

LICENSING COMMITTEE REPORT

Stan Weisser, RPh, Chairperson Greg Murphy, Vice Chairperson Ricardo Sanchez, Public Member Albert Wong, PharmD Allen Schaad, RPh Victor Law, RPh

1. Call to Order and Establish of Quorum

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

Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. [Government Code Sections 11125 and 11125.7(a)]

3. Consideration of Possible Revisions to Regulation(s) Regarding Pharmacy Technician Training Programs (Title 16 CCR §1793.6)

For several meetings, the committee has been discussing the requirements for licensure as a pharmacy technician. As part of its discussion the committee has reviewed the various pathways to licensure, as well as enforcement actions and denials of applications. The committee has heard presentations about the certification exams used for licensure, presentations by various employers about their training programs, as well as a presentation about upcoming changes to technician training programs accredited by the American Society of Health Systems Pharmacists.

The committee and board have expressed concern about some individuals that are seeking licensure through technician training programs (programs that can be quite costly) that have criminal backgrounds that most likely will result in denial of the application. The committee recognizes that not all such training programs are equal in terms of the quality of the program, but expressed concern that the minimum requirements established in law for such programs may no longer be adequate.

During the January 2016 board meeting, the board agreed with the recommendations of the committee in concept to modify Title 16 CCR section 1793.6 to strengthen the requirements of some pharmacy technician programs to include a minimum age requirement at admission (18 years old), a criminal background check and to administer at

least one drug test. Further, the program would be required to administer a final examination.

The committee discussed these possible changes again during its March meeting and advised the board during the April Board Meeting that it continues its efforts.

Update

Since the April Board Meeting, staff and counsel have revised the regulation proposal to further refine the language and address the specific areas identified by the board for discussion.

During This Meeting

The committee should discuss the proposed language as provided in **Attachment 1**.

4. Consideration of the Duties of a Pharmacy Technician and Discussion on the Pharmacist to Pharmacy Technician Ratio in the Community Pharmacy Setting

Business and Professions Code section 4115 specifies that a pharmacy technician may perform packaging, manipulative, repetitive or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. Further, Title 16 California Code of Regulations section 1793.2 specifies specific duties that may be performed by a pharmacy technician, as listed below. **Attachment 2** contains the various statutory and regulatory references related to pharmacy technicians.

Removing the drug or drugs from stock
Counting, pouring, or mixing pharmaceuticals
Placing the product into a container
Affixing the label or labels to the container
Packaging and repackaging

During the April Board Meeting the board requested that this committee discuss the current pharmacist to pharmacy technician ratio.

To begin this discussion, board staff suggests that the committee focus on the community practice setting first. In preparation for this first discussion, board staff reviewed how various states regulate pharmacy technicians. Based upon our review, it appears that forty-five states require either registration or licensure as a pharmacy technician.

The tasks that may be performed by technicians vary as well. For example, in Alabama pharmacy technicians may not handle controlled substances, whereas in Utah, in addition to duties consistent with pharmacy technician duties in California, pharmacy technicians may also counsel for OTC drugs and dietary supplements under the direct supervision of a pharmacist as well as accept new prescription drug orders left on a voice-mail for pharmacist review. In Alaska, if a pharmacy technician will assist in the preparation of

sterile pharmaceuticals, the technician must have completed a minimum of 40 hours of on-the-job training in the preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform the tasks.

Ratio requirements vary as well. For example, in Washington the general ratio is 1:1 unless the medication is dispensed to a patient in a healthcare facility (where the ratio is 1:3). Washington also allows a pharmacy to submit a service plan to increase the number of pharmacy technicians a pharmacist may supervise. In South Carolina the ratio is one pharmacist to two technicians, however the ratio may increase to one to three if two of the three technicians are certified by a board approved program. Some states do not have specified ratios.

During this Meeting

The committee may wish to discuss both the duties of a technician as well as the ratio as part of its discussion.

Consideration of Possible Revisions to Pharmacist Renewal Requirements and Content-Specific Continuing Education (Title 16 CCR §1732.5)

In November 2015, the board initiated a rulemaking to amend Section 1732.5 to amend continuing education requirements to specify that six of the 30 hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

Emergency/Disaster Response

Patient Consultation

Maintaining Control of a Pharmacy's Drug Inventory

Ethics

Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility

Compounding

During the February 2016 Board Meeting, the board discussed this proposal and expressed some concern that the proposal may be overregulating the continuing education requirements. Comments also included that pharmacist should be allowed to use their professional judgement to determine what continuing education he or she needs while others indicated that the board should consider simplifying the list. At the conclusion of the board's discussion the board voted to refer the proposal back to the Licensing Committee to review the continuing education content areas and report back to the board.

Attachment 3 includes a copy of the regulatory proposal.

6. Consideration of Ownership Structures for Pharmacies, Including a Presentation by the Office of the Attorney General Regarding Trusts

The board tracks the beneficial interest of business owners for pharmacies, whether they be natural persons or entities. Board regulation specifies the reporting of a transfer in the beneficial interest in the business and specifies the threshold as to when a change of ownership must be submitted to the board.

Business and Professions Code section 4035 defines a "person" as follows: "Person" includes firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.

As the committee was advised during its last committee meeting, when processing a pharmacy application, the board identifies and records all levels of ownership of the applicant business. This is done through a careful analysis of all information submitted in support of the application, and often times identifies inconsistencies with respect to the ownership reported. For some, what is initially reported as (what appears to be) a simple, two- or three-level ownership structure, when staff uncovers details, it often turns out to be multiple levels of ownership with multiple stakeholders. It is common for applicants with complex ownership structures to argue that the board doesn't need to know all of the information related to a pharmacy's ownership.

