstances under which a prescription can be refilled.

Ms. Herold stated that the committee discussed a possible amendment to the provision to require the patient's consent before a 90-day supply can be dispensed.

Public Comment

Mary Staples, National Association of Chain Drug Stores (NACDS), stated that NACDS is the sponsor of the bill. She advised the board that the intent is to improve patient adherence to medications and to give patients the option to request a 90-day supply if authorized by the prescriber for maintenance medications. Ms. Staples stated that other states have implemented similar provisions.

Ms. Veale cautioned the board from over-regulating in this area.

John Jones, Optum Rx, discussed that decisions in this area should be made based on the professional judgment of the pharmacist in concert with discussion with the patient on how best to meet their needs. He also cautioned the board from over-regulating in this area.

Mr. Jones advised that there are not consistent rules for non-resident pharmacies. He stated that the member's benefit plan dictates what can be dispensed and takes the place of the interaction between the pharmacist and the patient. Mr. Jones discussed that prescribers are often not receptive to calls from pharmacists in this situation. He encouraged the board to support the ability of pharmacists to exercise their professional judgment.

Mr. Jones provided that Optum Rx has a neutral position on this bill. He did note that physicians often question why the pharmacist is calling to confirm a 90-day supply.

Steve Gray, Kaiser Permanente, advised that a newer version of the bill is available and now does not apply to psychotropic drugs. He spoke in support of the bill and stated that it does not try to overrule or interfere with any drug benefit plan. Dr. Gray discussed that this bill addresses the problem of proper adherence to medication therapy and the issue of automatic refills.

Dr. Kajjoka sought clarification on enforcement of this proposal.

Mr. Room indicated that the board would not be able to take enforcement action against a licensee for deviating from a prescription for this purpose of dispensing a 90-day supply if ordered on the prescription as future refills. He stated that in this case, the statute would override the prohibition on deviation from a prescription under Section 1716. He stated that Section 1716 can be modified to provide clarity to the profession.

MOTION: Legislation and Regulation Committee: Establish a position of Support on SB 1301.

Support: 7 Oppose: 0 Abstain: 1

5. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Board Position: Oppose (*Ver. Jan. 17, 2012*)
Last Amend: January 17, 2012
Location: Senate Third Reading File (*4/26/12*)

Summary: AB 389 seeks to establish standards for service for providers of blood clotting products for home use by imposing specified requirements on providers of blood clotting products for home use. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. The January 17, 2012, version of the bill removed references to home nursing services, one source of the board's opposition. The board reaffirmed its position of oppose at the January 2012 board meeting.

Ms. Wheat provided that this measure has not changed since the board last reaffirmed a position of Oppose at the January 2012 Board Meeting.

There was no board discussion or public comment.

6. AB 1442 (Wieckowski) Common Carriers to Transport Pharmaceutical Waste

Last Amend: March 27, 2012
Location: In Assembly. Referred to Appropriations Suspense File
(4/18/12)

Summary: AB 1442 amends the Medical Waste Management Act (under the jurisdiction of the CDPH) to define “pharmaceutical waste” and “common carrier”; to provide a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The measure excludes from the definition of “pharmaceutical waste” drugs that must be returned via a reverse distributor pursuant to section 4040.5 of the Business and Professions Code. As amended, supplies of dangerous drugs would be able to be transported by common carriers.

The Legislation and Regulation Committee discussed the bill at its recent meeting and discussed the need for controls in the movement of the drugs that are picked up and shipped.

COMMITTEE RECOMMENDATION: Oppose Unless Amended

MOTION: Legislation and Regulation Committee: Establish a position of Oppose Unless Amended on AB 1442.

Support: 8 Oppose: 0 Abstain: 0

7. AB 2369 (Valadao) Prisoners: Pharmacy Services

Introduced: February 24, 2012
Location: ASM Business, Professions and Consumer Protection
Status: Hearing set for April 24, 2012

Summary: Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for facilities under the jurisdiction of the DCR that is cost effective and efficient, and that may incorporate a requirement for the use of generic medications, when available, with certain exceptions. AB 2369 would *require* the use of generic medications, when available, with certain exceptions. AB 2369 does not seek to modify existing Pharmacy Law.

AB 2369 was heard in the Assembly Committee on Business, Professions and Consumer Protection on April 17th and failed passage. Reconsideration was granted, and the bill is again set for hearing for April 24, 2012.

Ms. Wheat provided that the committee did not recommend a position on this measure.

There was no board discussion or public comment.

8. AB 2348 (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics

Last Amend: March 29, 2012 (Introduced on 2/24/12)
Location: ASM Rules
Status: Passed out of ASM Business and Professions and was referred to ASM Rules

Summary: The Nursing Practice Act authorizes a registered nurse to provide drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse- midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

The committee discussed AB 2348 but did not recommend a position on the measure. Staff is awaiting a response from the Board of Registered Nursing and will provide any updated information during the meeting.

COMMITTEE RECOMMENDATION: Watch

Discussion

Ms. Shellans indicated that this bill is a scope of practice issue. She requested clarification to ensure that the registered nurse is not acting as a dispenser and that the dispensing is being done directly to a patient according to the appropriate procedures.

Ms. Sodergren stated that staff contacted the Board of Registered Nursing which indicated that a RN's education and training may not apply to how to dispense and consult a patient on a specific medication. She stated there is a requirement that a RN be deemed clinically appropriate to perform services in this area.

Dr. Kajioka expressed concern with the measure and stated that it lacks appropriate controls.

Public Comment

Steve Gray, Kaiser Permanente, discussed that this dispensing would be done in licensed clinics regulated by the board and would be subject to oversight by a consulting pharmacist. He discussed that the intent of the bill is to make oral contraception more available.

Dr. Gray expressed concern that there is no reference to the labeling and dispensing requirements that would hopefully be covered by standardized procedures. He encouraged the board to support the bill if amended to include reference to the labeling and dispensing requirements and to permit a nurse to dispense on an order by a prescribing pharmacist under Section 4052.2.

MOTION: Legislation and Regulation Committee: Establish a position of Watch on AB 2348.

Support: 8 Oppose: 0 Abstain: 0

Licensing and Pharmacy Operations

9. SB 1095 (Rubio) Pharmacy: Surgical Clinics

Introduced: February 16, 2012
Location: Senate Appropriations (Fiscal: yes)
Status: Set for Hearing April 30, 2012

Summary: SB 1095 would expand the definition of a clinic in Section 4190 to include not only surgical clinics licensed by the CDPH under H&SC Section 1204, but also to accredited outpatient settings and to Medicare certified ambulatory surgical centers, as specified. SB 1095 would provide that board licensure is optional, and that the board is authorized to inspect only those clinics which are licensed by the board. A clinic licensed by the board would be able to comingle the drug stock of the clinic and would authorize the clinic to purchase drugs at wholesale.

The committee discussed SB 1095 at its meeting held April 24, 2012. It was the consensus of the committee that staff would work with the author on a solution for issues of concern, because the policy behind the bill has been supported by the board in the past.

COMMITTEE RECOMMENDATION: Support if Amended

Discussion

Ms. Shellans expressed concern regarding the committee's recommendation. She also expressed concern that under the measure, clinics are exempt from all regulatory oversight by the board or by the California Department of Public

Health. Ms. Shellans recommended that the board establish a position of Oppose Unless Amended to ensure that the board's concerns are addressed. She stated that the board can change to a position of Support if the board's amendments are accepted.

Dr. Castellblanch spoke in support of Ms. Shellan's recommendation.

Public Comment

Bryce Docherty, Amubulatory Surgery Association, provided that Health and Safety Code section 1204 stipulates that it is an option for a surgical clinic to be licensed. He recommended that the board take a Support if Amended position if the board wishes to have regulatory oversight over more clinics and cautioned that an Oppose Unless Amended position may negatively impact the bill.

Ms. Herold clarified the board's concerns with the drafting of the bill and the amendment to Section 4190 to strike the requirement that a surgical clinic be licensed by the board.

MOTION: Legislation and Regulation Committee: Establish a position of Support if Amended on SB 1095.

Support: 3 Oppose: 4 Abstain: 1

MOTION: Establish a position of Oppose Unless Amended on SB 1095.

M/S: Castellblanch/Hackworth

Support: 4 Oppose: 2 Abstain: 2

10. SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies

Introduced: February 24, 2012
Location: Senate Appropriations (Fiscal: yes)

Summary: This bill would exempt from clinical laboratory licensing requirements and regulations, specified tests performed by a pharmacist in a community pharmacy. These are the same tests that pharmacists are currently authorized to perform pursuant to Section 4052.4 in specified clinic settings. Tests deemed CLIA waived are those tests approved by the FDA as over-the-counter tests. Proponents believe this measure will result in greater access to safe, simple and economic tests that will play a crucial role in improving drug therapy, and improve patient health.

The committee spoke in support of the measure.

COMMITTEE RECOMMENDATION: Support

There was no board discussion or public comment.

MOTION: Legislation and Regulation Committee: Establish a position of Support if Amended on SB 1481.

Support: 8 Oppose: 0 Abstain: 0

11. AB 377 (Solorio) Hospital Central Fill Pharmacies

Last Amend: April 14, 2011
Board Position: Support if Amended (Ver. 4/14/11)
Location: Senate Appropriations
Status: No hearing date set as of 4/16/12

Summary: AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment, and staff has been advised that the bill will be moving forward in 2012.

The committee noted that the measure has not changed since the board established its position in April 2011. During the meeting the committee was advised by the sponsor that amendments will be made that should address the board's concern.

COMMITTEE RECOMMENDATION: No Change

There was no board discussion or public comment.

12. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners

Last Amend: March 27, 2012
Location: Assembly Third Reading File (4/26/12)

Summary: This measure seeks to codify into state law existing federal law (the Patient Protection and Affordable Care Act). This bill would specify that a healthcare professional employed by a tribal health program is exempt from state licensure if that health professional holds a license from another state. The committee did not recommend a position on this bill.

COMMITTEE RECOMMEDATION: No Position

There was no board discussion or public comment.

