



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

**DATE:** Dec. 14, 2016

**LOCATION:** Hilton Glendale  
100 W. Glendale Blvd.  
Glendale, CA 91202

**BOARD MEMBERS  
PRESENT:** Amy Gutierrez, PharmD, President  
Deborah Veale, RPh, Vice President  
Victor Law, RPh, Treasurer  
Ryan Brooks, Public Member  
Lavanza Butler, RPh  
Greg Lippe, Public Member  
Allen Schaad, RPh  
Stanley Weisser, RPh  
Albert Wong, PharmD

**BOARD MEMBERS  
NOT PRESENT:** Valerie Muñoz, Public Member  
Ricardo Sanchez, Public Member

**STAFF  
PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Desiree Kellogg, Deputy Attorney General  
Janice Dang, Supervising Inspector  
Katherine Sill, Inspector  
Trang Song, Inspector  
Debbie Damoth, Staff Manager

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**Note:** A webcast of this meeting may be found at:  
<http://www.pharmacy.ca.gov/about/meetings.shtml>

**Wednesday, Dec. 14, 2016**

Call to Order

8:37 a.m.

**I. Call to Order, Establishment of Quorum and General Announcements**

President Gutierrez called the meeting to order at 8:37 a.m. Board members present: Ryan Brooks, Greg Lippe, Debbie Veale, Amy Gutierrez, Victor Law, Stan Weisser, Lavanza Butler, Allen Schaad.

**II. Closed Session**

President Gutierrez announced the board would meet in closed session to discuss the following litigation: Santa Clara County Superior Court Case No. 16 CV 302071.

The board recessed into closed session at 8:38 a.m.

Dr. Wong arrived at 8:38 a.m.

The board ended closed session at 9:46 a.m. and recessed for a break. The board reconvened in open session at 9:56 a.m.

**III. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

A speaker said the board should have followed the order of items on the agenda and waited until the end of the meeting to go into closed session.

A speaker from Providence Health & Services asked for guidance from the board on whether replacing the word “expiration” on inpatient medication labels with “Do not use after” would be acceptable under new compounding regulations taking effect in 2017. President Gutierrez said the board would refer the question to Enforcement and Compounding Committee for discussion at its Jan. 24 meeting. Ms. Herold requested the speaker provide examples for the committee meeting.

**IV. Discussion and Consideration of Proposed Regulations to Amend and Add Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements**

President Gutierrez reported that at the July 2013 board meeting, the board approved proposed text to amend and/or add Title 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

President Gutierrez said the 45-day comment period began on Aug. 12, 2016, and ended Sept. 26, 2016, and the board received a few comments. At the October 2016 board meeting, the board approved a modified text to address concerns expressed by stakeholders and initiated a 15-day comment period.

President Gutierrez said the 15-day comment period began on Oct. 27, 2016, and ended on Nov. 11, 2016. She said the board received no comments during the 15-day comment period.

President Gutierrez said staff requested the board to discuss the regulation and formally adopt the regulation as noticed for comment on Oct. 27, 2016. She noted that a copy of the text was included in the meeting materials as Attachment 1.

There was no board discussion.

There was no public comment.

**Motion:** Adopt the regulation language as noticed on Oct. 27, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

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 . omitting ~~Traffic infractions under \$300 \$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 adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproof.
- (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: 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.

Adopt 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, 2017~~4~~.
  - (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 adverse licensure

- or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
- (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: 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.

Adopt 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, 2017~~4~~.
- (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 adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
- (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 : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**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. 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.
- (b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproof.

Authority: Section 4005, Business and Professions Code.

Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

M/S: Weisser/Butler

Support: 9      Oppose: 0      Abstain: 0

| Name      | Support | Oppose | Abstain | Not Present |
|-----------|---------|--------|---------|-------------|
| Brooks    | x       |        |         |             |
| Butler    | x       |        |         |             |
| Gutierrez | x       |        |         |             |
| Law       | x       |        |         |             |
| Lippe     | x       |        |         |             |
| Muñoz     |         |        |         | x           |
| Sanchez   |         |        |         | x           |
| Schaad    | x       |        |         |             |
| Veale     | x       |        |         |             |
| Weisser   | x       |        |         |             |
| Wong      | x       |        |         |             |

**V. Discussion and Consideration of Proposed Regulation to Add Title 16 CCR section 1715.65 Relating to Inventory Reconciliation Report of Controlled Substances**

President Gutierrez reported that at the July 2016 board meeting, the board approved proposed text to add section 1715.65 of Title 16 CCR, related to Inventory Reconciliation Reporting. The 45-day comment period began Sept. 16, 2016, and ended Oct. 31, 2016, during which the board received several comments.

