Call to Order

Chair Deborah Veale called the meeting to order at 9:45 a.m.

Chair Veale conducted a roll call. Board Members Albert Wong and Victor Law were present.

Board President Stan Weisser was in attendance in the audience.

1. Licensing Committee Meeting Dates for the Remainder of 2013: September 24 and December 11.

Chair Veale identified the remainder meeting dates for the Licensing Committee and reminded the committee members to place these dates in their calendars.
2. **Staff Recommendations for Regulation Changes to Require or Standardize the Reporting of Convictions and Discipline at the Time of Renewal for Pharmacists, Pharmacy Technicians and Designated Representatives.**

**Relevant Statutes and Regulations**

Business and Professions Code Section 4036 provides the definition for “pharmacist” and specifies that the holder of an unexpired and active pharmacist license is entitled to practice pharmacy as defined in pharmacy law.

Business and Professions Code Section 4022.5 provides the definition of “designated representative” and Business and Professions Code Section 4038 provides the definition of a pharmacy technician.

California Code of Regulations Section 1702 details the fingerprint and criminal conviction requirements that are currently required as a condition of renewal for a pharmacist.

**Background**

As part of the Consumer Protection Enforcement Initiate in 2008/2009, the board undertook review and evaluation of several areas of its enforcement and licensing functions to identify areas where the board could improve its ability to ensure it received or had access to information necessary to make appropriate licensing decisions as well as ensure it received relevant information to initiate investigations and take appropriate action to better protect consumers.

As part of this effort the board sought new regulatory authority to require fingerprinting of pharmacists that had not previously submitted fingerprints to the Department of Justice in an electronic format. To augment this effort, the board also sought to require as a condition of renewal, that a pharmacist also self-report any convictions. These changes took effect in December 2010. At the time the board adopted the changes, they requested that similar provisions be implemented for pharmacy technicians and designated representatives.

**Prior Committee Action**

During the April 2013 Licensing Committee meeting, the committee discussed a staff recommendation that would make changes to the existing pharmacist renewal as well as place similar renewal requirements for the pharmacy technician and designative representative licenses. The proposed changes specific to the pharmacist renewal include:

- Disclosure of disciplinary action
- Removing reference to the implementation date
- Clarifying that disclosure of criminal conviction information and disciplinary action is for action taken since the last renewal of the license.

At the April 2013 Licensing Committee meeting, Chair Veale directed staff to determine the number of pharmacy technicians and designated representatives that require retro fingerprinting and to provide information relating to the costs associated.
Board staff estimates approximately 13,588 licensees will require Live Scan to be completed consisting of 13,305 pharmacy technicians and 283 designated representatives. The cost of the Live Scan to the licensee is approximately $51 plus rolling fees that vary based on the Live Scan location.

Based on the comments received during the committee and counsel, the language was revised and presented to the committee for consideration.

**Discussion**
Chair Veale reviewed and referenced the language provided in the meeting materials and asked if the committee members had any questions or concerns.

Virginia Herold inquired if the committee’s intent was to define formal discipline as formal reprimands were not mentioned. Kristy Shellans indicated a public reprimand is the lowest form of formal discipline. Anne Sodergren expressed the intent is not to be an exclusive list but rather a list to identify various types of actions. The committee could elect to provide more examples. Ms. Herold offered the alternative that differentiations between types of actions could be addressed in the instructions. Chair Veale confirmed the committee’s intent to include letters of reprimand. Ms. Shellans added if the committee wished to be clear the types of actions should be specified. Chair Veale agreed clarifying this is fair to the applicants.

**Motion**
To recommend to the board to initiate a rulemaking with the proposed changes and include in the language the term “letter of reprimand.”

No public comment was provided.

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**Title 16. Board of Pharmacy**

**Proposed Language**

To Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1702. Pharmacist Renewal Requirements**
(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee’s fingerprints does not exist in the Department of Justice’s criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee’s or registrant’s renewal date that occurs on or after December 7, 2010.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under $300 to $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an administrative action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, or probation.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Add Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee’s fingerprints does not exist in the Department of Justice’s criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee’s or registrant’s renewal date that occurs on or after July 1, 2014.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last
renewal. Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an administrative action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, or probation.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

To Amend Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee’s fingerprints does not exist in the Department of Justice’s criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee’s or registrant’s renewal date that occurs on or after July 1, 2014.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions under $500 not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an administrative action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, or probation.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.
3. **Staff Recommendation for Regulation Changes to Require Site Licenses to Report Disciplinary Actions by Other Entities at Time of Renewal.**

**Relevant Statutes and Regulations**

Business and Professions Code Section 4112 provides for the regulation of a pharmacy located outside of California that ships, mails, or delivers, in any matter, controlled substances, dangerous drugs, or dangerous devices into this state.