13. AB 1904 (Block) Military Spouses: Temporary License

Introduced: February 22, 2012
Location: Assembly Appropriations Suspense File

Summary: This measure would permit the board to issue a temporary permit to an applicant that submits an application, fees, and fingerprints and satisfies specified requirements including proof of licensure in good standing in another state with similar requirements. It would require the board to expedite the processing for the purpose of issuing a temporary license, would specify the term that a temporary license would be valid, and authorize the board to promulgate regulations to implement the provisions. Staff anticipates that this may impact two primary license types: Pharmacist, and Pharmacy Technician.

The committee spoke in support of the measure, noting that the bill would require that a new license type be established, and that the board may need to specify in regulation how these licenses would be handled.

COMMITTEE RECOMMENDATION: Support

Discussion

Ms. Shellans discussed some concerns with the bill and areas where clarification is needed. She indicated that the bill requires that the applicant hold a current license in another state. Ms. Shellans suggested a change to this requirement to specify that the applicant must hold a current, active, and unrestricted license.

Ms. Shellans advised that subdivision (a)(4) would require that the board verify whether or not the applicant has committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the code at the time the act was committed. She stated that bill does not

address what happens to the temporary license after the permitted 180-days as well as if the board would have the authority to discipline the temporary license.

Ms. Shellans advised that these concerns cannot be clarified by regulation. She recommended that the board establish a position of Support if Amended to address these concerns. She stated that the board could also choose to draft a letter to the bill's author to express these concerns.

Ms. Veale discussed that the committee did have similar concerns but felt it was important to support the bill. She spoke in support of drafting a letter to the bill's author as suggested by Ms. Shellans.

It was the consensus of the board to instruct staff to send a letter to the bill's author as suggested.

No public comment was provided.

MOTION: Legislation and Regulation Committee: Establish a position of Support on AB 1904.

Support: 8 Oppose: 0 Abstain: 0

Other

14. SB 1185 (Price) Centralized Intelligence Partnership Act

Last Amend: April 9, 2012

Location: Referred to Senate Appropriations Committee

Summary: This bill would create a Centralized Intelligence Partnership ("partnership") consisting of various agencies, including the Department of Consumer Affairs, that would be charged with combating the underground economy, and would specify the general scope of the committee's process. This bill would allow information to be shared between committee participants and would provide that shared information would retain its confidential status as authorized by law.

The committee noted that the bill was scheduled for hearing in Senate Committee on Governmental Organizations on April 24, and determined that staff will bring back to the committee or the board issues that may need to be addressed. The committee did not recommend a position on this measure.

Discussion

Ms. Shellans expressed concern with some of the provisions of the bill. She stated that it may require that the board refer cases on unlicensed activity to the partnership for investigations. Ms. Shellans advised that the bill does not provide details on the foundation and funding for the partnership.

Ms. Sodergren provided that staff has spoken with the board's sponsor. She stated that the bill is not intended to require all investigations initiated by the board to be evaluated and investigated through the partnership. Ms. Sodergren indicated that the partnership will be developing guidelines on the types of investigations that will be under its purview. She stated that the board can conduct its own investigation on cases that have been referred to the partnership. Ms. Sodergren advised the board that there will most likely be a fiscal impact to the board.

No public comment was provided.

15. SB 1195 (Price) Pharmacy Benefits: Audits

Last Amend: March 26, 2012
Location: Senate Committee on Health
Status: Do Pass from Senate Health. Re-referred to Senate Rules

Summary: SB 1195 would follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers (PBMs). Pharmacy benefit managers are currently not regulated. Although the board does not have jurisdiction over the auditing of claims for reimbursement, board staff receives complaints on a somewhat routine basis from licensees complaining about the perceived unjust auditing practice of an auditing company receiving payment based on the number of claims rejected. This proposal would appear to address this issue.

The committee did not recommend a position on SB 1195, noting that the bill addresses issues between pharmacies and payors – which is not an area in which the board exercises jurisdiction.

No position taken by the committee.

There was no board discussion or public comment.

16. SB 1250 (Alquist) Medical Records: Confidentiality

Introduced: February 23, 2012

Location: Senate Judiciary Committee hearing scheduled for May 8, 2012

Summary: The Confidentiality of Medical Information Act specifies the confidentiality of information maintained in medical records by health care providers, health coverage plans, pharmaceutical companies and others. Section 56.35 of the Civil Code also provides for monetary penalties for individuals and entities that violate the act. This bill would specify that in addition to other legal remedies, a defendant may be required to pay for credit monitoring and reporting services for one year from the unauthorized release of medical information.

The committee did not recommend a position on this measure.

There was no board discussion or public comment.

17. AB 2342 (Torres) Controlled Substances

Staff has been advised that AB 2342 in its current form will not be moving forward this year. No analysis was provided, and the committee did not make a recommendation on this measure.

There was no board discussion or public comment.

18. AB 1733 (Logue) Telehealth

Last Amend: April 16, 2012

Location: Assembly Committee on Health

Status: Hearing Scheduled April 24, 2012

Summary: AB 1733 impacts the coverage of telehealth benefits for health care service plans and programs. This bill would specify that the mandated in-person contact prohibition would also apply to health care service plan contracts with the Department of Health Care Services for services provided by the Medi-Cal program, other publicly supported programs, as well as to organizations implementing the California Program of All-Inclusive Care for the Elderly (PACE).

The committee did not make a recommendation on this measure.

There was no board discussion or public comment.

Additional Legislation Impacting the Board or its Regulatory Jurisdiction

19. AB 2570 (Hill) Licensees: Settlement Agreements

Introduced: February 24, 2012
Location: Assembly Committee on Business Professions and Consumer Protection
Status: Hearing set for April 24, 2012

Summary: This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board.

The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

Discussion

Ms. Shellans expressed concern that this bill would prohibit the board from ordering restitution to a consumer. She recommended that the board establish a position of Oppose Unless Amended.

Mr. Room spoke in support of the gag clause provision and indicated that there may be some difficulties with the second portion of the provisions regarding restitution.

No public comment was provided.

MOTION: Establish a position of Oppose Unless Amended on AB 2570.

M/S: Veale/Hackworth

Support: 7 Oppose: 0 Abstain: 1

PART III – LEGISLATION AND REGULATION COMMITTEE

Ms. Wheat referenced the third quarterly report on the committee's goals provided in the meeting materials.

RECESS FOR DAY

The board meeting was recessed at 4:43 p.m.

Wednesday, May 2, 2012

XII. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the board convened in closed session to deliberate on disciplinary matters.

Open Session

President Weisser called the open session to order on Wednesday, May 2, 2012 at 9:20 a.m. Board Members Zee, Veale, Hackworth, Wheat, Badlani, Kajioka, and Weisser were present.

President Weisser recognized Jim Pinder and thanked the staff at Loma Linda University for their accommodations for this meeting.

President Weisser recognized Executive Director Linda Whitney and Assistant Executive Director Kim Kirchmeyer from the Medical Board of California.

Ms. Herold recognized Board Inspector Robert Venegas for his 50 years of service as a California pharmacist and 18 years as an inspector for the board. Ms. Herold and President Weisser presented Dr. Venegas with a pin and a copy of his original picture from his licensing file.

Dr. Venegas shared that he graduated from the University of Southern California in 1962. He worked as an independent pharmacist before working as an inspector for the board.

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee this past quarter.

President Weisser referenced the following information regarding the board's organizational information provided in the meeting materials.

There was no board discussion or public comment.

a. Budget Update/Report

1. Budget Report for 2011/12

The budget year began July 1, 2011 and will end June 30, 2012. The governor's budget for this FY included \$14.4M spending authorization for our board. Projections for this fiscal year indicate that the board will again need to redirect from other budget line items to address the underfunding in the Attorney General line item. This will be the third consecutive year that the board has significantly overspent on this budget item. Such spending is necessary and consistent with the board's consumer protection mandate and underscores the board's significant efforts to discipline errant licensees.

During the first 9 months of the fiscal year the board has collected almost \$10.5M in revenue and expended almost \$9.5M. The board's largest expenditures thus far are personnel services (57 percent) and enforcement costs (16 percent).

2. Fund Condition Report

According to a fund condition report prepared by the department (Attachment 1), the board will have the following fund conditions at the end of the identified fiscal years:

2010/11*	\$13,678,000	11.5 months in reserve
2011/12	\$11,484,000	9.1 months in reserve
2012/13	\$8,423,000	6.6 months in reserve
2013/14	\$5,053,000	3.9 months in reserve

3. Governor's Proposed Budget for 2012/13

Every January, as part of the budget process, the Governor releases the budget for the upcoming fiscal year. This year the Governor released his proposed budget on January 5, 2012. Included in this budget was \$15.289,000 in authorized spending for the board, a slight increase from the board's current year authorization. The Governor will release a revised proposed budget in mid May.

4. Update on BreEZe, DCA's Plans for a New Computer System

As the board has previously been advised, for a number of years, the department has worked to replace and/or enhance its legacy licensing and enforcement tracking systems used by most DCA agencies that were developed in the 1980s. A few years ago, the department initiated an "I-Licensing" project which would have offered online application and renewal of licenses (a much needed relief from mail-in renewals).

Nearly two years ago, DCA's proposed Consumer Protection Enforcement Initiative also sought computer system upgrades with a new proposal for a department-wide computer system called BreEZe. Once in place the new system would allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. BreEZe will piggyback on the efforts of the initial I-Licensing system and will ultimately allow for improved services for applicants and licensees as well as provide for a more robust internal computer system.

This new system is vital to the board's operations as the current system limitations significantly impede our ability to perform efficiently. Based on the current timeline for implementation, the board will be in the second phase of programs transitioning to the new system. As such, the board is now less than 2 years away from changing to this new system.

Recent Update

We continue to commit a significant amount of resources to this project to ensure the board's operational needs are met. The executive officer continues to serve as an executive sponsor of this project and serve on a change control board, part of the established governance plan for this project. Two board staff are working part-time for this project, assisting the department in documenting system requirements that meet the needs of our board as well as others throughout the project. As we had previously reported, identified board staff has started attending configuration meetings for board's slated for implementation in this first phase of role out. This participation allows staff to better understand the functionality of the new system as well as advocate for some system requirements that all programs may benefit. Further as the implementation date approaches additional staff will be redirected to ensure the necessary transition plans and data clean-up are in place to mitigate problems during the transition.