President Gutierrez said staff asked the board to discuss the regulation and the comments received and to determine a course of action. She said the board's options include:

1. Adopt the regulation as approved at the July 2016 board meeting.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

President Gutierrez added that the meeting materials included a copy of the noticed text as approved at the July board meeting; a modified text with staff-recommended changes dated Dec. 2, 2016; a compilation of comments received during the 45-day comment period; and copies of the complete comments.

President Gutierrez said staff also recommended accepting a comment regarding section 1715.65(e) clarifying that a countersignature is not required if the pharmacist-in-charge or professional director of the clinic personally completed the inventory reconciliation. She agreed with the staff recommendation.

President Gutierrez said staff recommended rejecting all other comments. Ms. Sodergren informed the board that the modified text with staff-recommended changes includes grammatical changes that were made to improve the language of the regulation.

Public comment: Steve Gray of Kaiser Permanente asked the board to clarify whether a perpetual, manually maintained inventory would satisfy the regulation requirement. He said electronic data interchange (EDI) with automatic transfer of shipments from the wholesaler to the pharmacy provides a better safeguard against diversion than a perpetual inventory maintained by pharmacy staff.

Mark Johnston, NABP Executive Committee member and senior director of regulatory affairs for CVS Health, described CVS' perpetual inventory system and asked whether it would comply with the regulation requirement. Ms. Herold said a supervising inspector would be asked to advise CVS.

**Motion:** Amend the regulation language as recommended by staff, address the concerns expressed by stakeholders regarding countersignatures and notice the modified text for a 15-day comment period.

**Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

## 1715.65. Inventory Reconciliation Report of Controlled Substances

- a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
- b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
- c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
  - 1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
  - 2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
  - 3) A comparison of (1) and (2) to determine if there are any variances; and
  - 4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
- d) A pharmacy or clinic shall report in writing identified losses and possible causes, shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and security improvements necessary to prevent additional losses of controlled substances.
- e) Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
- e)f) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director, if a clinic, and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
- f)g) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report as required in subdivision (c).



~~g)~~ h) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

~~h)~~ i) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

- 1) All controlled substances added to an automated drug delivery system are accounted for;
- 2) Access to automated drug delivery systems is limited to authorized facility personnel;
- 3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- 4) Confirmed losses of controlled substances are reported to the board; ~~and~~
- 5) ~~A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

M/S: Weisser/Lippe

| Support: 9 |         | Oppose: 0 |         | Abstain: 0  |  |
|------------|---------|-----------|---------|-------------|--|
| Name       | Support | Oppose    | Abstain | Not Present |  |
| Brooks     | x       |           |         |             |  |
| Butler     | x       |           |         |             |  |
| Gutierrez  | x       |           |         |             |  |
| Law        | x       |           |         |             |  |
| Lippe      | x       |           |         |             |  |
| Muñoz      |         |           |         | x           |  |
| Sanchez    |         |           |         | x           |  |
| Schaad     | x       |           |         |             |  |
| Veale      | x       |           |         |             |  |
| Weisser    | x       |           |         |             |  |
| Wong       | x       |           |         |             |  |

**VI. Discussion and Consideration of Proposed Regulation to Amend Title 16 CCR sections 1735.2 and 1751 Relating to the Compounding Self-Assessment Form**

President Gutierrez reported that at the Aug. 31, 2016, Enforcement and Compounding Committee Meeting, the committee reviewed and discussed a new compounding self-assessment form that would reflect new regulation requirements and new compounding law enacted since the last iteration of the compounding self-assessment form. The

proposed new form includes the new compounding regulation components that will take effect Jan. 1, 2017.