Board staff has identified where (revocable or irrevocable) trust(s) is/are reported as owners of the applicant business. Pharmacy Law does not currently recognize a "trust" as a person to which the board is authorized to issue a license; however, in researching older licensing records, some trusts have been found to be on record as "shareholders" of existing licensees.

During the board meeting, the board was advised that as with other ownership structures, trusts can be used as a legitimate form or ownership, however they can be manipulated to hide ownership.

During this Meeting

The committee will hear a presentation from an attorney from the Department of Justice to provide the board with additional information pertaining to trusts. The committee should carefully consider this issue and determine if they want to recommend to the board that trusts be authorized to own pharmacies and, if so, what information should be reported to the board.

A copy of various pharmacy statutes and regulation related to ownership as well as letters from various stakeholders regarding this issue are provided in **Attachment 4.**

7. Licensing Statistics

Licensing Statistics for July 1, 2015 – May 31, 2016

As of May 31, 2016, the board has 138,855 licensees, including 43,813 pharmacist and 73,542 pharmacy technicians. The board has renewed 58,837 licenses.

The board has received 14,950 applications and issued 11,232 licenses during the first eleven months of the fiscal year. During this same period, the board denied 92 applications. In addition, the board received 2,996 status inquiries via e-mail and responded to 2,109. The response numbers can be lower to account for one response to multiple emails received (i.e., the person emails once a day until they get a response). The Licensing Statistics for Fiscal Year 2015/16 ending May 31, 2016, is provided in **Attachment 5**.

Since July 2015, the board has been closely tracking the licensing unit's processing times for various application types. The board continues to work with the department to develop more robust reporting reports. The department is implementing Licensing Performance Measures (LMP) processing times for the boards and bureaus. Staff has been validating the reports provided, and has been advised that the LPM should be in production soon. The LPM reports will provide more detail on the board's processing times, deficiency rates, etc.

General processing information by license type is provided below and as of June 10, 2016. The numbers reflect the time an application is received by the board through the time either a deficiency letter is issued or a license is issued. If an incomplete application is received, there will be additional processing time involved.

Site Application Type	Number of Days
Pharmacy	29
Nonresident Pharmacy	30
Sterile Compounding	18
Nonresident Sterile Compounding	30
Hospital	14
Clinic	25
Wholesaler	4
Nonresident Wholesaler	21
Third-Party Logistics Provider	0
Nonresident Third-Party Logistics Provider	2

In addition to general processing times, the processing time for evaluating deficiency mail of site licenses is averaging between 10 and 29 days, depending on the license type, with one exception: sterile compounding deficiency mail is at 50 days and staff is working to reduce this number to an acceptable range.

Individual Application Type	Number of Days
Pharmacist Exam	39
Pharmacist Initial License	7
Pharmacy Technician	46
Intern Pharmacist	25
Designated Representative	3
Designated Representative – 3PL	7

In addition to the foregoing, the processing time for evaluating deficiency mail of individual applicants is averaging between 4 and 14 days, depending on the license type.

Between April 22 and June 1, the board received and processed 885 exam applications from eight schools of pharmacy.

8. Future Committee Meeting Dates for 2016

September 21, 2016, is the next scheduled committee meeting. Board staff will be working to secure additional meeting dates. If finalized, these dates will be provided during the meeting.

Attachment 1

Draft Proposal to Amend Section 1793.6

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

- (a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,
- (b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
- (c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
 - (1 A) Knowledge and understanding of different pharmacy practice settings.
 - (2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
 - (3 <u>C</u>) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
 - (4 <u>D</u>) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
 - $(5 \underline{E})$ Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
 - $(\underbrace{\bullet} F)$ Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
 - (7 <u>G</u>) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
- (2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:
 - (A) Prior to admission to the course of training, the administrator or instructor must conduct a criminal background check and counsel applicants to the program about possible risks to securing licensure if the background check reveals criminal history.
 - (B) Administer at least one drug screening to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine acceptance into the course of training or appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.
 - (C) Require students to be at least 18 years of age prior to the beginning of instruction.
 - (D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, <u>4115.5</u>, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Attachment 2

BUSINESS AND PROFESSIONS CODE - BPC DIVISION 2. HEALING ARTS CHAPTER 9. Pharmacy [4000 - 4426] ARTICLE 7. Pharmacies [4110 - 4126.5]

- **4115.** (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other ¹nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
- (b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.
- (c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
- (d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
- (e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
- (f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.
- (2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.
- (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.
- (g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence.

 $^{^{\}rm 1}$ Nondiscretionary tasks defined at 16 CCR § 1793.2

This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

- (h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.
- (i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
- (1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
 - (2) Sealing emergency containers for use in the health care facility.
- (3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures. (Amended by Stats. 2015, Ch. 303, Sec. 5. Effective January 1, 2016.)
- **4115.5.** (a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.
- (b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.
- (2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.
- (3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.
 - (4) A pharmacist may only supervise one pharmacy technician trainee at any given time.
- (5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.
- (c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.
- (2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.
- (d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.
- (e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status. (Amended by Stats. 2005, Ch. 621, Sec. 54. Effective January 1, 2006.)

§ 1793.2. Duties of a Pharmacy Technician.