5. Reimbursement to Board Members

Expenses and per diem payments claimed by board members during the indicated periods are provided in the meeting materials. Board members are paid for each day of a board meeting, but in accordance with board policy, may also submit hours for work performed doing additional board business.

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

Since July 2005, the board has acknowledged 1,189 pharmacists with 50 or more years of licensure as pharmacists in California. There were 14 pharmacists who reached this milestone between February and April 2012. When a pharmacist reaches this milestone, the board sends a certificate and an invitation to attend a future board meeting for public recognition.

c. Personnel Update

1. Board Member Vacancies

The board has 10 sitting board members, and three board member vacancies. The vacant positions are Governor appointments and are for professional members.

2. Staff Changes

As reported last quarter, in early November 2011 the board was advised the Operation Efficiency Plan was approved by the Department of Finance. This approval relieved the board of the state hiring freeze. Since that time we have been aggressively recruiting to fill vacant positions. Below are changes in our staff roster:

New Staff

- Lisa Chullino started with the board as an Association Governmental Program Analyst (AGPA) responsible for managing administrative cases pending at the AG's Office.
- Jan Jamison joined the board as a Public Information Officer.
- Christina Metzen accepted a position as an Associate Governmental Program Analyst responsible for issuing citations and fines.
- The board hired two student assistants, Kaitlyn Rainey and Monica Ramos. Both student are providing assistance to licensing unit staff.

Transfers and Promotions

- Chee Vang transferred to a new position within the board, processing pharmacy technician applications.
- Todd Clinton transferred to a new position and is now processing applications for the pharmacist exam as well as applications for initial licensure as a pharmacist.
- Dani Adamson was promoted to a staff services analyst primarily responsible for processing wholesale, nonresident wholesale and designated representative applications.
- Jenna Weddle was promoted to an Associate Governmental Program Analyst in the criminal conviction unit.
- Sue Durst was promoted to an Associate Information Systems Analyst position.

Departures

- Linda Kapovich retired from state service.
- Eleonor Steiner accepted a position with the Dental Hygiene Committee.
- Kim Brown accepted a position with the California State Library.

The board currently has a total of 15 positions vacant. The breakdown is as follows:

- 13 Supervising inspector and inspector positions
- 1 Office technician receptionist

- 1 Office technician position providing data entry support to various licensing unit staff as well as support to the receptionist positions

d. Third Quarterly Report on the Committee's Goals for 2011/12

President Weisser referenced the second quarterly report on the Organizational Development Committee's goals provided in the meeting materials.

XIV. ENFORCEMENT COMMITTEE REPORT

Discussion of the Meeting Held March 21, 2012

NOTE: Agenda items were taken out of order.

Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

a. Discussion about the Presence of Counterfeit Avastin in California Physician Offices

Background

In January, the FDA notified the board and the Medical Board of California about the identification of counterfeit Avastin discovered in California. Avastin is a cancer-treatment medication that is typically administered to patients (rather than dispensed to them) and high priced. The counterfeit Avastin contained no active ingredient.

The counterfeit drugs have been traced from a Tennessee wholesaler who sold the product to 19 physician offices through the US; 16 of these physician offices are located in California.

Presentation

Ms. Herold provided a presentation on the counterfeit Avastin incident that recently occurred. A copy of this presentation is attached, following this meeting summary.

Ms. Herold compared examples of counterfeit and brand medication and demonstrated the challenges involved in identifying suspect medication.

Mr. Room discussed that the board only sees a portion of the counterfeit incidents each year as many more adulterated products are never detected.

No public comment was provided.

b. Discussion on Presentations Made During the Committee Meeting

Dr. Kajioka reviewed the following presentations given during the Enforcement Committee Meeting.

1. Summary of a Presentation Made to the Committee by the Pharmaceutical Distribution Security Alliance on a Proposed Federal Model

The PDSA is a coalition of various members of the pharmaceutical distribution chain: manufacturers, wholesalers and pharmacies. This proposal would call for a different, and less extensive tracking model for prescription medication for the US than those required by California's e-pedigree model. If enacted, these requirements would preempt California's requirements.

The PDSA proposal would require manufacturers to add a serialized number to each saleable unit of medication produced; however, this number would NOT be required to be used by wholesalers or pharmacies. Instead the lot number, which can apply to hundreds of thousands of saleable units of medication, would be tracked by wholesalers. Pharmacies would be exempt from reading or tracking any information about the drug product they purchase or dispense. The proposal also would establish federal requirements for licensure and the operations of wholesalers that would preempt all other state laws regarding wholesalers. The proposal would push back full implementation of these and other requirements until mid 2020. And because the proposal would prohibit aggregation from being a requirement of the federal drug distribution system, serialized tracking of each saleable unit of medication – as required by California – would not be achieved.

Discussion

Dr. Kajioka reviewed the presentation provided to the committee and discussed several of the concerns the committee had with the proposed provisions and indicated that it is not as robust as the solution currently in California law.

Dr. Veale indicated that she does not believe that the proposed solution is sufficient and will not provide adequate tracking of the product.

The board discussed the proposal with respect to barcode requirements and identification of counterfeit product. Mr. Room advised that the proposal would not require a comprehensive chain of custody document and would prohibit the FDA from requiring aggregation.

No public comment was provided.

2. Summary of the Presentation Made by Connie Jung, RPh, PhD, Acting Associate Director for Policy and Communications, US Food and Drug Administration

During the Enforcement Committee Meeting, Dr. Jung provided information on the FDA's proposal for pharmaceutical supply chain safety. This proposal calls for a track and trace model with serialization at the unit level, a model very similar to California's requirements.

Dr. Jung provided information about the growing number of counterfeit drug cases the FDA has opened in the last few years. She provided specific details about what components are needed in a tracking system to protect the US drug supply, how some of the data sharing and storage could be accomplished, what type of tracking numbers are needed, and the role of each entity in the manufacturing and distribution of prescription drugs.

Discussion

Dr. Kajioka highlighted Dr. Jung's presentation.

Mr. Room provided comment on the FADAA Act and the development of track and trace guidelines.

Ms. Herold provided that in 2008, the FDA had open cases in California.

No public comment was provided.

3. Summary of a Presentation by Kimberly Fleming, Senior Manager, Product Security, EMD Serono, Inc.

Ms. Fleming provided an overview of EMD Serono and the company's efforts to combat diversion and counterfeiting of their products in the US and worldwide. This is first manufacturer to describe publicly the details and challenges of serializing their product lines for California's requirements.

Ms. Fleming described the need for product security that can be assured with components that include track and trace, authentication, specialized packaging, collaboration and communication. She shared that.

Discussion

Dr. Kajioka provided an overview of Ms. Fleming's presentation.

Mr. Room stated that, as discussed by Ms. Fleming, EMD Serono has serialized several of its product lines, and will be ready to meet California's deadlines for e-pedigree requirements.

Ms. Herold provided that Ms. Fleming shared that one of EMD Serono's products had been counterfeited and provided to patients within four months of market introduction.

No public comment was provided.

4. Robert Celeste, Director, Healthcare, GS1 US

During the committee meeting, Mr. Celeste provided an overview on GS1 and efforts to implement global standards to improve the safety, efficiency and visibility of supply chains globally and across countries.

Mr. Celeste discussed the use of the global trade identification number (GTIN) and other standards worldwide. He

Discussion

Dr. Kajioka stated that Mr. Celeste announced that GS1 will be releasing an implementation guideline for applying GS1 standards to U.S. pharmaceutical supply chain business processes on its Web site tentatively in April 2012.

No public comment was provided.

5. Gabrielle Cosel, PEW Charitable Trust

Ms. Cosel reviewed findings from a report released by PEW on protecting the public from the risks of substandard and counterfeit drugs. She stated that many stakeholders support a strong national standard rather than separate state requirements.

Ms. Cosel discussed the Pharmaceutical Distribution Security Alliance (PDSA) proposal (described above) and stated that this proposals fall short as it calls for tracking of drug product at the lot level. It also would prohibit aggregation which would result in no tracking at the package level. Also, the PDSA proposal does not require the pharmacy or any other party to verify the authenticity of the drugs.

Ms. Cosel stated that PEW supports a national serialization and authentication standard. Ms. Cosel indicated that PEW is currently working on efforts to strengthen oversight and controlled systems for the manufacturing and distributing of drugs.

There was no board discussion or public comment.

6. Marjorie Powell, Pharmaceutical Research and Manufacturers of America (PhRMA)

During the committee meeting, Ms. Powell stated that the California Board of Pharmacy has been the catalyst to bring all the parties within the pharmaceutical supply chain together to enact an interoperable electronic pedigree system. She stated that PhRMA member companies are in the process of implementing unit level serialization numbers on products and developing data systems to manage and share unit level information. Ms. Powell stated that pilot projects are underway in this area and emphasized the need for a uniform national system.

Ms. Powell stated that PhRMA will continue to work with PDSA on the draft legislation for federal introduction. She encouraged the board to consider increased licensing standards nationwide and increased penalties for violations in this area.

Ms. Powell also offered support to the board in drafting regulations in this area.

Discussion

Ms. Veale discussed that it appears that several presentations and comments that occurred after the PDSA proposal were not in support of that solution with the exception of Marjorie Powell, PhRMA.

No public comment was provided.

c. Discussion and Possible Action to Initiate a Rulemaking to Adopt Regulation Requirements Specifying a Unique Identification Number for Prescription Medication Pursuant to California's E-Pedigree Requirements

Discussion

Dr. Kajjoka provided that California will need to promulgate regulations to implement e-pedigree requirements. He stated that regulations will be needed to clarify a number of requirements, including:

- Inference (relating a single number affixed to a pallet or case, to all serialized products contained within the pallet or case so that each product does not need to be hand-scanned and read)
- Closure of a Pedigree (when all product has been sold and the pedigree needs to be "ended")
- How pedigrees can be compliant when product is drop shipped (where the product is shipped directly to the pharmacy, but the wholesaler that never possesses product still is an owner of the product, and thus must be listed on the pedigree)
- Pedigree annotation to link shipping information to that which occurs on an invoice (the invoice is required to be tracked as part of the pedigree, but arrives typically after the product does, to prevent delays in distributing product)

Mr. Room provided that one of the first proposals being brought to the board as a proposed regulation is to establish the parameters for the unique, serialized number that must be affixed to each saleable product. He stated that the origins of these

requirements are in the FDA's requirements for a unique identifier for a single product. The proposed language is provided below:

Unique Identification Number

Pursuant to Business and Professions Code section 4034, the "unique identification number" established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to the Standardized Numerical Identifier (SNI) set forth in the Guidance for Industry published by the U.S. Food and Drug Administration (FDA) in March 2010, consisting of a serialized National Drug Code (NDC) identifier (or equivalent product identifier for dangerous drugs for which no NDC has been assigned) combined with a unique numeric or alphanumeric serial number that is no more than twenty (20) digits or characters in length.