President Gutierrez noted that at the October 2016 board meeting, the agenda inadvertently omitted the compounding self-assessment form. As a result, the board could not consider this self-assessment form when it reviewed and moved to public notice the self-assessment forms for pharmacies and wholesalers.

President Gutierrez said staff asked the board to move to the initial 45-day notice period for the compounding self-assessment form provided in an attachment. She said staff also specifically requested the following amendment to 16 CCR section 1735.2:

**1735.2. Compounding Limitations and Requirements; Self-Assessment.**

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. ~~02/12~~ 12/2016.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Mr. Law asked about the use of the abbreviation APP on Page 2 of the assessment form. Ms. Herold said it was an error that would be corrected as APH, the new license abbreviation for advanced practice pharmacist.

**Motion:** Move the compounding self-assessment form and the requested amendment to 16 CCR section 1735.2 to an initial 45-day comment period.

M/S: Lippe/Weisser

Support: 9      Oppose: 0      Abstain: 0

| Name      | Support | Oppose | Abstain | Not Present |
|-----------|---------|--------|---------|-------------|
| Brooks    | x       |        |         |             |
| Butler    | x       |        |         |             |
| Gutierrez | x       |        |         |             |

|         |   |  |  |   |
|---------|---|--|--|---|
| Law     | x |  |  |   |
| Lippe   | x |  |  |   |
| Muñoz   |   |  |  | x |
| Sanchez |   |  |  | x |
| Schaad  | x |  |  |   |
| Veale   | x |  |  |   |
| Weisser | x |  |  |   |
| Wong    | x |  |  |   |

**VII. Discussion and Consideration of Proposed Regulation to Amend Title 16 CCR section 1793.5 Relating to the Pharmacy Technician Application**

President Gutierrez reported that Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. She noted that Title 16 CCR section 1793.5 establishes the application requirements for licensure as a pharmacy technician and incorporates by reference the application form.

President Gutierrez informed the board that earlier this year, B&PC section 4202 was amended to modify one of the pathways, specifically the certification pathway. The amendment takes effect Jan. 1, 2017.

President Gutierrez noted that during the October 2016 board meeting, the board took action to accept either certification by the Pharmacy Technician Certification Board or certification by the ExCPT to satisfy the licensure requirement. She said that because the board’s application form requires updating to incorporate this change, a second regulation section must be amended.

President Gutierrez said staff recommends that the board review the proposed amended language and application form, approve the proposal and initiate a rulemaking.

**Motion:** Approve the draft regulation language to section 1793.5 and the application incorporated by reference to initiate the rulemaking process. Delegate authority to the executive officer to make clarifying changes consistent with the board’s policy direction upon recommendations by control agencies.

**§ 1793.5. Pharmacy Technician Application.**

The “Pharmacy Technician Application” (Form 17A-5 (Rev. ~~10/15~~ 10/2016)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

- (a) Each application for a pharmacy technician license shall include:
  - (1) Information sufficient to identify the applicant.

- (2) A description of the applicant's qualifications and supporting documentation for those qualifications.
- (3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
- (4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.
- (b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.
- (c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.
- (d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

M/S: Law/Weisser

Support: 9      Oppose: 0      Abstain: 0

| Name      | Support | Oppose | Abstain | Not Present |
|-----------|---------|--------|---------|-------------|
| Brooks    | x       |        |         |             |
| Butler    | x       |        |         |             |
| Gutierrez | x       |        |         |             |
| Law       | x       |        |         |             |
| Lippe     | x       |        |         |             |
| Muñoz     |         |        |         | x           |
| Sanchez   |         |        |         | x           |
| Schaad    | x       |        |         |             |
| Veale     | x       |        |         |             |
| Weisser   | x       |        |         |             |
| Wong      | x       |        |         |             |

**VIII. Stakeholder Summit Discussion on Implementation of Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including Its Impact on Pharmacy Translations and Interpretations**

Mr. Law informed the board that relevant provisions of the Section 1557 implementation rule require covered entities (e.g., pharmacies) to take reasonable steps to provide meaningful access to individuals with limited English proficiency (LEP). “Reasonable steps” may include providing language assistance services, such as oral language assistance or written translations. The rule specifically requires covered entities to post three types of publications:

- A notice of nondiscrimination
- A nondiscrimination statement
- Taglines - A tagline is a short statement written in a non-English language indicating that language assistance services are available at no cost.

