California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES

DATE: September 27, 2016

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1747 North Market Blvd
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Stanley Weisser, Chairperson
Debbie Veale, Vice-Chairperson
Albert Wong, Licensee Member
Lavanza Butler, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel

Note: To accommodate presenters' schedules, the committee took agenda items out of order. For ease of use, the minutes reflect the discussion of the committee in the order the items were included on the agenda.

1. Call to Order and Establishment of Quorum

Chairperson Weisser called the meeting to order at 9:08 a.m. Roll call was taken with the following members present: Lavanza Butler, Stan Weisser, Debbie Veale and Albert Wong.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

A representative from the California Society of Health Systems Pharmacists (CSHP) expressed concerns with testing date availability for the CPJE and indicated that they believe the exam is getting more difficult. In addition public comment requested that the committee discuss the 90-day waiting periods for the NAPLEX and CPJE and expressed concern about how the waiting period can impact an individual's residency.

3. Discussion on Implementation of Provisions Contained in Senate Bill 1193

Chairperson Weisser advised the committee that Senate Bill 1193 was recently signed by the Governor. Mr. Weisser noted that the bill provides for an extension of the board's sunset date as well as includes many important changes to pharmacy law. Chair Weisser advised the committee of three areas of pharmacy law impacted by this measure that impact application and/or licensure requirements.

a. Incorporate Trusts as an Entity Authorized of Obtain Licensure

Chair Weisser reminded the committee that for several meetings, the committee discussed the issue of trust ownership, primarily related to pharmacy ownership structures and more recently during the July 2016 Board Meeting, the board approved statutory changes as the first step to allowing such ownership. Chair Weisser referred the committee to the proposed regulation language.

Matthew Heyn with the Office of the Attorney General providing an overview of the proposal. Mr. Heyn indicated that the proposal is intended to provide the board with information to determine who owns and who controls a trust. He noted that the board needs this information to understand the ownership and control of the trust. Mr. Heyn also explained why the regulation includes an age restriction related to the disclosure as well as the need for various individuals involved in the trust to be disclosed.

Mr. Heyn indicated that if assets are transferred upon death, a change of ownership would be required, however if the trust currently owns the pharmacy, then the death would not result in a change of ownership because there is no change in the ownership or control of the pharmacy.

The committee discussed the proposal and noted that some of the proposed changes were not related specifically to the implementation of the trust ownership. Further, public comment expressed concern with the changes related to reporting changes in officers and administrators.

Motion: Recommend approval of the proposed regulation change to CCR section 1709 that include the provisions relating to the trust ownership as well as formatting changes. Remove provisions that are not related to the trust ownership.

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709.
(a) Each ~~permit~~ <u>license</u> to operate a pharmacy shall <u>display</u> ~~show~~ the name and address of the pharmacy, the form of ownership ~~(individual, partnership or corporation)~~ and the pharmacist-in-charge. ~~Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.~~

(b) Each pharmacy, in its initial application and on the annual renewal form, shall report the name of the pharmacist-in-charge, and the name of each owner, manager, administrator, member, officer, director, associate, partner, or any other person in any position with management or control of the pharmacy. Any changes in the pharmacist-in-charge, or in the owner, manager, administrator, member, officer, director, associate, partner, or in any other position with management or control of the pharmacy, shall be reported to the board within 30 days.

~~(b)~~ (c) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.

~~(c)~~ (d) A license issued by the board shall not be transferred from one owner to another. The following shall constitute ~~a transfer of permit and require application for~~ a change of ownership of a business entity licensed by the board: any transfer in a single transaction or in a series of transactions of ~~a~~ 50 percent or more of the beneficial interest in a business entity licensed by the board ~~a business entity licensed by the board, in a single transaction or in a series of transactions,~~ to any person or persons that did not hold a beneficial interest at the time the original permit was issued, ~~which results in the transferee's holding 50% or more of the beneficial interest in that license~~. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.

(e) The board may issue a license to an entity that is controlled by a revocable or irrevocable trust.