Business and Professions Code Section 4161 provides for the regulation of a wholesaler located outside of California that ships, sells, mails, or delivers dangerous drugs or devices into this state or that sells, brokers or distributes such products.

**Background**

As part of the requirements for initial licensure as either a nonresident pharmacy or nonresident wholesaler an applicant must hold a current license in the resident state. Prior to issuance of a CA license, such applicants provide the board with license verification from the resident state that provides our board with confirmation of the current standing with the other state board as well as notification if the license has been disciplined. This information is very valuable when making a licensing decision; however, it only provides information at the time of licensure.

During the April Licensing Committee meeting, board staff recommended that the committee discuss, and if it so chooses, recommend to the full board, initiation of a rulemaking that would require, as a condition of renewal, disclosure of any disciplinary action taken against the entity in its home state.

The committee discussed the proposal to require as a conditional of renewal, disclosure of any disciplinary action taken against the entity in its home state. The committee discussed the policy behind the recommendation and expressed support for the concept. Chair Veale directed staff to refine the language and to clarify exactly what staff is requesting the licensee provide.

Based on the comments received during the committee and counsel, the language was revised and presented to the committee for consideration.
Discussion
Chair Veale referenced the language provided in the meeting materials and then asked if committee members or the public had any questions or concerns.

Chair Veale began the discussion posing the question as to whether this would include the disciplinary action taken from the home state or all states the nonresident licensee is licensed. Albert Wong clarified all disciplinary action in all states and not only the home state. Virginia Herold stated reprimand and probation should be included. Kristy Shellans suggested including reprimand, revocation, suspension and probation. Anne Sodergren suggested providing a little more specificity possibly using federal guidelines and look at their language to incorporate into our instructions.

Chair Veale inquired about the circumstances from New England Compounding Center (NECC). Ms. Herold indicated the action taken was considered non-discipline and therefore non-reportable to other states which was part of the agreement. Ms. Shellans suggested the board look at the National Practitioner Data Bank and the Health Integrity and Protection Data Bank (NPDB-HIPDB). Ms. Sodergren requested clarification as to whether this would be included in the instructions for the application or in regulation. Ms. Shellans recommended regulations. Victor Law recommended providing the information on both instructions for the application and regulation. Ms. Sodergren suggested updating this item to be similar to the previous agenda item.

Motion
To accept staff’s recommendation and include in the language the term “letter of reprimand” and include a better definition of disciplinary action as well and recommend to the full board for consideration.

No public comment was provided.

Title 16. Board of Pharmacy
Proposed Language

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.

(b) For purposes of this section, “disciplinary action” means any administrative action that resulted in a restriction or penalty against the license, such as revocation, suspension or discipline. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.
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Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4112, 4161, 4300, 4301, Business and Professions Code

M/S: Wong/Law

Support: 3    Oppose: 0    Abstain: 0

4. Review of Request from Det Norske Veritas (DNV) to Renew Board of Pharmacy Approval as an Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies.

Relevant Statutes
Business and Professions Code Sections 4127 – 4127.8 provides for the regulation of pharmacies that compound sterile injectable drug products in a pharmacy. Pharmacy law creates an exemption from the licensure requirements for a pharmacy that is accredited by a private accreditation agency approved by the board (B&PC 4127.1 (d) and 4127.2 (c)).

Background
For the past several years the board has been discussing several elements of pharmacies that compound sterile injectable products, including the requirements for private accreditation agencies. As part of the current approval process, such agencies apply to the board for consideration and approval by the board.

Det Norske Veritas (DNV) was previously approved by the board for a three year period. This approval will expire later this year. As such DNV has submitted a new request to the board. Regrettably because the April Licensing Committee meeting was rescheduled, a representative from DNV was unable to attend the committee meeting. The committee recommended to the board to extend DNV’s approval for three months so that DNV would be able to attend the May Licensing Committee meeting. The board approved this recommendation.

Supervising Inspector Janice Dang conducted an inspection of four hospitals accredited by DNV. This summary was provided as part of the meeting materials.