Mr. Law reported that a cursory review indicates that the federal rule has a limited impact on existing California pharmacy laws and statutes. He said the key issue for the board’s concern would appear to be taglines, which resemble the “Point to your language” requirement in **CCR section 1707.6(c)**:

- CCR section 1707.6(c) requires “point to your language” text to be printed in 12 specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese.
- The Section 1557 rule requires that taglines be provided in the top 15 languages spoken in the state by people with LEP. In California, those languages are Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Mon-Kher/Cambodian, Hmong, Hindi and Thai. (Sources: [U.S. Department of Health and Human Services, Office for Civil Rights](#); CA Department of Finance.)

Two subsections of CCR section 1707.5, regarding patient-centered labels, include wording regarding languages on matters that does not appear in the federal rule:

- 1707.5(b) requires the board to translate label directions into five languages but does not specify which languages. The new federal rule appears silent on this matter.
- 1707.5(d) requires pharmacies to provide language assistance with label information for patients with LEP. However, 1707.5(d) does not specify which languages nor how many languages must be provided. The federal rule appears silent on this matter.

In response to a question from Mr. Lippe, Ms. Freedman informed the board that the federal rule supersedes CCR section 1707.6(c) and would apply to pharmacies that have 15 or more employees and that receive federal funding.

Mr. Lippe and Ms. Veale asked if the board would have to change section 1707.6(c). Ms. Herold said section 1707.6(c) would have to be amended to match the federal rule so that state and federal standards on translation and interpretation requirements are consistent and a single standard of care applies to all pharmacies. She reported that stakeholders who

were invited to discuss the issue were unable to attend the board meeting because of scheduling conflicts. She suggested the board refer the matter to the Communication and Public Education Committee to hear from stakeholders and to get answers to ambiguities in the federal rule.

President Gutierrez asked why section 1707.6(c) would have to be changed, since it would be superseded by federal law. Ms. Freedman explained that the federal requirement would not apply to pharmacies that have fewer than 15 employees and do not receive federal funding. Ms. Herold added that the language of the federal law is ambiguous about what is required and when.

Ms. Veale noted that the federal rule identifies Chinese as one of the required languages, while the state regulation specifies Mandarin and Cantonese. Mr. Wong explained that Mandarin and Cantonese are the same in written form.

Mr. Brooks asked if a certain software program or standard for translating languages is required. Ms. Herold said that a statutory modification allows pharmacists to do translations if they wish, or they can use 15 examples of directions for use in five languages created by the board, if appropriate – but the board does not recommend any particular type of translation service for use. Mr. Brooks expressed concern that pharmacists might use flawed translation software programs or online services, leaving patients at risk of harm. President Gutierrez added that companies that offer translation services often assume no responsibility for flawed translations.

President Gutierrez asked if, in light of the new federal requirement for translation services, state regulations are needed at all. She suggested that very few pharmacies do not receive federal funding, and therefore very few pharmacies would not be covered by the federal rule. President Gutierrez suggested that the board use the federal requirements as the standard and eliminate state regulations that duplicate the federal rules.

Ms. Herold noted the state regulations include other patient-centered requirements beyond translation and interpretation requirements. Ms. Veale said the Communication and Public Education Committee should review the differences between state and federal regulations in order to make a recommendation to the board.

President Gutierrez asked the Communication and Public Education Committee to review the federal rule and its impact on state regulations and to return with a recommendation to the board. Ms. Veale said the committee also could look at information that was included in the board meeting materials on best practices for making prescription drug labels accessible to patients who are blind, visually impaired or elderly.

Public comment: Steve Gray of Kaiser Permanente expressed support for more discussion of the federal rule by the Communication and Public Education Committee. He said the federal

rule raises questions about who is covered and what is required under the law. He also noted that some pharmacies accept cash only and do not receive federal funding.