(f) Where an applicant for an entity is controlled by a trust, the applicant shall disclose the full name of the trust, and shall provide to the board a complete copy of and any amendments to the trust document. A trust document and any related amendments shall not be subject to disclosure by the board.

(g) The applicant shall disclose at application and at each renewal the name, address and contact information for each grantor, settlor, trustee, trust protector, as applicable, all of which shall be subject to approval by the board. In addition, the applicant shall disclose the name, address and contact information for each beneficiary named in the trust that is age 18 or greater, which shall be subject to approval by the board.

(h) The trustee or trust protector or any other position with management or control of the pharmacy, shall notify the board within 30 days of any change to the trustee or trust protector. A new trustee or trust protector shall be subject to the approval of the board.

(i) The trustee or trust protector or any other position with management or control of the pharmacy, shall notify the board within 30 days of any change in beneficiaries of the trust, where the beneficiary is age 18 or older. Each new beneficiary age 18 or older shall be subject to the approval of the board.

(j) Where a license is held or controlled by a revocable trust, the t trustee or trust protector or any other position with management or control of the pharmacy, shall notify the board within 30 days of the trust being revoked.

(k) Where a license is held or controlled by an irrevocable trust, the trustee or trust protector or any other position with management or control of the pharmacy, shall notify the board within 30 days of the trust being dissolved.

(l) The trustee or trust protector or any other position with management or control of the pharmacy, shall provide to the board within 30 days any amendment(s) to the trust document not provided with the original application.

(m) A trust that has a beneficiary or trustee or any person that is prohibited from management or control of a license issued by the board shall not hold a pharmacy license nor possess a material beneficial interest in a business entity licensed by the board.

M/S: Veale/Butler
Support: 4 Oppose: 0 Abstain: 0

b. Licensure of Outsourcing Facilities

Chair Weisser advised the committee that under federal law an outsourcing facility is a facility that compounds human drugs under specified conditions. Mr. Weisser noted that
the FDA's regulation of an outsourcing facility will be done according to compliance with good manufacturing practice requirements and the other requirements of Section 503B.

The committee discussed the provisions in SB 1193 which establish the board's ability to regulate outsourcing facilities that provide compounded medications in California. As part of the discussion, the committee noted that similar to the board's regulation of sterile compounding pharmacies, outsourcing facilities will be inspected by the board prior to issuance of a license as well as prior to renewal.

The committee was advised of implementation efforts underway including working with the department's information systems to secure changes to the computer system as well as an interim workaround system that will be manual process.

c. E-mail Notification List Requirement

Chair Weisser indicated that for many years the board has used an email subscriber alert system as a quick and efficient way to communicate with licensees. Chair Weisser referenced the Business and Professions Code section 4013 which establishes the requirement for businesses licensed by the board to join the board's email notification list within 60 days of obtaining a license or at the time of renewal.

The committee discussed similar provisions in SB 1193 that will impact pharmacists, interns, pharmacy technicians and designated representative-3PLs. The committee discussed efforts underway to implement the new requirements.

As part of the discussion, the committee was advised of a drafting error with the provisions in SB 1193 in that the designated representative license category was inadvertently not included. As part of its discussion, the committee discussed the need

to secure a statutory change to remedy the drafting error and proposed language that could be used to facilitate the change.

MOTION: Recommend approval of the proposed statutory change to amend section 4013 to include designated representatives in the list of individuals required to join the email notification.

Section 4013 of the Business and Professions Code is amended to read:
(a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.

(b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

(d) (1) Each pharmacist, intern pharmacist, pharmacy technician, <u>designated representative,</u> designated representative-3PL licensed in this state shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.

(2) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall update his or her email address with the board's email notification list within 30 days of a change in the licensee's email address.

(3) The email address provided by a licensee shall not be posted on the board's online license verification system.

(4) The board shall, with each renewal application, remind licensees of their obligation to report and keep current their email address with the board's email notification list.

(5) This subdivision shall become operative on July 1, 2017.