Mr. Room shared that the committee is recommending that the board promulgate this regulation as part of a regulation package.

Ms. Shellans expressed concern regarding the language and suggested that the "equivalent product identifier" be clarified. She suggested that language be added to describe the elements involved.

Mr. Room stated that the board can move forward with the regulation and direct that clarification be added in this area.

President Weisser questioned if action by the board would be prudent now, or if it is preferred that the board hold the regulation to be part of a regulation package.

Shirley Wheat requested an implementation timeline.

Mr. Room reviewed the following timeline:

- By January 1, 2015, manufacturers must have 50 percent of their products serialized
- By January 1, 2016, manufacturers must have the remaining 50 percent of their products serialized.
- By July 1, 2016, all product received by a wholesaler must be serialized and pedigreed.
- By July 1, 2017, all product received by pharmacies and pharmacy warehouses must be serialized and pedigreed.

Ms. Herold indicated that industry has requested that the board move forward with the unique identifier and grandfathering provisions. She stated that the board will strive to have the regulation in place no later than January 1, 2013.

Mr. Room advised that holding the regulation for a regulation package may delay this process.

Ms. Herold provided that an emergency regulation is an option; but is not recommended.

The board considered the recommendation from the committee to hold the proposed language.

Ms. Shellans recommended that clarification be added to the language now, rather than later in the process.

Dr. Kajioka clarified that the committee recommends that the language be held to allow for clarification and input from industry.

Ms. Herold clarified that that the language is modeled after the FDA requirements in this area. She recommended that the board stay in line with the FDA to eliminate confusion for industry and to ultimately facilitate a solution at the federal level.

Public Comment

Ron Bone, McKesson, shared that industry worked very closely with the FDA to create the SNI requirements. He explained why the SNI works well and indicated that industry would like clear expectations from the board in this area by 2013.

Ms. Shellans asked if the guidance document is sufficient to direct industry in what the board would require and was advised that it is sufficient.

John Valencia, counsel for several manufacturers, spoke in support of the committee's recommendation to allow for input from industry. He recommended that the board issue a draft document to facilitate this process.

Ms. Shellans suggested that the board convene a workgroup as a subpart of the Enforcement Committee to facilitate this effort.

MOTION: Enforcement Committee: Hold the proposed language to specify a unique identification number for prescription medication pursuant to California's e-pedigree requirements to be pursued with other e-pedigree regulations as part of a regulation package.

Support: 7 Oppose: 0 Abstain: 0

President Weisser requested that this item be discussed again at the next Enforcement Committee Meeting and requested that the guidance document be provided as part of the information provided to the committee.

d. Discussion and Possible Action to Initiate a Rulemaking to Establish “Grandfathering” Provisions for Prescription Drugs in California Commerce After Activation of e-Pedigree Requirements

Discussion

Mr. Room discussed background on the grandfathering provisions and detailed the intent of the language.

Mr. Room reviewed the implementation requirements in Business and Professions Code section 4163.5(b). He clarified that before January 1, 2015, each manufacturer of a dangerous drug distributed in California must identify those dangerous drugs representing a minimum of 50 percent of its drugs that will be serialized and the remaining 50 percent must be serialized by January 1, 2016. Wholesalers have until July 1, 2016 to append the e-pedigree required information. Pharmacies and pharmacy warehouses have until July 1, 2017 to read and append pedigrees, making the system fully operational.

Mr. Room advised the board of a required change in subdivision (b) that will need to be incorporated regarding manufacturers that still have non-pedigreed product.

Ms. Shellans spoke in support of the committee’s recommendation to hold the proposed language to allow for modification to the language.

No public comment was provided.

MOTION: Enforcement Committee: Hold the proposed language to develop “grandfathering” provisions for non-pedigreed dangerous drugs pursuant to Business and Professions Code section 4163.2 to be pursued with other e-pedigree regulations as part of a regulation package.

Support: 7 Oppose: 0 Abstain: 0

Mr. Room discussed that the term “grandfathering” is a misnomer for the regulations. He suggested that an alternative term be used as the process moves forward.

President Weisser also requested that this item be discussed at the next Enforcement Committee Meeting.

e. Minutes of the Meeting Held March 21, 2012

Dr. Kajioka referenced the minutes of the March 21, 2012 Enforcement Committee provided in the meeting materials.

f. Enforcement Statistics

Dr. Kajjoka referenced the board's third quarter enforcement statistics provided in the meeting materials.

g. Third Quarterly Report on the Committee's Goals for 2011/12

Dr. Kajjoka referenced the third quarter's update report on the committee's strategic plan provided in the meeting materials.

Additional Discussion on Enforcement Issues

President Weisser provided additional comment regarding California's requirements for e-pedigree. He requested, and the board agreed, to direct Mr. Room to draft a letter to convey the board's desire to have the California law implemented on a federal level.

Public Comment

Ron Bone, McKesson, indicated support of the board's action. He requested that the board consider several issues including uniform law for wholesalers and clarification on returns processing in the Prescription Drug Marketing Act (PDMA).

Rob Calia, Medline Industries Inc., encouraged the board to review the Bennet-Burr Amendment prior to sending the proposed letter. He stated that this amendment expands on the RxTEC proposal and offers greater specificity on how supply chain members use unit level data. Mr. Calia provided the board a copy of this language.

Steve Gray, Kaiser Permanente, spoke in support of Mr. Calia's comment. He also encouraged the board to review this language.

Dr. Gray stated that guidance is needed on the impact of grandfathering for other locations where a drug is stored such as a physician's office, clinics, etc. He suggested that this issue be discussed at the next Enforcement Committee Meeting.

The board recessed for a break at 10:55 a.m. and reconvened at 11:13 a.m.

Presentation

Ms. Herold provided a presentation on drug adulteration and drug diversion. A copy of this presentation is attached, following this meeting summary.

Ms. Herold presented pictures of pharmacy shelves containing hundreds of empty manufacturer containers. Board inspectors have encountered large numbers of such

empty containers in multiple pharmacies. She discussed that this activity is just one reason to reinforce the need to include pharmacies in the e-pedigree requirements.

XV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Summary of the Committee Meeting Held March 27, 2012

a. General Discussion on the Implementation of Existing Regulation Requirements for Patient-Centered Prescription Drug Container Labels and Review of Labels in Use

Background

The board has a legislative requirement to provide a report to the Legislature by January 1, 2013 on implementation of the patient-centered labels. The specific requirement is:

4076.5(f)(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.

Discussion

Ms. Herold provided that the committee and the board's staff have begun activities aimed at compiling information for the report and to identify any additional changes in the requirements that may be needed. She stated that since January 1, 2012, board inspectors have been directed to pick up sample prescription container labels from every pharmacy they enter. Ms. Herold provided that the committee will continue to review the labels and identify the best labels to be placed on the board's Web site.

Ms. Herold provided that the board has created a web section dedicated to patient centered labels. She stated that this section of the board's Web site houses the sample labels, the specific regulations in this area, the first report to the Legislature submitted in 2010, a consumer survey, and the translations of the standardized directions for use listed in the labeling requirements of section 1707.5.

Ms. Herold shared that she is on two industry committees to institute the standardized directions for use into the e-prescribing standards.

No public comment was provided.

b. Discussion on the Design of New Notice to Consumers Posters (as Required by Title 16 California Code of Regulations Section 1707.6)

Discussion

Ms. Herold reviewed sample designs for the new Notice to Consumers poster. She stated that board staff has worked to incorporate the required information and direction provided by the committee onto one poster. Ms. Herold discussed that the new design may be larger than the current notice currently in use to promote better readability.

Ms. Veale provided that the committee briefly discussed enlarging the poster size but did not reach a consensus. She stated that the committee is sensitive to the fact that pharmacies may currently be using frames or holders that are sized for the current poster.

Ms. Herold provided that once the new design has been finalized, it will be published and mailed to all pharmacies. She stated that staff will secure translated versions of the posters in the same design and make these available to pharmacies that wish to display the posters in additional languages.

No public comment was provided.

c. Discussion about the Video Display Format Option for Notice to Consumers (as Required by Title 16 California Code of Regulations Section 1707.6)

Discussion

Ms. Herold presented the proposed video version for the Notice to Consumers which includes the required text as required by the regulation. She requested comments from the board and noted that the timing of the slides is too slow and will be revised to meet the requirements specified in the regulation.

The board indicated approval of the video.

Public Comment

Anita Le, PALS for Health, asked whether the video will be available in multiple languages.

Ms. Herold indicated that the goal is to produce the video in multiple languages.

Mr. Room discussed that there is no requirement that the video be in a different language. Instead, he indicated, consumers will be directed to the required notice regarding interpreter services for assistance in a language other than English.

Ms. Herold provided that the board will continue to print the Notice to Consumers poster in languages other than English.

d. Discussion on the Format for Notice of Interpreter Availability (as Required by Title 16 California Code of Regulations Section 1707.6)

Discussion

Ms. Herold reviewed the finalized notice of interpreter availability. She advised that the notice will be posted on the board's Web site and is required to be placed in every pharmacy at or adjacent to each counter where drugs are dispensed.

Public Comment

Anita Le, PALS for Health, commented on the use of Cantonese as a spoken Chinese language only. She asked whether the notice can be modified to also include traditional Chinese.

Mr. Room advised that a regulation change would be needed to add traditional Chinese to the list of languages. He stated that this issue was never voiced during the regulation process.