**IX. Discussion and Consideration of a Proposal Regarding Ambulances Restocking Medications Using Automated Drug Delivery Systems**

Ms. Kellogg informed the board that California pharmacy law currently allows for one method of distributing medications to approved service providers within emergency medical services systems: pursuant to Business and Professions Code section 4119(b), a pharmacy may furnish dangerous drugs or devices to ambulances within an emergency medical services system in accordance with the policies and procedures of the local emergency medical services agency. She noted that federal bills to amend the Controlled Substances Act to provide for the distribution of controlled substances to emergency medical services agencies are pending.

Ms. Kellogg explained that the board is being asked to consider securing the enactment of another statutory or regulatory option for distribution of dangerous drugs and devices to emergency medical services systems. In response to a question from President Gutierrez, Ms. Kellogg indicated that section 4119 addresses only how a pharmacy may dispense drugs to an emergency medical services agency and does not address a physician or anyone else receiving from a wholesaler.

Mr. Weisser acknowledged that EMTs already are dispensed controlled substances and use them. He said that the board should learn more about how EMTs are trained to use controlled substances before making them more available to EMTs. President Gutierrez said that since EMTs already are receiving them, the issue is how are drugs are furnished to them and how are they controlled.

President Gutierrez said current law does not allow firefighters to have automated dispensing cabinets in fire departments. She explained that the Los Angeles County Fire Department wants the board to help sponsor or support legislation that would allow fire departments to have automated dispensing cabinets to track and control drug inventory in fire stations and ambulances.

Ms. Herold said some fire departments have wholesaler licenses and they buy the drugs centrally under the authority of the medical director, who uses the drugs to distribute and to replenish ambulances. She said LA County Fire Department wants the system to be more operational so that, instead of going out to deliver drugs to ambulances, the ambulances can go to nine different regional fire stations where the automated drug dispensing cabinets would be placed and could receive the wholesale drugs. She said the EMTs could sign and remove the drugs from the machines, which would have a count and an inventory. President Gutierrez added that the automated cabinets in the fire stations would be connected to a central brain at the warehouse that could manage and monitor the drugs.

President Gutierrez added that the issue is how to provide tools so that the medical director, whose DEA license is responsible, can better track and monitor the drugs. Ms. Kellogg said current law covers locating automated drug dispensing machines only in pharmacies and could not be applied to fire stations. She said the board's options to remedy the situation include changing the law to allow the machines in fire stations or getting a new law passed to cover fire stations. President Gutierrez added that another option would be to add fire departments that are part of an emergency medical services system to hospitals and clinics as locations that can house the automated cabinets.

Ms. Herold said that fire departments may use a wholesaler licensed by the board, but the wholesaler can only ship to a licensed entity. She said that makes it problematic for fire departments to ship to an automated drug dispensing machine because it is not in a licensed location with oversight.

Mr. Weisser expressed concerns about allowing controlled drugs in environments with no oversight. Ms. Veale said the proposed system would provide more control over the drugs.

Public comment: Steve Gray of Kaiser Permanente expressed support for a full discussion. He said that most ambulances are resupplied from pharmacies at hospitals.

A speaker from Orange County Health Care said that EMS practices differ among counties, so the board should get statewide input. He also urged the board to address paramedic units as well as ambulances and noted that paramedics are able to use more drugs than ambulances. He said that since 1999, Orange County has used automated dispensing machines by setting up purchasing through specialized wholesalers for EMS who treat the fire department as a physician's office or clinic and send those drugs to that office, which has the automated drug dispensing machines at the fire stations.

The speaker said that the EMS director has multiple DEA registrations for all the sites that have automated dispensing machines. He noted that fire departments have limited budgets and asked if departments would be required to hire pharmacists. He noted that some fire stations already have DEA registrations because the CDC has placed antidotes at these sites.

In response to a question from Mr. Weisser, the speaker said the number of drug losses has decreased since the automated dispensing machines were installed. He said drugs are ordered at a central location under a physician's DEA number and sent out to be loaded into the automated dispensing machines. The drugs are delivered to the sites by EMS, a paramedic or a supervising nurse. Each paramedic has his own ID to get the drugs out.

## **X. Closed Session**

The board met in closed session to discuss disciplinary matters. The board did not discuss any examination items in closed session.