M/S: Veale/ Wong
Support: 4 Oppose: 0 Abstain: 0

4. Discussion and Consideration of Possible Revisions to the Board's Fee Schedule (Title 16 CCR §1749) to Implement the Provisions Contained in Senate Bill 1039

Chair Weisser reminded the committee that the board has been discussing its budget and the structural imbalance between its authorized expenditures exceeding its revenue. To address this issue the board worked with the Department of Consumer Affairs on a fee analysis, where the department determined the cost the board incurs to provide various services. Mr. Weisser noted that the results of this analysis were included in the board's Sunset Report Mr. Weisser noted that the results of the fee analysis were also the basis for the new fee structure included in Senate Bill 1039 which was awaiting action by the Governor. The committee was advised that, if approved, the new fees will take effect July 1, 2017.

The committee discussed the need to pursue a regulation change to provide the board's regulated public with a clear understanding of the fees that will be assessed for the various services, including application and renewal as well as delinquent fees.

Dr. Wong suggested that the board should offer more free continuing education on prescription drug abuse with the Drug Enforcement Administration and offer such education in different locations as a way to give back to its licensees.

Dr. Gray requested information on how the renewal fees were established and was advised renewal fees were based on the fee analysis prepared by the DCA.

The committee reviewed a regulation proposal to amend Title 16 CCR 1749 with the goal to have the regulation change in effect by July 1, 2017, to avoid confusion for the regulated public.

Motion: Assuming the Governor signs SB 1039, approve the draft regulation proposal to amend 16 CCR section 1749. (language below)

Proposal to Amend California Code of Regulations Section 1749 Fee Schedule

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is ~~three hundred twenty-five dollars ($325)~~ six hundred sixty five dollars ($665). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars

($325).
(c) The fee for the issuance of a pharmacy technician license shall be ~~one hundred five dollars ($105)~~ one hundred and forty dollars ($140). The fee for the biennial renewal of a pharmacy technician license shall be ~~one hundred thirty dollars ($130)~~ one hundred forty dollars ($140). The penalty for failure to renew a pharmacy technician license is ~~sixty-five dollars ($65)~~ seventy dollars ($70).
(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).
(e) The fee for regrading an examination is one hundred fifteen dollars ($115).
(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).
(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.
(g) (1) The fee for the biennial renewal of a pharmacist's license is ~~one hundred ninety-five dollars ($195)~~ three hundred sixty dollars ($360). The penalty fee for failure to renew is ~~ninety-seven dollars fifty cents ($97.50)~~ one hundred fifty dollars ($150).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150).
(h) The fee for the issuance or renewal of a wholesaler's license or third-party logistics provider is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.
(i) The fee for the issuance ~~or renewal~~ of a hypodermic license is ~~one hundred sixty five dollars ($165)~~ one hundred seventy dollars ($170). The fee for the annual renewal of a hypodermic needle license is two hundred dollars ($200). The penalty for failure to renew is ~~eighty two dollars fifty cents ($82.50)~~ one hundred dollars ($100).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code or designated representative-3PL pursuant to Section 4053.1 ~~shall be three hundred thirty dollars ($330)~~ is one hundred fifty dollars ($150). The fee for the annual renewal of a license as a designated representative shall be ~~one hundred ninety five dollars ($195)~~ two hundred and fifteen dollars ($215). The penalty for failure to renew is ~~ninety seven dollars and fifty cents ($97.50)~~ one hundred seven dollars and fifty cents ($107.50).
(k) The fee for the issuance or renewal of a license as a nonresident wholesaler or nonresident third-party logistics provider is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is five hundred dollars ($550).
(l) The fee for an intern pharmacist license is ~~one hundred fifteen dollars ($115)~~ one hundred sixty-five dollars ($165). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for the reissuance of any license that has been lost or destroyed or