Mr. Zee provided comment on both the written and spoken forms of Chinese and indicated that the notice is appropriate as presented.

e. Discussion on Pharmacy Compliance with Interpreter Availability and Patient-Centered Labeling Requirements

Discussion

Ms. Herold reviewed the following statistics on general compliance reported by inspectors on the profession's adoption of the patient-centered labeling requirements and interpreter availability.

Patient Centered Labels:

Number of inspections:	294
Those in compliance:	90 percent
Those not in compliance:	10 percent
Those printing in 10 point only:	12 percent
Those printing in 12 point only:	67 percent
Those printing in 10 & 12 point jointly:	21 percent

Interpreter Services:

Those in compliance:	71 percent
Those not in compliance:	29 percent

<u>If in Compliance:</u>		
Provided by staff	17 percent*	May not be compliant for all patients
Provided by telephone	28 percent	
Provided by telephone & staff	54 percent	

Ms. Herold provided that board inspectors are issuing correction notices with requirements to come into compliance within 30 days. She advised that the board will begin to transition from corrections to other enforcement actions such as letters of admonishments. Ms. Herold stated that board inspectors are also advising pharmacies about the availability of telephone translation services to ensure compliance with the diversity of patients who may present in a pharmacy.

<u>Number of corrections ordered:</u>	
Patient-centered labels:	25
Interpreter service:	71

Dr. Kajioka asked how many consumer complaints have been received regarding the new labeling and interpreter service requirements.

Ms. Herold provided that the board has received several complaints in this area. She discussed that as the new notices are not yet finalized, there has not been aggressive outreach to consumers. Ms. Herold reminded the board that the next report to the Legislature regarding the implementation of the requirements is due January 1, 2013.

Public Comment

Steve Gray, Kaiser Permanente, reminded the board that the regulation allows for pharmacies to seek approval by the board to use another format or display methodology for the notice to better meet the needs of their patients. Dr. Gray also asked if there has been any further publicity to remind prescribers that they must include the purpose or conditions of the medication on the prescription if requested by the patient.

Ms. Herold provided that the Medical Board of California has agreed to include an article in their newsletter regarding this issue.

Anita Le, PALS for Health, asked how the quality of oral interpretive services is being assessed and shared a personal story in this area.

Ms. Herold responded that the board is not in a position to evaluate the quality of the translation services. She stated that board inspectors will be inspecting for the availability of the service, not the quality of the service provided and reviewed possible actions for failure to have services available.

Mr. Room advised that there is no requirement in the law that the interpretive services meet a minimum standard.

Ms. Le encouraged the board to implement additional regulations to secure safety measures and standards in this area.

Linda Whitney, Executive Director, Medical Board of California, advised the board that there is an association of interpretative services for consumers to submit complaints in this area.

f. Discussion on Securing Consumer Comments on the Board's Regulation Requirements for Patient-Centered Labels and Translations for Limited English Speaking Individuals

Ms. Herold reported that the committee will be working on the development of consumer surveys to evaluate the new patient-centered labels and translations. She stated that these comments will be included in the 2013 Legislative Report.

There was no board discussion or public comment.

g. Update on an Assessment of the Board's Public Education Materials

Ms. Herold provided that the committee's future plans include an assessment of the board's public educational materials. She stated that older brochures produced by the board over the years will be evaluated for updating.

There was no board discussion or public comment.

h. Update on The Script

Ms. Herold provided that the most recent issue of The Script was released in March 2012. She stated that work on the next issue has begun.

There was no board discussion or public comment.

i. Public Outreach Activities Conducted by the Board

Ms. Herold referenced the following public and licensee outreach activities performed during the third quarter of fiscal year 2011/12. She advised that the board's outreach activities have been limited by the Governor's directive on travel expenses.

- January 18 – Executive Officer Herold provides a presentation on the board's enforcement program's components and new pharmacy laws for 2012 to 80 pharmacists at the Sacramento Valley Pharmacists Association Meeting.
- February 3 and 4 – The board staffs an information booth about the board's program at the annual California Pharmacists Association Meeting in Sacramento.

- February 3 – Assistant Executive Officer Sodergren provides a presentation about the board at a consumer focus meeting at the California Pharmacists Association Meeting in Sacramento .
- February 4 – Board President Weisser and EO Herold provide a presentation on the board’s enforcement program at the California Pharmacists Association Meeting in Sacramento; this presentation had the largest attendance of any at the conference (179).
- February 6 – SI Nurse does a presentation at Loma Linda University on the requirements of being a PIC and how to prevent drug diversion to students and faculty.
- February 9 – EO Herold attends the NDPDP Technology Meeting in San Diego, the standards setting group for electronic data transmissions in pharmacy to describe the requirements of California’s e-pedigree requirements.
- February 10 – EO Herold and AEO Sodergren provide a presentation to 15 members of a Chinese delegation visiting the US on California pharmacy law.
- March 13 – EO Herold provides a presentation to 200 pharmacy students at Touro University on the board’s enforcement program and accessing board services.
- March 21 – Inspector Toevs provides a presentation to Western University School of Pharmacy students on duties of a PIC, pharmacy law and the functions of the board.

j. Minutes of the Communication and Public Education Committee Meeting Held January 19, 2012

Ms. Herold referenced the minutes of the committee meeting provided in the meeting materials.

k. Third Quarterly Report on the Committee’s Goals for 2011/12

Ms. Herold referenced the third quarter’s update on the committee’s goals for 2011/12 provided in the meeting materials.

XVI. EXECUTIVE OFFICER’S REPORT

a. Discussion of the Sunset Review Process by the Senate Committee on Business, Professions and Economic Development

The board postponed discussion of this item to be discussed at the July 2012 Board Meeting.

b. Update on the Pain Summit, a Board Co-Sponsored Conference with the Medical Board of California Scheduled for November 28 and 29, 2012, Medical Board Executive Director Linda Whitney to Appear

Ms. Herold introduced Linda Whitney, Executive Director of the California Medical Board. Ms. Herold indicated that the board and the Medical Board will be working together to convene a Pain Summit.

Ms. Whitney conveyed the Medical Board's appreciation to work together with the board on the development of the Pain Summit as well as the partnership between the staff of both boards to help promote the relationship between prescribers and pharmacists. Ms. Whitney highlighted some areas that impact both boards including e-pedigree, SB 1441, legislation, the CURES program, implementation of BreZE, and other administrative issues.

Ms. Whitney referenced a recently released book by Dr. Fishman who will be a member of the working group along with Lorie Rice from UCSF. She stated that representatives from the Board of Registered Nursing and Physician Assistant Committee will also be invited to participate in the Pain Summit.

Ms. Herold provided additional comment on the partnership between prescribers and pharmacists. She discussed anticipated outcomes of the Pain Summit including educational outreach and better use of the CURES program.

Ms. Whitney indicated that it is anticipated that the Pain Summit will be convened for two days to cover the large breadth of topics. She stated that continuing education credit will be awarded to licensees in attendance.

No public comment was provided.

c. Proposal to Convene a One-Day Automation Technology Summit to Display Technology in Use or Proposed for Use in Pharmacies, Hospitals and Skilled Nursing Facilities

Ms. Herold discussed that board inspectors are finding automated dispensing machines in various forms that do not comply with pharmacy law. She proposed that the board authorize staff to convene a summit to evaluate this issue. Ms. Herold stated that vendors will be invited to demonstrate their technology to determine compliance with requirements in this area.

The board discussed the current requirements for use of automated dispensing machines.

It was the consensus of the board to convene the summit as requested. The board indicated interest in scheduling the summit in concert with a future Board Meeting to allow for attendance by the board.

No public comment was provided.

d. Change in July 2012 Board of Pharmacy Meeting Dates to July 17 and 18, 2012

Ms. Herold advised that dates for the July 2012 Board Meeting have been changed to July 17 and 18, 2012.

XVII. CLOSED SESSION

The board did not convene in closed session as agendized.

XVIII. PETITION FOR REINSTATEMENT

- Carol Simon, RPH 41523

XIX. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the board convened in closed session to deliberate on the petition for reinstatement.

Open Session

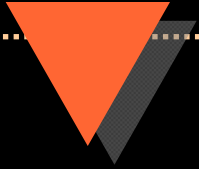
The board reconvened in open session at 3:11 a.m. The board moved to postpone discussion of the Sunset Review Process (Agenda Item XVI. a).

MOTION: Table discussion of the Sunset Review Process by the Senate Committee on Business, Professions and Economic Development until the July 2012 Board Meeting.

M/S: Veale/Wheat

Support: 7 Oppose: 0 Abstain: 0

The open session of the board meeting was adjourned at 3:20 p.m.



Counterfeit Drugs

California State Board of Pharmacy

Enforcement Committee

March 21, 2012



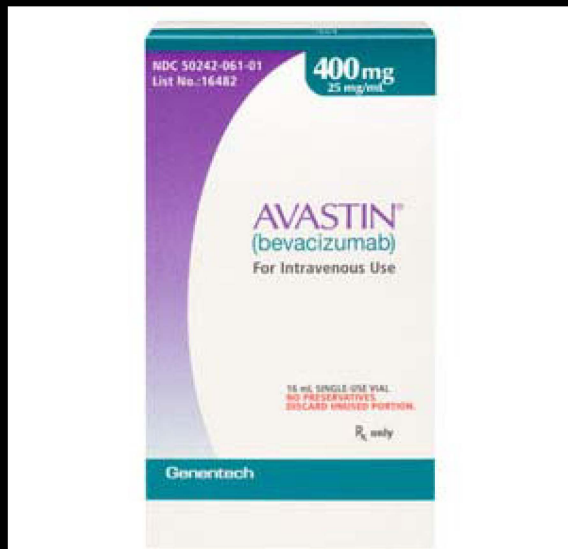
Statutory Mandate

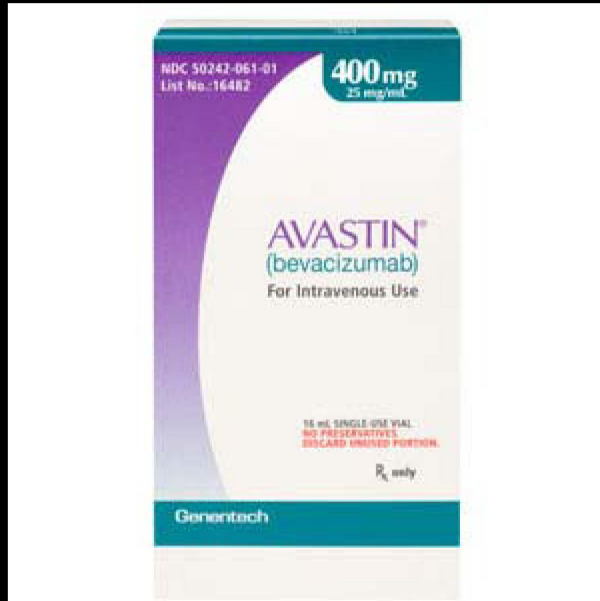
Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions.

Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

CA Business and Professions Code 4001.1













Counterfeit

Genuine



Reporting Counterfeits in CA

- If a manufacturer, wholesaler or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify the Board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or throughout CA

CA Business & Prof Code 4034(h)



Drug Adulteration and Diversion in Pharmacies



Board of Pharmacy

Enforcement Committee

March 21, 2012

California State Board of Pharmacy

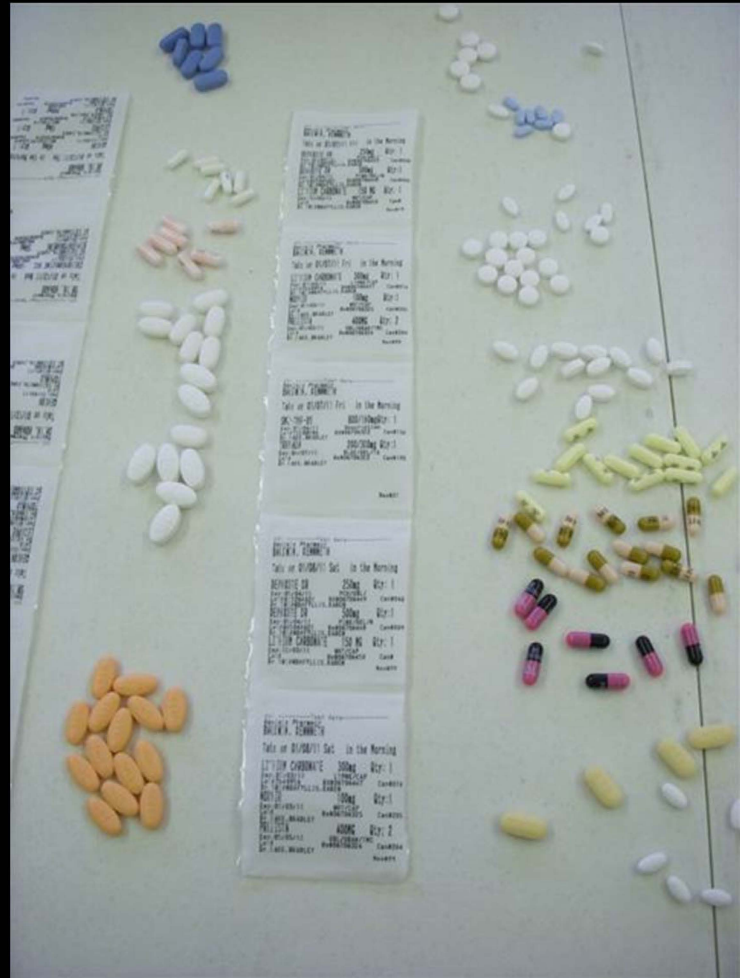
- We license about 10 percent of the nation's pharmacies -6,350 community and nearly 500 hospital pharmacies, and 350 non resident pharmacies
- We license 550 CA wholesalers and over 700 nonresident wholesalers