The board recessed into closed session at 11:03 a.m. and reconvened in open session at 11:37 a.m.

**XI. Discussion and Consideration of a Proposal Regarding Ambulances Restocking Medications Using Automated Drug Delivery Systems (continued)**

Dr. Clayton Kazan, medical director of the Los Angeles County Fire Department, gave the board a brief presentation on the various fire departments serving communities in Los Angeles County and provided background on the issue of restocking ambulance medications. He said the LA County Fire Department serves 4 million people in 58 cities with 170 fire stations spread over 2,300 square miles.

Dr. Kazan said his department carries morphine and midazolam and historically has obtained them through the county hospital system. The drugs are taken in a locked bag from the hospital pharmacies to the field units. He said the system is so slow and onerous that paramedics are reluctant to use the drugs, which has resulted in a vast undertreatment of pain in patients. Dr. Kazan said the county also will not dispense fentanyl to the fire department because the drug has higher rate of diversion, even though fentanyl has become the standard of care for EMS across the country. As a result, paramedics must use IVs to deliver morphine to children, but many paramedics lack experience in giving IVs to children, so pediatric patients often receive no pain medication at all.

Dr. Kazan said the county hospital pharmacy director informed the fire department about a year ago that “we want to get the fire department off of our DEA license” and transition it to Dr. Kazan’s license. Dr. Kazan said he was unwilling to use his license because the department has such a poor system of tracking and monitoring drugs in the restocking process. Instead, the department wants to create a system that will allow better tracking and monitoring of drugs over a broad geographic area. He said the way to do that is to use automated drug dispensing machines, which would allow field paramedic units to restock themselves while allowing the central hub to monitor where every drug is throughout the county without having to be present for a live restock.

Dr. Kazan said the major EMS players met with county pharmacies and the DEA in May or June 2016. He said local DEA regulators advised the fire department to apply for a waiver from DEA in Washington. Dr. Kazan said the DEA denied the waiver but advised the fire department that current DEA regulations would not preclude the department from moving forward as long as the department complied with all reporting and tracking requirements.

Dr. Kazan said the issue is with the state of California. He said the county fire department would probably need about 25 automated drug dispensing machines, and tracking shipments to 25 machines would be a high risk. He said a large department is better served by a hub-and-spoke model, where deliveries would be made to a central hub and distributed out to satellite machines from the hub. But if the department delivers more

than 5 percent of its total deliverables out to satellite machines, the department become a drug distributor and falls under the board's jurisdiction.

Dr. Kazan told the board that the fire department would like to install a C2 safe and hire a pharmacist to administer the program at its headquarters, which is in a secure location, and receive deliveries at that central location. From there, he said, medications would be scanned in and scanned out for delivery to satellite machines.

In response to a question from Mr. Lippe, Dr. Kazan and President Gutierrez said the Los Angeles County hospital pharmacy director wants to remove the fire department from his DEA registration because of the risk of possible diversion and the inability to track and monitor drugs under the current system. In response to a question from Mr. Weisser, President Gutierrez said she was not aware of any board investigations of the LA County Fire Department because of drug diversions.

Mr. Weisser expressed concern about controlled drugs going to entities with no oversight. He urged the board to look into how oversight would be provided in a situation where an EMT takes a 3 cc ampule of morphine but administers only some of it. Dr. Kazan said that currently, the par level of every vehicle is inspected every day and signed by two medics, and the records are kept at the EMS headquarters. He said that any morphine waste is done at the hospital and signed by a nurse, and the waste is accounted in the daily check off.

Dr. Kazan said the fire department is working with outdated technology that has not kept pace with the growth of the department and the EMS system. He added that many other EMS systems face the same issue. He said the proposed system potentially could also be used by private agencies, including AMR. Mr. Weisser said he would be concerned about oversight of controlled drugs used by private companies as well.

Ms. Veale asked if LA County Fire Department was seeking a waiver or a change in statute. Dr. Kazan said he was seeking a waiver from the board to allow all fire departments within Los Angeles County to proceed with using automated drug dispensing systems. He said there also is shift under way to move to using medical directors' licenses, which raises concerns for medical directors who could lose their licenses if drugs are diverted.