Discussion
Chair Veale provided an update on the agenda item. Chair Veale advised the committee that prior to the meeting; Executive Officer Herold informed Chair Veale that DNV would not be present at the Licensing Committee meeting. Supervising Inspector Janice Dang provided an overview of the impression of DNV by the four hospitals accredited by DNV that she inspected.

Supervising Inspector Dang answered questions from the committee with regard to the types of the four hospitals inspected as well as the membership of the survey team used by DNV. Chair Veale asked Supervising Inspector Dang if she believed the DNV’s standards were adequate and if a pharmacist was involved in the survey of the hospitals by DNV. Supervising Inspector Dang stated she believe DNV’s standards were similar to the Joint Commission’s standards but that a pharmacist was not involved in the survey of the four hospitals she inspected. Dr. Dang indicated that there appeared to be a...
miscommunication from DNV in that DNV has sterile compounding survey but the hospital must request a sterile compounding survey specifically.

Chair Veale indicated DNV was required to forward deficiencies to the board. Dr. Dang replied in December 2012, the board sent a letter to all accrediting agencies requesting the following: 1) A list of all accredited pharmacies in California; 2.) A list of all changes in standards; and 3.) A list of significant deficiencies. DNV did not report any significant deficiencies in their hospitals. Chair Veale asked if the four hospitals were acceptable. Dr. Dang indicated that four hospitals she inspected accredited by DNV did not have significant deficiencies.

Albert Wong inquired as to who DNV hired to do the accreditation surveys. Dr. Dang responded that a majority of the professionals are nurses and some are generalists such as administrators or specialists such as social services or dietitians. Dr. Wong inquired as to if there were pharmacist involved. Dr. Dang indicated that there are pharmacists available for large hospitals or if there are problems in the pharmacy but not for routine survey inspections. Dr. Wong stated he thought it would be a good idea to have a pharmacist involved.

Chair Veale noted that during prior discussions about such accreditation agencies, the board requested a pharmacist to be involved. Ms. Herold recalled all accrediting agencies agreed with the exception of the Joint Commission. Dr. Dang added DNV indicated they could try to have a pharmacist on survey teams but couldn’t guarantee a pharmacist on the survey team. DNV commented to Dr. Dang that if the board desired a pharmacist, the price would be increased for accreditation to the hospitals. DNV also commented to Dr. Dang that if DNV was required to have a pharmacist on each survey team the other board approved accrediting agencies and the Joint Commission should be required to have a pharmacist on their respective survey teams.

Ms. Shellans clarified the Joint Commission is not required to have a pharmacist on a team because the board is required to allow the Joint Commission to accredit by statute. The other accrediting agencies are approved based on the board’s criteria. Chair Veale recalled that the board was clear that a pharmacist was required for approved accrediting agencies.

Ms. Herold asked Dr. Dang if the four hospitals inspected required correction. Dr. Dang advised the committee that she conducted routine inspections and that all four hospital pharmacies required corrections after the inspections. Chair Veale asked how the required corrections compared to other corrections required after other sterile compounding inspections and was advised that they were common corrections. None of the corrections were a threat to public health and most didn’t require written proof of correction. Dr. Dang provided to the committee an overview of the four hospitals she inspected and the issues she found during the inspections.

Mr. Law asked if there were criteria that could be sent to the accrediting agencies. Ms. Sodergren added that the regulation to formalize the criteria was put on hold due to pending legislation. If the legislation is unsuccessful, the committee will need bring the regulation back to the board to move forward with promulgating the regulations as the board may request the accrediting agencies update their criteria but do not have a statute or regulation to enforce the request. Ms. Herold added that such criteria would not impact the Joint Commission.
Chair Veale advised the committee that the board’s bill to better regulate compounding pharmacies, SB 294 (Emerson) made it out of Senate appropriations the previous week and was moving to the Senate floor. Ms. Herold indicated that pending legislation has to be out of the Senate which is the house of origin during the current week and provided the committee that the board is sending a floor letter this week. If approved, the new law will supersede accrediting approval. Chair Veale indicated if the bill fails, accrediting will be required. Ms. Herold suggested providing a one year extension. Ms. Sodergren added to the one year extension along with a letter reiterating the board’s expectations as they continue to accredit in California.

Motion
To recommend to the board to approve one year on the current DNV accreditation with a letter to DNV letter reminding DNV of the elements the board requires including adding a pharmacist to the survey team, providing information to the board, and updating the board when the deficiencies have been corrected.

There was no public comment.

M/S: Veale/Law

Support: 3    Oppose: 0    Abstain: 0

5. Overview of the Upcoming Evaluation of the Pharmacy Technician Certification Board (PTCB) Exam and the Examination for the Certification of Pharmacy Technician (ExCPT).