Empty Manufacturer Containers







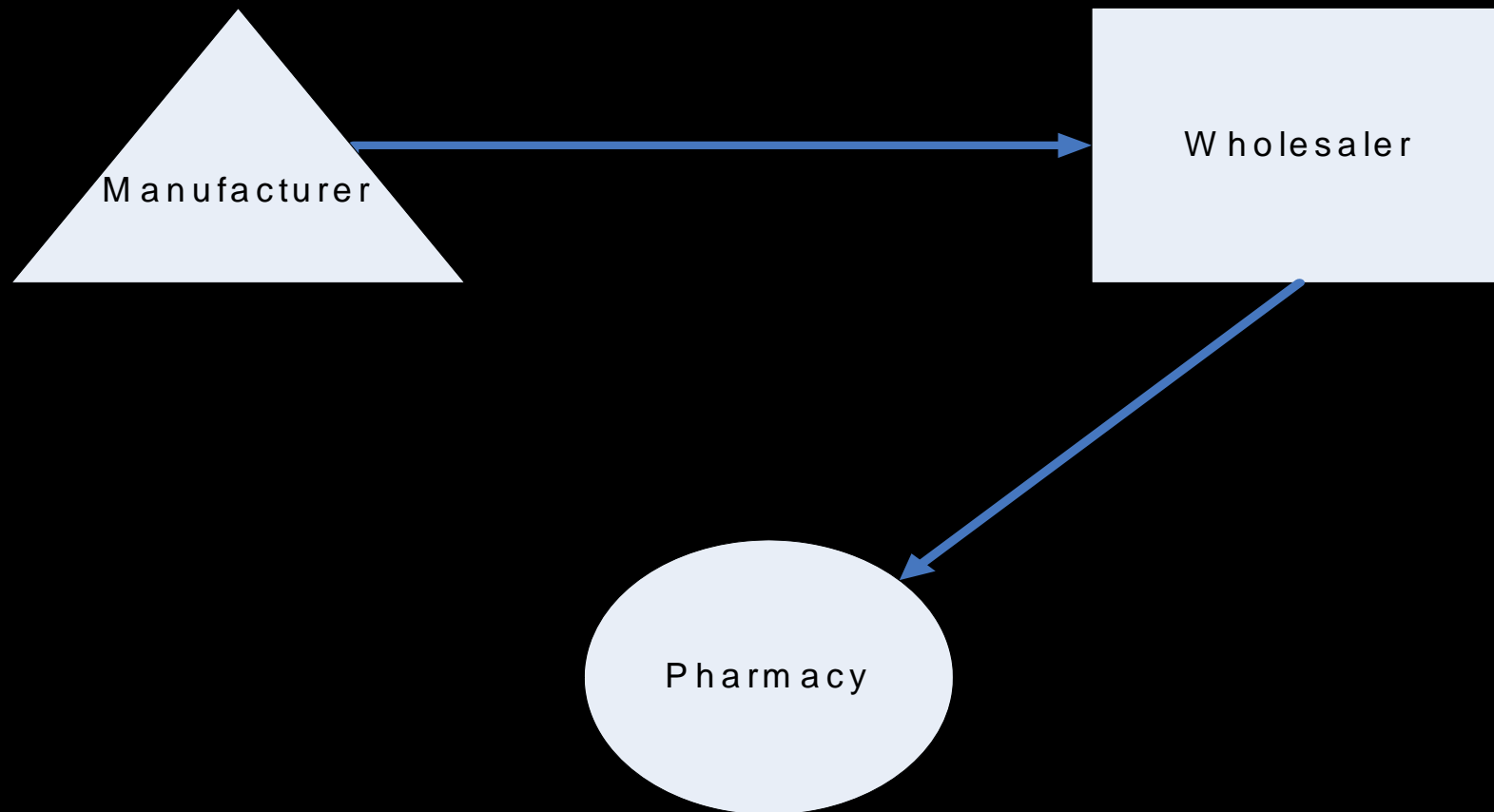




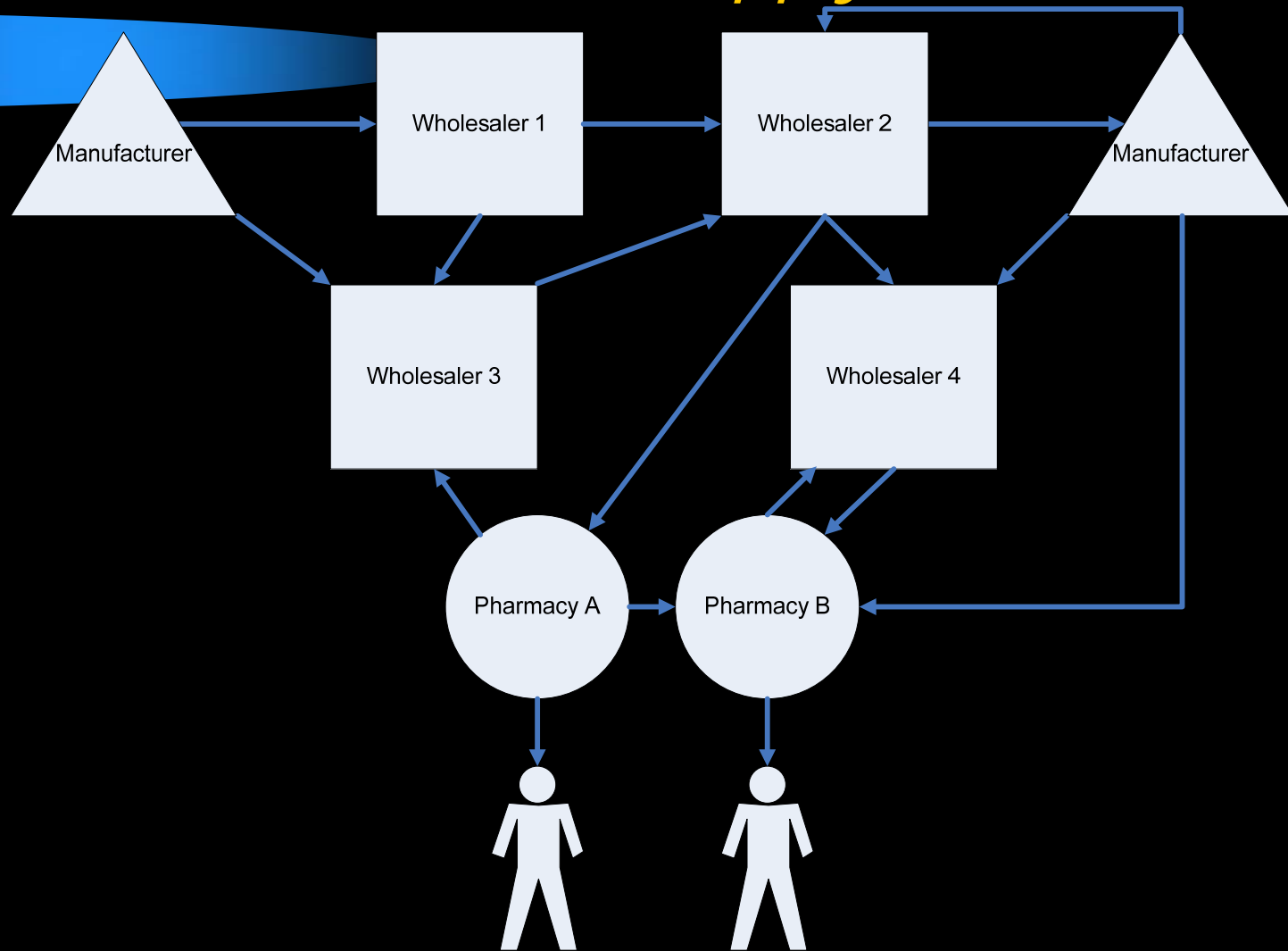




Pharmaceutical Supply Chain



Another Derivation of the Supply Chain



**Wholesale Broker: Unlicensed California Wholesaler
Arranges Sales & Purchases Through the Following**

WHOLESALER Nevada CA Licensee	WHOLESALER Puerto Rico Not CA licensee	WHOLESALER New York Not CA licensee	WHOLESALER Ohio CA Licensee	WHOLESALER Kentucky CA Licensee	WHOLESALER Mexico Not CA licensee	WHOLESALER New Jersey Not CA licensee	WHOLESALER Louisiana Not CA licensee	WHOLESALER Ohio Not CA licensee	WHOLESALER Texas Not CA licensee	WHOLESALER 2 Individuals Location unknown Employer unknown
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WHOLESALER
Oregon
Not CA licensee

WHOLESALER
Oregon
Not CA licensee

WHOLESALER
Oregon
Not CA licensee

WHOLESALER
Minnesota
Not CA licensee

PHARMACY
California
CA Licensee

Pedigree is created by Pharmacy Located in California
Same address as another Pharmacy
Address on ALL pedigrees show purchase by Pharmacy
located in California – licensed as a pharmacy, not as a wholesaler.

WHOLESALER
California
CA Licensee

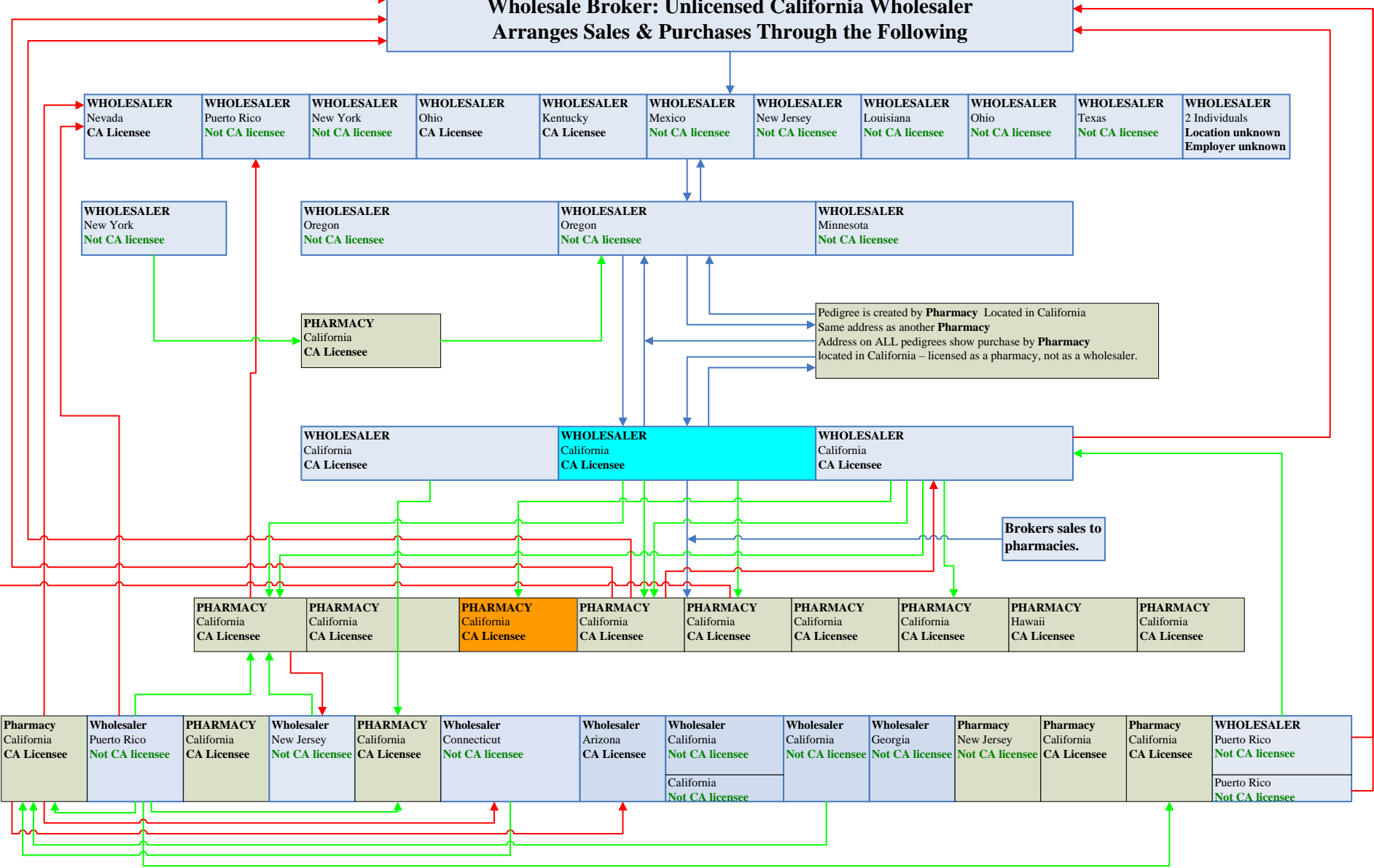
WHOLESALER
California
CA Licensee

WHOLESALER
California
CA Licensee

Brokers sales to
pharmacies.

PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY Hawaii CA Licensee	PHARMACY California CA Licensee
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Pharmacy California CA Licensee	Wholesaler Puerto Rico Not CA licensee	PHARMACY California CA Licensee	Wholesaler New Jersey Not CA licensee	PHARMACY California CA Licensee	Wholesaler Connecticut Not CA licensee	Wholesaler Arizona CA Licensee	Wholesaler California Not CA licensee	Wholesaler California Not CA licensee	Wholesaler Georgia Not CA licensee	Pharmacy New Jersey Not CA licensee	Pharmacy California CA Licensee	Pharmacy California CA Licensee	WHOLESALER Puerto Rico Not CA licensee	WHOLESALER Puerto Rico Not CA licensee
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**Wholesale Broker: Unlicensed California Wholesaler
Arranges Sales & Purchases Through the Following**

WHOLESALER Nevada CA Licensee	WHOLESALER Puerto Rico Not CA licensee	WHOLESALER New York Not CA licensee	WHOLESALER Ohio CA Licensee	WHOLESALER Kentucky CA Licensee	WHOLESALER Mexico Not CA licensee	WHOLESALER New Jersey Not CA licensee	WHOLESALER Louisiana Not CA licensee	WHOLESALER Ohio Not CA licensee	WHOLESALER Texas Not CA licensee	WHOLESALER 2 Individuals Location unknown Employer unknown
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WHOLESALER
New York
Not CA licensee

WHOLESALER
Oregon
Not CA licensee

WHOLESALER
Oregon
Not CA licensee

WHOLESALER
Minnesota
Not CA licensee

PHARMACY
California
CA Licensee

Pedigree is created by **Pharmacy** Located in California
Same address as another **Pharmacy**
Address on ALL pedigrees show purchase by **Pharmacy**
located in California – licensed as a pharmacy, not as a wholesaler.