Ms. Herold informed the board that there is no waiver process because there currently is no law to be waived. She said there is no authorization for a fire department to establish an automated drug delivery system. In response to a question from President Gutierrez, Ms. Herold said the board cannot grant a waiver to allow a pilot program using language allowing automated dispensers in clinics and hospitals, because that is a statutory provision. She said that the board can do pilot studies only on regulations, and the only regulation available is one that allows a refill dispensing machine to be immediately adjacent to a pharmacy. She said there is nothing that would allow an automated dispenser to be located in a building where no health care is being delivered.

Ms. Kellogg said two pending federal bills might resolve the problem. In addition, she said the board could seek amendments to existing statutes on automated drug dispensers or seek a new statute. Dr. Kazan said HB 4365 and SB 2932 both propose amendments to the Controlled Substances Act that would allow EMS departments to store drugs and give the medications on standing orders. He said HB 4365 passed but did not get through the Senate before the winter break, so the bill would have to be reintroduced in Congress in 2017.

In response to a question from Mr. Brooks about possible board action, Ms. Freedman said the board would first have to amend a statute to allow an automated drug delivery system to be located somewhere else. Ms. Herold said the LA County Fire Department would work with the board to develop a proposed statute for the Legislature that would include a pharmacy-based solution as opposed to the proposed federal legislation, which would create an EMS-based solution. In response to a timeline question from President Gutierrez, Ms. Herold said a bill could be in place by the end of 2017. She said working with fire department on a proposed bill would create a solution giving the fire department what it needs to take care of patients while providing the board with a way to maintain security of automated drug dispensers in locations where no health care is being provided. She said that having fire departments hire pharmacists to run the system is one of the requirements that the board could set.

Mr. Weisser said any proposal should first go to a board committee to explore opportunities for working with the fire department and perhaps help draft language and then refer it to the full board. Board members suggested the Licensing Committee review the matter at its Jan. 10, 2017, meeting. In response to a question from Mr. Brooks, Dr. Kazan said there is no draft language yet, but a working group of statewide EMS directors has been set up to work with the board on a bill.

Dr. Kazan added that the LA County Fire Department faces a July 1, 2017, deadline to be out of the county pharmacy system, and that without a method of procuring drugs that is safe and reliable, all paramedic functions would cease. President Gutierrez clarified that the July deadline is to transfer responsibility from the county license to the physician DEA number. She said the county pharmacies are willing to continue the process, but they do not want responsibility for a process over which they have no oversight.

Dr. Kazan told the board the he is not willing to take responsibility for the current system under his DEA license. Ms. Herold suggested that LA County Fire Department may be able to use draft statutory language to obtain a reprieve from the county while the bill moves through the legislative process.

**Motion:** Direct staff to report to the Licensing Committee at its next meeting on the statute that would have to be changed and make recommendations that could be presented to the full board at its January meeting.

M/S: Veale/Weisser

Support: 8                      Oppose: 0                      Abstain: 1

| <b>Name</b> | <b>Support</b> | <b>Oppose</b> | <b>Abstain</b> | <b>Not Present</b> |
|-------------|----------------|---------------|----------------|--------------------|
| Brooks      | x              |               |                |                    |
| Butler      | x              |               |                |                    |
| Gutierrez   |                |               | x              |                    |
| Law         | x              |               |                |                    |
| Lippe       | x              |               |                |                    |
| Muñoz       |                |               |                | x                  |
| Sanchez     |                |               |                | x                  |
| Schaad      | x              |               |                |                    |
| Veale       | x              |               |                |                    |
| Weisser     | x              |               |                |                    |
| Wong        | x              |               |                |                    |

## **XII. Closed Session**

President Gutierrez announced the board would meet in closed session to discuss the following items of litigation:

- Sacramento Superior Court Case No. 34-2016-80002456
- Riverside County Superior Court, Palm Springs Branch, Case No. PSC 1604591
- Los Angeles Superior Court Case No. SC126060

The board recessed into closed session at 12:07 p.m. and reconvened in open session at 1:10 p.m.

## **XIII. Adjournment**

The board adjourned at 1:11 p.m.