Relevant Statutes
Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. There are several routes to licensure:

- Obtain an associate’s degree in pharmacy technology,
- Completion of a technician training course specified by the board,
- Graduation from a school of pharmacy recognized by the board, or
- Certification by the Pharmacy Technician Certification board.

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

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

The results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam, consistent with the requirements in B&PC 139. The board was advised in 2010 that the Department of Consumer Affairs’ Office of Professional Examination Services (OPES) will conduct these evaluations for the board. The board signed an interagency agreement with the OPES.
Recent Update
Board staff has been working with OPES to coordinate two workshop dates required for this as part of this review. The workshop dates have been identified as June 5-6, 2013, and July 16-17, 2013, in Sacramento, CA. Board staff has been recruiting licensed pharmacy technicians and pharmacist to participate in the workshops.

Discussion
Chair Veale provided an overview of the agenda item. Virginia Herold informed the committee there would be more information after the July review.

There was no additional committee or public discussion


Relevant Statutes
Business and Professions Code Section 4062 sets forth the general parameters for furnishing dangerous drugs during an emergency.

Business and Professions Code Section 900 sets for the general provisions that allow for health care practitioners licensed in another state to provide services in CA upon request of the Director of the California Emergency Medical Services Authority.

Background
Over the years, the board has dedicated resources to the subject of emergency response. The board’s current policy statement was developed and subsequently published in the January 2007 newsletter. Following that, the board’s licensing committee and the full board have discussed several aspects of emergency response and disaster planning.

Chair Veale provided a brief synopsis of actions taken by the board in this area:

January 2007 – Board published its Disaster Response Policy Statement. The plan essentially directs health care practitioners to use sound judgment and “take care of patients.”

September 2009 – Board secured a statutory amendment to Business and Professions Code Section 4062 to allow for the use of a mobile pharmacy in the event of a natural disaster.

October 2009 – Board voted to expand on the board’s emergency response policy to allow for any three members of the board to convene a meeting by teleconference, by electronic means or by other means of communication to exercise the powers delegated to the full board.

May 2012 - Board approved a draft regulatory proposal to require continuing education in specific content areas. One targeted area of continuing education is emergency response planning, as the board recognized the need of continuing education in this subject. (This regulation change has not been noticed yet.)
May 2013 - Board staff participated in Rx Response’s upcoming discussion-based disaster response exercise. The disaster response exercise is scheduled to include participants from the entire pharmaceutical supply chain.

Chair Veale identified copies of the relevant statutes, the board’s 2007 Disaster Response Policy Statement as well as information from CPhA and other agencies on disaster preparedness and opportunities for pharmacists to become involved provided in the committee meeting materials.

Discussion
Anne Sodergren provided the committee with an overview of the Rx Response’s discussion-based disaster response exercise that she and a board inspector participated in the previous week. Virginia Herold discussed the board’s current plan and indicated it was time to republish it again.

Satinder Singh from Walgreens addressed the committee and spoke in support of the board’s efforts in emergency response. Mr. Singh indicated that he assisted in the emergency response efforts for the Katrina disaster. Ms. Herold thanked him for his efforts.

No additional committee or public comment was provided.

7. Competency Committee Report.

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)
The board instituted a quality assurance review of the CPJE effective April 1, 2013. This process is done periodically to ensure the reliability of the examination. As of the date of this report, the quality assurance review is still under review. Based on historical patterns, the board anticipates results being released approximately May or June 2013. The board encourages all qualified applicants to continue to schedule and take the CPJE exam. The greater the number of applicants who take the exam during this review period, the sooner results can be released.

Examination Development
Competency Committee workgroups continued to conduct examination development meetings during the spring of 2013. Both Competency Committee workgroups will meet August 2013 at the annual meeting to discuss examination development.

Chair Veale provided an update of the agenda item. No committee or public comment was provided.

8. Licensing Statistics.

Licensing Statistics for July 2012 – April 2013
Chair Veale provided a summary of some of the licensing statistics for July 2012 to April 2013. During these past ten months, the board received over 13,300 applications and issued over 11,400 licenses. The number of applications received decreased approximately 10% and the number of licenses issued decreased approximately 3% when compared to the same time periods last fiscal year.
No committee or public comment was provided.

9. **Public Comment for Items Not on the Agenda**

No public comment was provided.

Chair Veale adjourned the meeting at 11:09 a.m.