WHOLESALER
California
CA Licensee

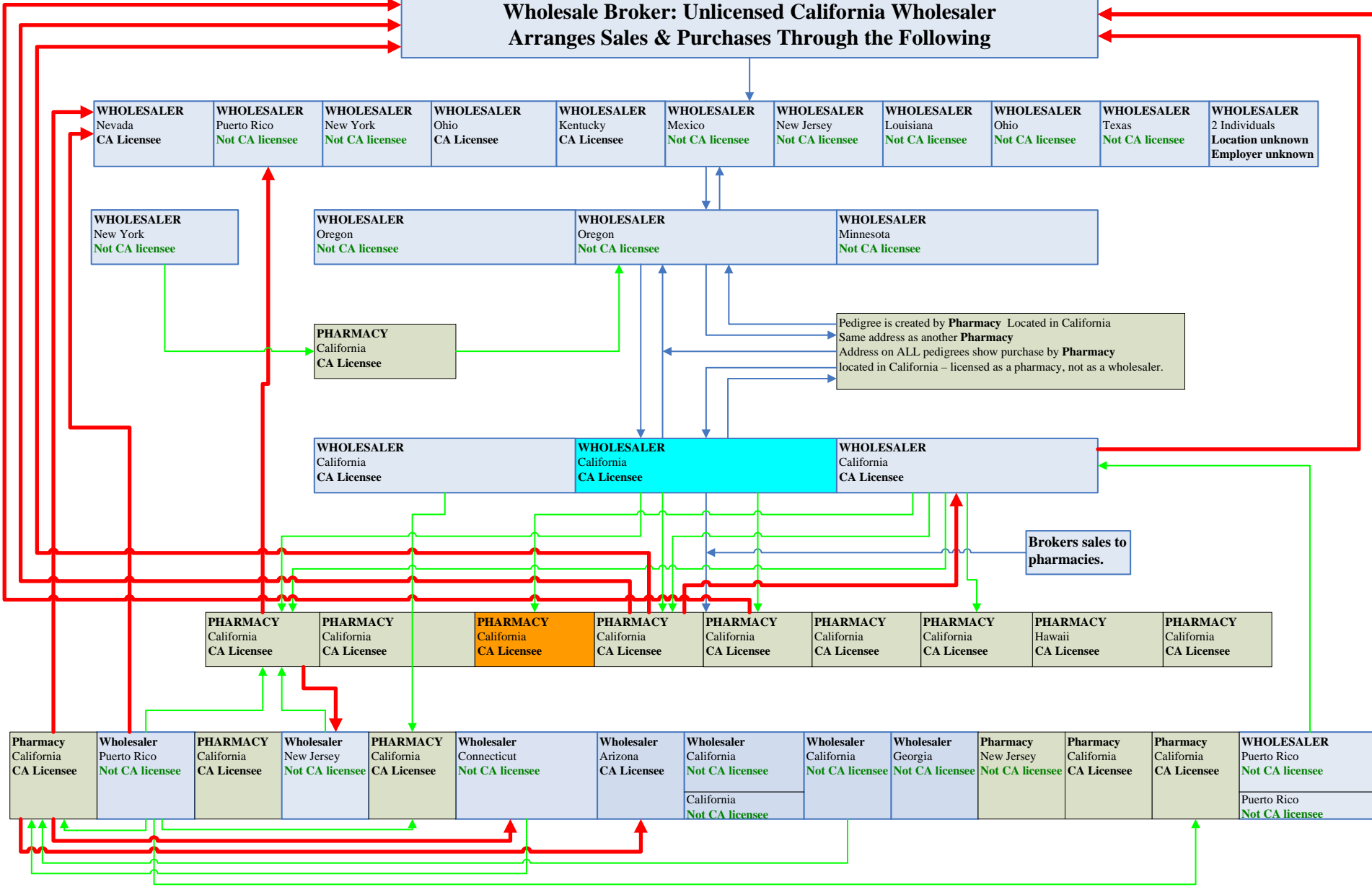
WHOLESALER
California
CA Licensee

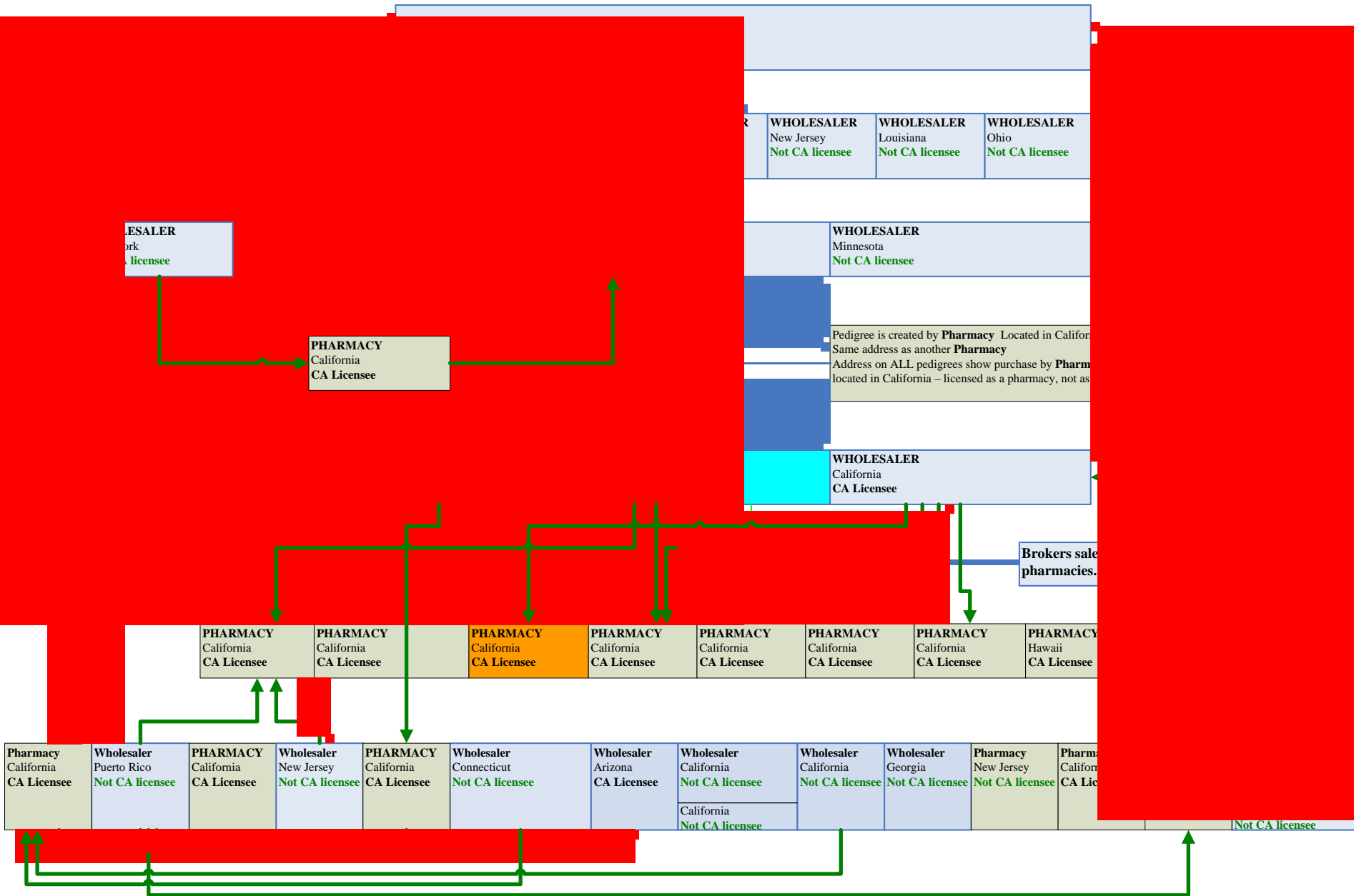
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California
CA Licensee

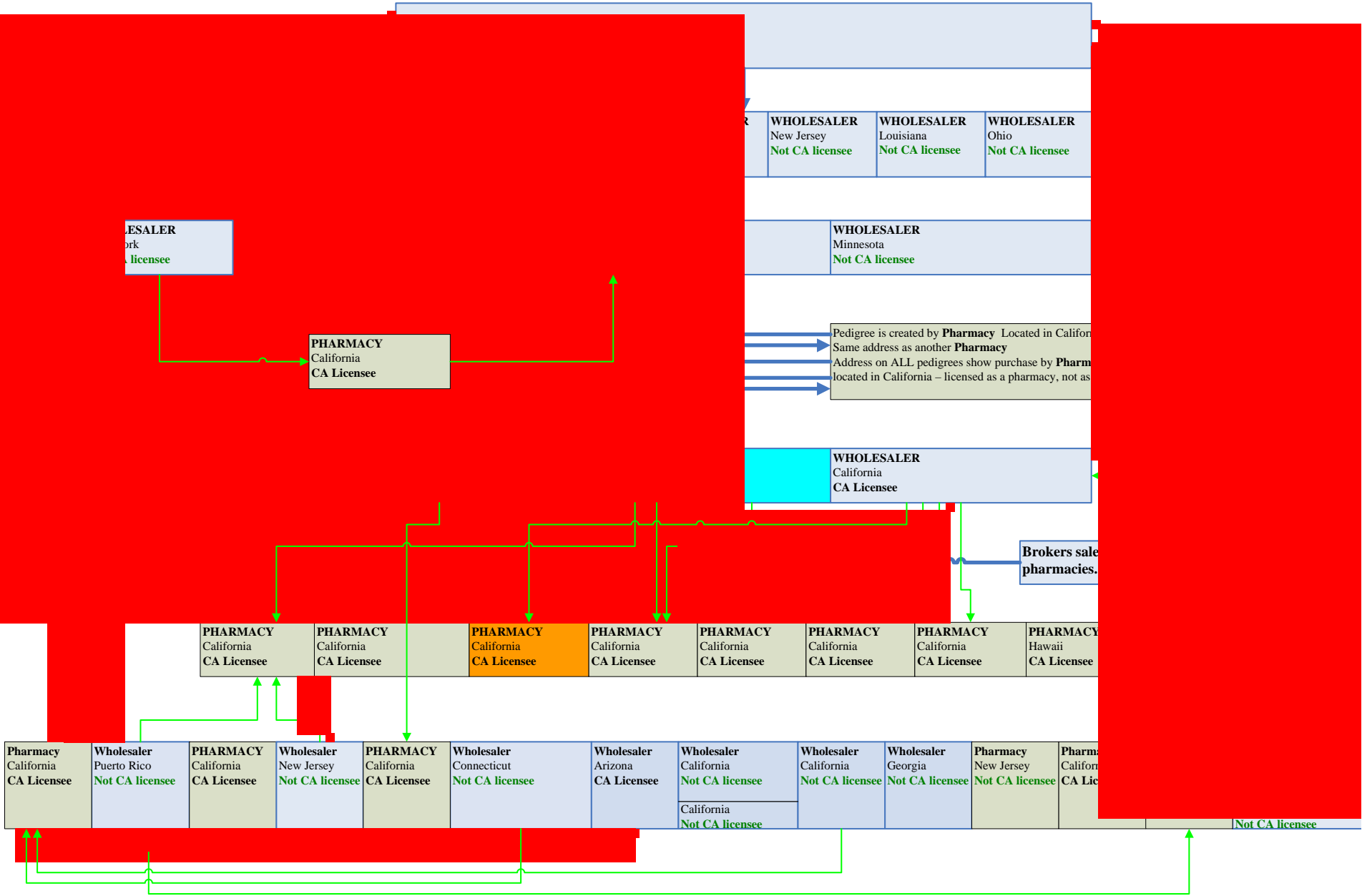
Brokers sales to
pharmacies.

PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY California CA Licensee	PHARMACY Hawaii CA Licensee	PHARMACY California CA Licensee
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							California Not CA licensee						Puerto Rico Not CA licensee







Future Meetings and Notices

- Calendar for 2012

June 12

Sept. 11

Dec. 4

- Join our email “subscriber alert” by going to www.pharmacy.ca.gov