reissued due to a name change is forty-five dollars ($45)
~~(n)~~ (o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
~~(o)~~ (p) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).
~~(p)~~ (q) The fee for the issuance of a nongovernmental license, ~~or renewal of a license,~~ to compound sterile drug products is ~~seven hundred eighty dollars ($780)~~ one thousand six hundred forty-five dollars ($1645). The fee for the annual renewal of a nongovernmental license to compound sterile drug products is one thousand three hundred twenty-five dollars ($1,325). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is five hundred dollars ($550).
(r) The fee for the issuance of a nonresident sterile compounding pharmacy is two thousand three hundred eighty dollars ($2,380). The fee for the annual renewal of nonresident sterile compounding pharmacy license is two thousand two hundred seventy dollars ($2,270). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary license is five hundred dollars ($550).
~~(q)~~ (s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer ~~shall be three hundred thirty dollars ($330)~~ is one hundred fifty dollars ($150). The fee for the annual renewal of a license as a designated representative ~~shall be one hundred and ninety-five dollars ($195)~~ is two hundred fifteen dollars ($215). The penalty for failure to renew is ~~ninety-seven dollars and fifty cents ($97.50)~~ is one hundred seven dollars and fifty cents ($107.50).
~~(r)~~ (t)The fee for a veterinary food-animal drug retailer license is ~~four hundred twenty-five dollars ($425)~~ four hundred and thirty-five dollars ($435). The annual renewal fee for a veterinary food-animal drug retailer is ~~three hundred twenty-five dollars ($325)~~ three hundred thirty dollars ($330). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is ~~one hundred twenty five dollars ($125)~~ one hundred fifty dollars ($150).
~~(s)~~ (u) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).
~~(t)~~ (v) The fee for the issuance of a centralized hospital packaging pharmacy license ~~shall be $800~~ is eight hundred twenty dollars ($820). The annual renewal fee for a centralized hospital packaging pharmacy license ~~shall be $800~~ is eight hundred five dollars ($805). The penalty for failure to renew is one hundred fifty dollars.
(w) The fee for the issuance of an outsourcing facility license is two thousand two hundred seventy dollars ($2,270). The annual renewal fee for an outsourcing facility is one thousand three hundred twenty-five dollars ($1,325). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary outsourcing facility license is seven hundred fifteen dollars ($715).
(x) The fee for the issuance of a nonresident outsourcing facility license is two thousand three hundred eighty dollars ($2,380). The annual renewal fee for a nonresident outsourcing facility is two thousand two hundred seventy dollars ($2,270). The penalty for failure to renew is one hundred fifty dollars ($150).

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4053, 4053.1, 4110, 4112(h), 4120, 4128.2, 4129.1,

4129.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

M/S: Veale/Butler
Support: 4 Oppose: 0 Abstain: 0

5. Discussion and Consideration of Next Steps Necessary to Implement Senate Bill 952 Relating to Pharmacy Technician Licensure Requirements (SB 952, Chapter 150, Statutes of 2016)

Chair Weisser referenced Business and Professions Code section 4202 noting that it provides the general pathways to licensure as a pharmacy technician and that Senate Bill 952 modified the requirements to expand the certification requirement to include other agencies. Chair Weisser indicated that because of the language in the measure, the board is required to approve certification programs.

Chair Weisser reminded the committee of prior presentations on two certification programs, one offered by the Pharmacy Technician Certification Board (PTCB) and a second one offered by the National Healthcare Association (NHA) and noted that as part of its March 2016 committee meeting, the committee compared the two certification programs. During these presentations the committee was advised that both certification programs are accredited by the National Commission for Certifying Agencies.

Chair Weisser indicated that to facilitate implementation of this new provision the committee should consider a regulation that identifies which certification programs are approved by the board. Chair Weisser stated that in the interim the committee needs to determine how or if it wishes to approve such programs in advance of the regulation.

The committee discussed the regulation language as well as the need to include an expiration date of the board's approval. The committee noted that the expiration date would allow the board the opportunity to reevaluate programs, which seems appropriate given both the committee as well as the board's consideration of possible changes to the pharmacy technician program in California. Counsel offered suggestions to include an expiration date as part of the proposed regulation text.

As part of the public comment provided, the committee was advised of a drafting error in the proposed regulation language related to the reference to the NHA program.