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Operative 10-22-2004

Attachment 3

Proposal to amend § 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read:

§1732.5 Renewal Requirements for Pharmacists

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

(b) At least six (6) of the thirty (30) hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

- (1) Emergency/Disaster Response
- (2) Patient Consultation
- (3) Maintaining Control of a Pharmacy's Drug Inventory
- (4) Ethics
- (5) Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
- (6) Compounding

Pharmacists renewing their licenses which expire on or after July 1, 2018, shall be subject to the requirements of this subdivision.

(b) (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

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

Attachment 4

Pharmacy Ownership

Section 4035 – "Person" defined

Section 4111 – Restrictions on Prescriber Ownership

Section 4201 - "Beneficial Ownership"

Section 4207 – Investigation by the board – applicants

16 CCR Section 1709 – Names of Owners and Pharmacist-in-Charge

4035.

"Person" includes firm, association, partnership,

4111.

- (a) Except as otherwise provided in subdivision
- (1) A person or persons authorized to prescribe
- (2) A person or persons with whom a person or
- (3) Any corporation that is controlled by, or in
- (b) Subdivision (a) shall not preclude the
- (c) The board may require any information the
- (d) Subdivision (a) shall not preclude the pharmacy to be owned or owned and operated

Act of 1975 (Chapter 2.2 (commencing with

as amended, whose ownership includes persons

defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

4201.

- (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.
- (b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:
- (1) If the applicant is a partnership or other unincorporated association, each partner or member.
- (2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.
- (3) If the applicant is a limited liability company, each officer, manager, or member.
- (c) If the applicant is a partnership or other

partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

- (d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.
- (e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary foodanimal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer if all of the provisions of this chapter have been complied with.
- (f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.
- (g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
- (h) Notwithstanding any other law, the thirdparty logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
- (i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and

dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

4207.

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being

this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

- (b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.
- (c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.
- (d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application

request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

§ 1709. Names of Owners and Pharmacist in Charge.

- (a) Each permit to operate a pharmacy shall 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) Any transfer, in a single transaction or in a

- 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) The following shall constitute a transfer of permit and require application for a change of
- a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in

beneficial interest in that license.

State of California DEPARTMENT OF JUSTICE



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March 28, 2016

Virginia K. Herold Executive Officer California State Board of Pharmacy 1625 North Market Blvd., Suite N-219 Sacramento, CA 95834

Re: ISSUING PHARMACY PERMITS TO TRUSTS

California State Board of Pharmacy

Dear Ms. Herold:

I am writing to provide you with an analysis regarding the issuance of pharmacy permits to trusts. As you are well aware, the law requires the Board to prevent pharmacies from being owned by the wrong types of persons, including convicted criminals and potentially self-interested prescribers.

Staff have recently raised concerns regarding trusts on two fronts: (1) Whether this form of ownership provides opportunities for hidden and/or undisclosed ownership shares; and (2) Whether the Pharmacy Law contemplates ownership of or beneficial interests in pharmacy licenses held by trusts. As to the former, there are certainly legitimate reasons to hold ownership in trust. However, there are also ways in which trust ownership can be manipulated to prevent full or accurate tracking of ownership shares or beneficial interests.

Trusts appear to be the vehicle of choice for hiding assets for the following reasons:

- (i) Unlike business entities which are legal persons, common-law trusts are mere contractual relationships between settlors (who place property into trust), beneficiaries (for whom the trust is operated), and trustees (who hold legal title to the property). Because they are not entities or persons, they usually do not have to register with any state authority. When business entities register with state authorities, they are subject to reporting requirements. Trusts do not operate in this manner.
- (ii) It is well established that common law trusts cannot be sued. (*Presta v. Tepper* (2009) 179 Cal.App.4th 909, 915; *Powers v. Ashton* (1975) 45 Cal.App.3d 783, 787.) If

¹ I remind you that what follows are solely my own opinion(s), my best effort(s) to provide legal assistance to you and/or to the Board. This is not an official "opinion" of the Attorney General.

Virginia K. Herold March 28, 2016 Page 2

you want to sue for actions done by the property in trust, you have to sue the trustee. If you want to sue a trustee, you have to find him, her, or it. If the trustee is located in a foreign jurisdiction, United States courts may have no jurisdiction over the trustee. Even if the trustee is merely in another state, California courts may have trouble reaching him or her.

- (iii) It is much easier for trusts to operate offshore in jurisdictions that have extensive privacy protections such as the Cayman Islands. Persons in these offshore jurisdictions are unlikely to be subject to California laws, and would not respond to subpoenas from California courts, let alone California agencies.
- (iv) Trusts are not required to follow any "corporate formalities" (e.g., annual meetings, registration with the secretary of state) the way most corporate entities are.
- (v) True ownership and control of property held in trust is often governed by complex documents and discretionary relationships. For example, a trust may have hundreds of nominal beneficiaries according to the trust document, though as a practical matter, the trustee holds property (and takes instructions from) one or two of the beneficiaries. A corporate entity is generally not allowed to have such discretionary relationships among its owners. Who has control of the property held by a trust is a highly fact specific determination.

Thus, the lack of oversight by government agencies and corresponding reporting obligations and complex structure make it much easier to hide ownership in trusts than business entities.

According to the plain language² of the applicable statutes, trusts are not authorized to conduct pharmacies in California. Namely, Business and Professions Code section 4110, subd. (a), provides that "no person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board." Business and Professions Code section 4035 defines "person" to "include[] firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision."