Motion: Recommend to the board approval of the proposed language with an amendment to include an expiration date of January 1, 2021 and an amendment to correct the name of the NHA program. (language below)

Proposal to Add Section 1793.65

1793.65 Certification Programs Specified by the Board.

Pursuant to Business and Professions Code Section 4202(a)(4), the board approves the following

pharmacy technician certification programs:

a. Pharmacy Technician Certification Board

b. National Healthcareer Association Pharmacy Technician Certification Program

Note: Authority cited: Business and Professions Code Sections 4005, 4038, 4202. Reference: Business and Professions Code Sections 4005, 4038 and 4202.

M/S: Butler/ Veale
Support: 4 Oppose: 0 Abstain: 0

The committee continued its discussion and heard public comment in support of an interim approval of the technician certification programs until the regulations could be promulgated.

Motion: Recommend interim approval of the NHA ExCPT and the PTCB certification programs until the effective date of the regulation.

M/S: Veale/Wong
Support: 4 Oppose: 0 Abstain: 0

6. Discussion and Consideration of the Regulatory Proposal to Establish Operation Requirements for Third-Party Logistics Providers

Chair Weisser provided background on the item, reminding the committee that during the July 2015 Board Meeting, the board approved proposed regulation text to amend Title 16 CCR section 1780 et. seq., to establish the regulatory framework for third-party logistics Providers. Chair Weisser noted that the proposed regulations would establish the minimum standards by which such providers would need to comply which are consistent with current minimum standards for wholesalers.

The committee was reminded that this matter was later referred back to the committee after staff identified that additional modifications may be necessary.

The committee reviewed the proposed language and was advised that the primary change in this version of the language is the removal of a reference to a prior version of the United States Pharmacopoeia Standards in Section 1780(b). It was noted that board staff and counsel confirmed that compliance with the USP standards is already established as a requirement in federal law, both in the U.S. Code as well as in the Code of Federal Regulations and as such removal of the reference is appropriate.

Motion: Recommend to the board, approval of the proposed regulation language. (language below)

Amend *Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:*

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

To Amend *Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:*

1780. Minimum Standards ~~for~~ ~~Wholesalers.~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the ~~United States Pharmacopeia Standards (1990, 22nd Revision)~~ official compendium.

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.

(d) All materials must be examined upon receipt and/or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code; Section 321 of Title 21, U.S. Code; and Section 205.05 of Title 21, Code of Federal Regulations.

***Amend** Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:*

1781. ~~Exemption Certificate~~ Designated Representative.

A registered pharmacist, ~~or an~~ designated representative or designated representative – 3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's, ~~or~~ wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

***Amend** Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:*

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each manufacturers~~,~~ ~~and~~ wholesalers~~

Authority cited: Sections 4005 and 4164, Business and Professions Code~~; and Section 26692, Health and Safety Code~~. Reference: Sections 4053.1, 4081, 4164, and 4332, Business and Professions Code~~; and Section 26692, Health and Safety Code~~.

Amend *Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:*

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or~~ wholesaler or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises

from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

M/S: Veale/ Wong
Support: 4 Oppose: 0 Abstain: 0

7. Presentation by the Office of Statewide Health Planning and Development (OSHPD) on its Scholarship Loan Repayment Program

Chair Weisser noted that in 2002 the California Pharmacist Scholarship and Loan Repayment Program was established with the Office of Statewide Health Planning and Development. Chair Weisser indicated that the program is funded by voluntarily contributions of $25 that are collected as part of the renewal of pharmacist and pharmacy licenses.

The committee heard a presentation from a representative of OSHPD on the Health Professions Education Foundation, which is administered through OSHPD. The presentation included background information on foundation which awards scholarships and loan repayments to qualified health professionals, including pharmacists. The committee learned about the application and eligibility requirements and was advised that two pharmacists were awarded loan repayments in fiscal year 2015/16.

As part of its discussion, the committee was advised that OSHPD currently does not have staff available to administer the California Pharmacist Scholarship and Loan Repayment Program.

A copy of the presentation is provided as an attachment to the meeting minutes.