A trust is not included within the definition of "person" in section 4035. The Legislative History reveals that in 1951, "business trust" was included within the definition of "person" in

³ The definition of "person" in section 4035 governs the construction of the term, "person" in Business and Professions Code section 4110, subd. (a). (Bus. & Prof. § 4015).

² California courts will give effect to the legislative intent of a statute, holding that the first and most important "source" for ascertaining the intent of a statute is its plain language. "[C]ourts are bound to give effect to statutes according to the usual, ordinary import of the language employed in framing them...it should first turn to the words of the statute to determine the intent of the Legislature... If the words of the statute are clear, the court should not add to or alter them to accomplish a purpose that does not appear on the face of the statute or from its legislative history." (See, e.g., California Teachers Assn. v. San Diego Community College Dist. (1981) 28 Cal.3d 692, 698; Dept. of Alcoholic Bev. Control v. Alcoholic Bev. Control Appeals Bd. (2003) 109 Cal.App.4th 1687, 1695-96; see Arnett v. Dal Cielo (1996) 14 Cal.4th 4, 22 ["Courts should give meaning to every word . . . if possible, and should avoid a construction making any word surplusage."].)

Virginia K. Herold March 28, 2016 Page 3

the predecessor statute to section 4035 but subsequently removed in 1953 and not added when the statute was reenacted in 1955, possibly omitting trusts intentionally from the definition.

Indeed, under California law, a common-law trust⁴ is not a legal "person" or entity; rather, it is a fiduciary relationship. (*Presta v. Tepper, supra*, 179 Cal.App.4th at 914 (a "trust is not an entity separate from its trustees. In contrast to a corporation which is a '...distinct legal entity separate from its shareholder and from its officers' and deemed a person within many legal constructs, a ...trust is not a person but rather a 'fiduciary relationship with respect to property' [citations omitted].")

Although many trusts are established for legitimate reasons, the Board needs the tools to assess whether a trust has been established for legitimate reasons or to hide ownership, in order to effectively fulfill its administrative mandate of preventing ownership of pharmacies by the wrong types of individuals. Therefore, if the Board decides to continue issuing pharmacy permits to trusts, we recommend that Business and Professions Code section 4201 and California Code of Regulations, title 16, section 1709 be amended to require trusts to disclose the identity of all trustees, beneficiaries and grantors of a trust and to deem trustees, beneficiaries and grantors to hold a "beneficial interest" in the assets of the trust, triggering disclosure whenever there is a change in *any* amount of beneficial interest.

I hope this analysis will be helpful to you and to the Board. As always, please feel free to contact me with questions.

Sincerely,

DESIREE I. KELLOGG Deputy Attorney General

For

KAMALA D. HARRÍS Attorney General

Cc: Linda K. Schneider (via email)
Joshua A. Room (via email)
Matthew C. Heyn (via email)

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⁴ Only specific types of trusts such as Real Estate Investment Trusts (REITS) and Registered Business Trusts are considered legal persons.



March 23, 2016

Virginia Herold, Executive Officer California State Board of Pharmacy Licensing Committee 1625 N. Market Blvd., N219 Sacramento, CA 95834

Re: Trusts as Owners or "Persons Beneficially Interested" In Licensed Pharmacies

Dear Ms. Herold:

I write to express the concern of the National Association of Chain Drug Stores (NACDS) regarding proposed limits on the ability of trusts to own or hold beneficial interests in licensed pharmacies. NACDS understands that the Licensing Committee will consider this issue in a meeting on March 30, 2016. We ask the Licensing Committee to maintain California's longstanding practice of allowing trusts to own or hold interests in pharmacies. A narrow interpretation of the applicable statute would harm patient care by unnecessarily restricting pharmacy operations in California.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies. NACDS chain member companies include regional chains, with a minimum of four stores, as well as national companies. Chain pharmacies employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries.

NACDS wholeheartedly supports the legal and factual analysis set forth in the letter to you from Christine Cassetta of Quarles & Brady LLP dated March 21, 2016. As that letter explains, the statutory definition of "person" includes a "firm," and a trust is clearly a type of "firm." *See* Ca. Bus. & Prof. Code § 4035; Black's Law Dictionary (definitions of "firm" and "company"). Therefore, a trust is a "person" that may own or hold an interest in a pharmacy.

A narrow interpretation of the statutory definition of "person" would be contrary to the Board of Pharmacy's longstanding practices. We understand that the Board has historically granted pharmacy licenses when trusts hold interests in pharmacies. The Board's own newsletter has suggested that a license may be granted where a trust owns a pharmacy. *See* California Board of Pharmacy, *The Script* (Jan 2008), *available at* http://www.pharmacy.ca.gov/meetings/agendas/2009/09_jun_lic_mat.pdf. Similarly, the Board has a longstanding practice of approving licenses for pharmacies owned by individuals, despite the fact that individuals are not listed as a type of "person" in the

statute. See Community Pharmacy Permit Application, Section B (pharmacy license for "Individual Owner who is not incorporated"), available at http://www.pharmacy.ca.gov/forms/phy_app_pkt.pdf. Likewise, the statutory definition of "person" does not expressly include Native American tribes, yet the Board has a longstanding practice of granting licenses to pharmacies owned by Native American tribes. See id., Section G (pharmacy license "for Native American tribe owned pharmacy"). A narrow interpretation of "person" would result in wholesale restructuring of the Board's approach to pharmacy licensure.

A narrow interpretation of "person" would also be contrary to the interests of pharmacy patients. We understand that trusts may often hold interests in pharmacies. Individuals, Native American tribes and others not specifically enumerated in the statutory definition of "person" also own or hold interests in pharmacies. Access to pharmacy care would be severely restricted if the Board of Pharmacy begins denying or revoking the licenses of such pharmacies. Rather than deny or revoke all of these pharmacy licenses, we ask the Licensing Committee to recognize that the term "firm" as used in the definition of "person" is a broad category that encompasses a wide range of business entities, including trusts.

Limiting the ability of trusts to hold interests in pharmacies would disrupt the operations of multi-state pharmacies that are partially or entirely owned by trusts. This is particularly true of publicly traded companies, which the Board of Pharmacy recognizes may have a shareholder that is a "trust company." *See* Requirements For Filing A Community Pharmacy Application, p. 4, available at http://www.pharmacy.ca.gov/forms/phy_app_pkt.pdf. The same is true for non-publicly traded companies that have trusts as shareholders. Multi-state pharmacy chains owned in whole or in part by trusts should not have to face the choice of either radically restructuring their ownership or being shut out of the California market. Such an onerous burden on interstate commerce would be inappropriate. Smaller pharmacy companies would also be harmed. As the Board's newsletter pointed out, pharmacies can be held in trusts as a proper estate planning mechanism, to help ensure that proper operation of pharmacies may continue from one generation to the next. A pharmacy's license should not be revoked just because a pharmacy owner uses a trust to maintain a family business.

There is no convincing rationale for preventing trusts from owning or holding interests in pharmacies. There is simply no reason to believe that trusts are somehow less trustworthy or less deserving of a pharmacy license than the individuals, Native American tribes, LLCs, corporations and other "persons" that are routinely granted pharmacy licenses. Without a legitimate basis and logical explanation for denying trusts a role in pharmacy ownership, it would be arbitrary and capricious for the Board of Pharmacy to reverse its longstanding practice of broadly interpreting the statutory definition of "person" to include trusts and other "firms."

In conclusion, NACDS respectfully requests that the Licensing Committee decline to adopt any change to the Board's longstanding practice of allowing trusts to hold interests in licensed pharmacies. We appreciate the opportunity to comment on this important issue. If you have any questions or would like additional information, please contact me at (703) 837-4231 or at dbell@NACDS.org.

Sincerely,

Don L. Bell, II

Senior Vice President and General Counsel

Om 2 Bella



April 21, 2016

Amy Gutierrez, Pharm.D. President, California Board of Pharmacy 1625 N Market Blvd. Ste., N-219 Sacramento, CA 95834

RE: Support of Continuing to Allow Trusts to Hold Pharmacy Ownership Interests in

California

Dear Dr. Gutierrez:

A number of members of the California Pharmacists Association (CPhA) are pharmacy and/or other licensed entity owners who hold their ownership interests in any number of different types of Trusts. Trusts are important, prevalent, and widely-accepted legal vehicles used by individuals, spouses, and families to allow for estate planning and control of assets therein.

We oppose any effort to stop allowing Trusts to hold ownership interests in any licensed facility, as well as any efforts to impose any additional administrative burdens regarding licensure renewals, change of ownership, or initial licensure issuances involving the same. While we appreciate the Board's need to safeguard Californians, we believe the current robust procedural processes imposed by the Board's Licensing and Enforcement Divisions more than adequately prevent would-be criminal enterprises and unlawful ventures.

We support and encourage the Board to continue allowing Trusts to hold ownership interests in pharmacies and other entities licensed by the California State Board of Pharmacy, and oppose any measure to either restrict ownership interest or create any additional administrative burden on Trusts.

Sincerely,

Brian Warren

Vice President, Center for Advocacy

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April 25, 2016

VIA UPS OVERNIGHT DELIVERY AND EMAIL: virginia.herold@dca.ca.gov

California State Board of Pharmacy c/o Virginia Herold, Executive Officer 1625 N. Market Blvd., N219 Sacramento, CA 95834

Re: Trusts as a Shareholder or Member "Person Beneficially Interested" in a Pharmacy

Dear California State Board of Pharmacy:

We previously provided a letter to the Licensing Committee (Committee) for its consideration at their March 30, 2016 meeting regarding trusts as a "person beneficially interested" in a pharmacy. The National Association of Chain Drug Stores (NACDS) also provided a letter to the Committee for its consideration. We assumed that the California State Board of Pharmacy (Board) would be provided with the same materials that the Licensing Committee had reviewed on this issue and neither we, nor NACDS, re-submitted our letters.

However, we viewed the materials posted on the Board's website and see that neither our letter nor NACDS's letter is among the materials on the website. Because we cannot be certain that these previous letters have been provided to the Board, we are providing the Board with those letters directly and also providing a copy of the March 28 letter from Deputy Attorney General Kellogg (Letter) to the Committee that was provided via the Board's website the day before the March 29th meeting. This Letter was also considered by the Committee. Because of the timing of the Letter, we were unable to provide a written response and only responded verbally at the Committee meeting. We are now responding in writing. We respectfully request that you consider our and NACDS's previous letters to the Committee and this letter at or before the April 27 - 28, 2016 meeting.

The Letter listed two general concerns regarding trusts and then went on to outline specific points in support of these concerns. The first general concern was whether this form of ownership provides an opportunity for hidden and/or undisclosed ownership shares. The second general concern was whether the Pharmacy Law contemplates ownership of or beneficial interests in pharmacy licenses held by trusts. The Letter acknowledged that there are legitimate reasons to hold ownership in trust, but also noted that there are ways in which trust ownership can be manipulated to prevent full or accurate tracking of ownership shares or beneficial

interests. The Letter also noted that "[t]rusts appear to be the vehicle of choice for hiding assets" and went on to list specific objections. We will respond to the points raised in the letter in order. Initially we note that while the concerns raised in the Letter are either highly unlikely or impossible with a trust, they are real concerns for corporate and other entities that are currently issued permits and to which the Letter does not object.