8. Discussion and Consideration of the National Association of Boards of Pharmacy's (NABP) Change in Policy Relating to the 91-Day Waiting Period for Candidates that Fail the NAPLEX

Chair Weisser noted that Business and Professions Code section 4200 establishes the requirements for licensure as a pharmacist including passage of the North America Pharmacist Licensure Examination (NAPLEX). Further section 4200.4 specifies that an applicant who fails the national examination may not retake the examination for at least 90 days or for a period established by regulation adopted by the board in consultation with the Office of Professional Examination Services (OPES).

Mr. Weisser advised the committee that in late July 2016, the NABP released information about changes in the administration of the NAPLEX including a change in the current waiting period a candidate must wait to retake the examination.

The committee asked about the logic behind the change and was advised by Ms. Herold

that the passing rate for the NAPLEX is going down and referenced the changes made to the administration of the NAPLEX.

The committee spoke in support of changes in the administration of the NAPLEX examination and requested that a letter be sent to the NABP acknowledging its support.

The committee discussed the current waiting periods for both the NAPLEX as well as the CPJE and if the changes would be appropriate.

The committee heard public comment in support of the reevaluation of the current waiting periods. Public comment also questioned, given the number of new pharmacy schools and students, if there are sufficient testing accommodations available to handle the additional students.

The committee noted the importance of safeguarding the integrity of the exam.

Motion: Work with the OPES to evaluate both the NAPLEX and CPJE and determine the appropriate waiting periods.

M/S: Butler/ Wong
Support: 4 Oppose: 0 Abstain: 0

The committee requested that this item be brought back to the committee after discussion and input from OPES.

9. Consideration of Request from Marshall B. Ketchum University, College of Pharmacy, for Recognition by the Board Under Title 16, California Code of Regulations Section 1719 for Purposes of Issuing Intern Licenses

Chairperson Weisser advised the committee of the provisions in regulation section 1719 states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE) or otherwise recognized by the board.

Chair Weisser noted that there are three levels to full ACPE accreditation status for new schools of pharmacy: pre-candidate status, candidate status and full accreditation. A school may be granted candidate status once the school has produced its first class of graduates. It was noted that before possessing candidate status and while students are moving through the program at a new school, the school may have pre-candidate status with ACPE which means that the school is progressing to meet the ACPE accreditation standards but has not yet completed the process nor graduated its first class. In such cases, the board must recognize the school for purposes of issuing an intern license in order to allow students to secure the training expected by ACPE.

The committee was advised that The Marshal B. Ketchum University, College of Pharmacy has been granted pre-candidate status by the ACPE. In order for the school's students to secure the training they need, the students need intern licenses.

Vice-Chair Veale advised the committee that she participated in the ACPE onsight survey of the school and indicated that the surveyors were impressed with the program. Ms. Butler indicated that she has participated in a review of another school and noted how thorough the reviews are by the ACPE.

The committee discussed the request from school.

Motion: Recommend the board recognize The Marshall B. Ketchum University, School of Pharmacy for purposes of issuing intern permits.

M/S: Veale/ Butler
Support: 4 Oppose: 0 Abstain: 0

10. Future Committee Meeting Dates

The committee reviewed meeting dates for 2017 detailed below:

- January 10, 2017
- April 4, 2017 (Pharmacy Technician Summit)
- June 29, 2017
- September 19, 2017

11. Licensing Statistics

The committee reviewed the licensing statistics for July 1, 2016 – August 31, 2016
The board has received 3,733 applications including:

- 1,083 pharmacy technicians
- 626 intern pharmacists
- 390 pharmacist exam applications

The board has issued 2,134 licenses and renewed 10,748 licenses. The board currently has 138,915 active licenses including:

- 43,974 pharmacists
- 6,607 intern pharmacists
- 73,318 pharmacy technicians
- 6,568 pharmacies
- 518 hospitals and exempt hospitals

The committee was advised that staff continues to work with the department on implementing Licensing Performance Measures (LPM) processing times for the boards and bureaus and is currently validating the board's monthly LPM reports for FY 2015/2016.

The committee also discussed the general processing times for various license types and was advised that processing times were longer for some categories then the 30-day time frame. These delays are due in part of vacancies as well as cyclical surges in workload that occur after graduation from the schools of pharmacy as well as enrollment in pharmacy schools.