The first point in the Letter is that trusts do not register with any state authority and have no reporting requirements. While it is correct that trusts do not register with state authorities and do not report in the same manner as public corporations, we do not see why this is an issue. Partnerships and non-resident LLCs also do not file reports. Trusts generally do not report for multiple acceptable reasons including that, other than an annual duty to account to the beneficiaries, there is no requirement that they do so. Also, there is no 510K or other securities requirement for a trust and a trust does not have the same business structure of a publicly traded corporation or an LLC. However, this is no different than the distinction between a publicly traded corporation and a partnership for example. A partnership also has no reporting requirement and, in many cases, need not even register with a state authority. Rather, a trust is governed by the terms of trust document and a partnership is governed by the terms of the partnership agreement. Also, trusts are generally stockholders or members of a corporation or an LLC that is beneficially interested in a pharmacy, sometimes many levels above the actual pharmacy entity. The corporate entities that hold the permit and in which trusts are shareholders or members are registered and do report if required. Finally, other stockholders and members that are not themselves corporations or LLCs also do not report. The failure to register with the state or report as does a corporation is a distinction without a difference.

The next point was that, under common law, trusts cannot be sued. Rather, the trustee must be sued and to sue a trustee, the trustee must be found and if the trustee is in a foreign country or another state, this can be difficult. Again, we do not see why this is an issue. The Board does not sue permit holders. The Board takes disciplinary action against the permit holder - the LLC or the corporation that actually holds the permit and not against the shareholders or members. Trusts are shareholders of a corporation or members of an LLC that is beneficially interested in the pharmacy. The corporations and LLCs can be sued.

The third point was that it is much easier for trusts to operate offshore in jurisdictions that have extensive privacy protections, such as the Cayman Islands, and are unlikely to be subject to California law and would not respond to subpoenas from California agencies. While trusts can operate offshore, corporations can also do so and it is no easier for a trust. We are aware of other applications filed with the Board where foreign corporations either own, or are beneficially interested in a pharmacy and there have been no issue with these filings. We see no distinction between these foreign corporations and a foreign trust. (We note that we have never filed an application involving either a foreign corporation or a foreign trust).

The fourth point was that trusts are not required to follow any corporate formalities, such as annual meetings, registration with the secretary of state, the way corporate entities are required to do so. We do not see why this is an issue. Partnerships and associations also do not follow corporate formalities. Again, trusts are generally stockholders or members of a corporation or an LLC that is beneficially interested in a pharmacy, sometimes many levels above the actual pharmacy entity. These corporate entities *do* register with the Secretary of State and do, where required, follow corporate formalities and report. Finally, other stockholders and members that are not themselves corporations or LLCs also do not register with the state or report. There are also extremely complex and novel forms of ownership held by LLCs and corporations and yet there is no objection to this type of ownership.

The fifth point was that, although a trust can have many beneficiaries, "as a practical matter, the trustee holds property (and takes instruction from) one or two of the beneficiaries." This point illustrates a basic misunderstanding of what a trust is and how it operates. The trustee controls the trust and is obligated to do so under the terms of the trust that are binding on the trustee. The beneficiaries, or a subset of beneficiaries, cannot control the trustee. Importantly, many beneficiaries of a trust do not even know that they are beneficiaries (much the same way an heir would not know he/she is an heir until there is a death). This risk of limited persons in control is not a risk specific to trusts. This perceived risk is no different than a subset of stockholders or board directors controlling the CEO or the board of directors. The Board has no current way of knowing if a majority shareholder of a publicly traded corporation is truly a criminal enterprise, yet corporations may hold beneficial interests in a pharmacy. In fact, control by factions is more likely an issue with a corporate or other entity where there is no trustee or trust document that describes exactly how the trust assets are to be managed.

The last concern was that "trusts are not authorized to conduct pharmacies" based on the definition of "person" (addressed below). This statement misses the point that the trusts *are not* conducting pharmacies. Rather, the directors and officers of the corporation or LLC that holds the permit are conducting the pharmacies. The trust is simply a shareholder of the corporation or a member of the LLC. Generally trusts have as the initial trustee individual persons, for example, the founder of the pharmacy and his/her spouse. On the death of this person and his/her spouse, a professional trustee is usually the successor trustee (JP Morgan or Northern Trust for example). The professional trustee wants absolutely nothing to do with running the business and leaves that activity to the officers and directors of the entity that holds the permit. The trustee does not show up and take over operations.

This recent change of position regarding trusts is apparently based on an internal change of opinion regarding what "person" means. We are aware of many currently licensed entities that have a trust as a shareholder or member of a person beneficially interested and we are certain that there are many thousands more. This position is a major departure from prior Board practice. This departure is evidenced by a *November 2015* Board newsletter that discusses and acknowledges that trusts may be owners (beneficially interested) in a pharmacy. This discussion

was under the heading "Estate Planning is Necessary for Pharmacy Owners" and urged pharmacy owners to have an estate plan at the ready. As part of this discussion "Answers to Estate Planning Questions Related to Pharmacies" instructed that a change of ownership was to be filed when the ownership of a pharmacy was to be placed in a trust after the death of a sole-surviving parent. If a trust was prohibited from being a shareholder or member of a person beneficially interested in a pharmacy, we are certain that the newsletter would not have instructed that a change of ownership be filed. Rather it would have indicated that a trust could not be a person beneficially interested in a pharmacy and instructed that the ownership of the pharmacy not be placed in trust.

(http://www.pharmacy.ca.gov/publications/15_fall_script.pdf). (See attached).

A trust is a frequently used estate planning tool that is designed to protect the interests of those who will benefit from the assets of the trust and is a common mechanism to avoid probate and protect an individual's life-long efforts. A trust also reduces tax liability to the survivors. If owners of a pharmacy have instituted an estate plan that utilizes a trust in accord with the laws of California or their state of residence, they should not be forced to change their plan and hold their asset in a manner that is not in their best interest. This change of position regarding the ability of a trust to be a shareholder or member of a person beneficially interested in a pharmacy is unnecessarily disruptive and will cause serious estate planning issues for those who are protecting their asset by holding it in trust. For example, if an individual currently owns ten pharmacies and has a trust as a person beneficially interested in the pharmacy to protect the asset when he/she dies, this person would not be able to add additional pharmacies to his/her business and also place them in the trust¹. As a result, the most profitable pharmacies may end up being held outside of the trust and be subject to probate and all accompanying taxes on the death of the individual. However, he/she could place the pharmacies in a non-United States corporation with individuals who are not United States citizens as the officers and directors without raising any concern. This is an absurd result.

Also, businesses rely on long-standing practices of the Board and the Board's newsletter. There are many deals that have been signed since this issue was raised at the end of February and are closing daily. Some of these deals are in the hundreds of millions or even more than a billion dollars - the ultimate dream of a pharmacy founder who is the seller. If the Board alters its approach to trusts, these deals will be void because the buyer, who may have a trust as a shareholder or member many levels above the pharmacy entity, can no longer be beneficially interested in the pharmacy. This cannot be what the Board wishes to see happen.

As we explained in our letter to the Committee, the newly stated position is that a trust cannot be a "person beneficially interested" in a pharmacy because "trust" is not included in the definition of "person." This position is incorrect for the multiple reasons explained in our letter to the Committee. These reasons include that:

¹ It is also unclear if a renewal application will process if a trust is identified.

- "Trust" is included in the definition of person because the definition of "person" include "firm" and "firm" is defined to include "trust"².
- A "person beneficially interested" is specifically defined in California law a shareholder, manager, or member of an LLC or a shareholder, officer or director of a corporation. There is nothing in this definition that precludes a trust from being a shareholder, manager, or member of an entity. Even if we accept that the definition of "person" controls, a "trust" is a "firm" as used in this definition.
- All California pharmacy permits that we have ever seen have the name of the pharmacy and the form of ownership of the entity that actually runs the pharmacy, not each and every entity that is beneficially interested in pharmacy. As such, the permit is issued to the entity that actually owns and operates the pharmacy. For most pharmacies, this is usually a limited liability company or corporation, both of which are included in the definition of "person".
- Section 4201 recognizes that there is an applicant for the permit the pharmacy entity and that the Board requires information from those persons beneficially interested in the pharmacy. It does not say that the applicant (the entity to whom the permit is issued) is the person or persons beneficially interested in the pharmacy. If so, again, each and every entity in the chain of those beneficially interested would be on the permit and named in any action against the pharmacy. We know that this is not the case. The requirement of section 4201 is to list those persons beneficially interested and they are not the same as the applicant and the ultimate permit holder.
- A trust will be listed as required on the application as either a member or manager of a limited liability company or a shareholder of a corporation and the relevant information regarding the trust will be provided. This identification stops the chain just as it would if we listed individuals as shareholders of a corporate entity at the top of the chain of

² "Firm" is not defined in California Pharmacy Law, but Black's Law Dictionary defines "firm" as follows: "firm n. (18c) 1. The title under which one or more persons conduct business jointly. 2. The association by which persons are united for business purposes. • Traditionally, this term has referred to a partnership, as opposed to a company. But today it frequently refers to a company." (emphasis added). A "company" is then defined as follows: "company (13c) 1. A corporation — or, less commonly, an association, partnership, or union — that carries on a commercial or industrial enterprise. 2. A corporation, partnership, association, joint-stock company, trust, fund, or organized group of persons, whether incorporated or not, and (in an official capacity) any receiver, trustee in bankruptcy, or similar official, or liquidating agent, for any of the foregoing. Investment Company Act § 2(a)(8) (15 USCA § 80a-2(a)(8)). — Abbr. co.; com." (emphasis added).

persons beneficially interested or if we indicated that the corporation was publicly traded.

• Subsection (f) of section 4201 says that the pharmacy license *authorizes the holder to conduct pharmacy*. This subsection, and subsection (a) support that the permit is issued to the applicant, be it a limited liability company or a corporation. Even if one was to accept the proposed definition of "person," a limited liability company and a corporation are absolutely qualified to hold the permit.

If the issue is that the beneficiaries of the trust may be "nefarious" individuals and must be identified and vetted, then the Board would also need to request the wills of shareholders and members of LLCs to confirm that their heirs are not problematic. This is a ridiculous result. Viewing a trust as you would the will of a shareholder or member of an entity illustrates that the position regarding trusts being prohibited from being beneficially interested in a pharmacy is a solution without a problem. There is no issue here and the Board's long-standing practice should continue.

We respectfully request that Board decline to adopt any change to the Board's long-standing practice of allowing trusts to be members or managers of limited liability companies or shareholders of a corporation. There is no policy reason for this proposed change in position and this position is not consistent with applicable California law or the Board's long-standing interpretation of the applicable law. Any decision to disallow trust ownership of pharmacies will have a far reaching and negative impact on pharmacies both inside and outside of California and will cause serious disruptions in patient care. Any existing California pharmacy, no matter how long it has been in operation, no matter the size of its patient population and no matter the risk nature of the patient population, would have to shut down if, somewhere among the persons beneficially interested in the pharmacy, a member or shareholder is a trust.

I will be present at the April 28 meeting to present our position and to answer any questions that you may have.

Very truly yours,

Christine Cassetta

Enclosures





The Schipt

BE AWARE & TAKE CARE: Talk to your pharmacist!

CALIFORNIA STATE BOARD OF PHARMACY

Fall 2015

Senate Bill 493 Implementation Underway

Senate Bill 493, enacted in 2013 (Hernandez, Chapter 469), adds a number of new duties that specifically trained or qualified pharmacists may perform. A full description of these services may be accessed in the Spring 2014 newsletter http://www.pharmacy.ca.gov/publications/14 spring script.pdf.

To implement the multiple provisions authorized by SB 493, the board formed the SB 493 Committee in June 2014, and held five additional meetings of this committee, as well as 11 other board meetings to approve or modify the regulations.

As this newsletter goes to print, regulations to implement all major components have been developed and are in various stages of approval required to secure the regulations. The text of the regulations may be accessed at http://www.pharmacy.ca.gov/laws_regs/regulations.shtml.

Here is the current status as we go to publish:

- Public Comment Completed, Board Approved, Undergoing Administration Review (Required step to adopting any regulation):
 - State protocol for nicotine replacement products, proposed section 1746.2

- Completed the initial 45-day public comment period, text approved by the board, rulemaking file being completed for administration review:
 - State protocol for hormonal contraception protocol, proposed section 1746.1
- Text to be modified and released for 15 day comment period:
 - Advance practice pharmacist licensure requirements, proposed sections 1730 and 1730.1
 - Vaccinations, proposed section 1746.4
- Undergoing the initial 45-day comment period:
 - Travel medications, proposed section 1746.5

For Naloxone Protocol (authorized by AB 1535, Bloom, Statutes of 2014):

- Undergoing 15-day comment period:
 - Permanent adoption of Naloxone protocol, proposed section 1746.3
- Currently in effect:
 - Emergency protocol for naloxone, section 1746.3

In the Future:

The board is now working on additional routes of qualification for advance practice pharmacists. These discussions will occur in public meetings throughout the fall. Watch for the notices via the board's subscriber alert system. To sign up, use this link: https://www.dca.ca.gov/webapps/pharmacy/subscribe.php

Registered for CURES?

Pharmacists are reminded that current law requires that all pharmacists with active licenses must be registered to access CURES. Legislation recently signed by the Governor now requires all pharmacists to be registered by July 1, 2016 (AB 679, Allen, Chapter 778, Statutes of 2015). For information about CURES and becoming registered, go to: http://www.pharmacv.ca.gov/licensing/cures.shtml

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Estate Planning is Necessary For Pharmacy Owners



When a California pharmacy owner dies, the operation of the pharmacy can be placed in jeopardy without proper estate planning.

This is especially true for an owner who holds more than a 50 percent ownership interest and especially for a sole owner, even if ownership is organized as a corporation or limited liability company.

In California, since pharmacy licenses are non-transferable, when ownership changes more than 50 percent, the current license may become invalid due to the change in ownership and a pharmacy may not continue to operate without a new license issued to the new owners.

Without proper planning, grieving family members are left trying to cope with not only their loss, but with making business decisions such as closing the pharmacy, installing a new pharmacist-incharge, arranging for an ownership change or selling the pharmacy. Meanwhile, patients can be left scrambling to try and get their medications while the ownership is appropriately transferred and approved by the board.

Making advance plans such as reevaluating the pharmacy's corporate structure, especially for sole owners, can give pharmacists, their families and their patients peace of mind.

Closing a Pharmacy

If survivors must close a pharmacy, the following information is important.

A very large part of closing the pharmacy is determining what to do with

the inventory, the hard copy prescription documents and the electronic records. Section 1708.2 of Title 16 of the California Code of Regulations directs pharmacies to contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory and to follow all official instructions provided by the board. The DEA must also be contacted for its instructions regarding the DEA registration.

Because only a licensed pharmacist can oversee the transfer of the pharmacy's inventory, a pharmacist must be present when the dangerous drugs and devices are inventoried and transferred to a board-licensed facility. The heirs will need to make these arrangements if the deceased owner had not. The board must be notified in writing of the following:

- Date of sale or transfer of all dangerous drugs and devices, and of chemicals used for compounding.
- Name and address of purchaser.
- Inventory of dangerous drugs and devices, showing their disposition; and
- Location of records of manufacture, sale, purchase (acquisition), and disposition of dangerous drugs and devices. California Business and Professions Code sections 4081 and 4333 require that these records be kept in a boardlicensed facility for three years. Board-licensed facilities includes a pharmacy, wholesaler or clinic. A storage unit, a record storage company, or the family garage are not board-licensed premises. Board-approved offsite waivers becomes invalid after a pharmacy discontinues business and records can no longer be stored at the offsite location.

Additionally, upon the death of a sole owner who is also the pharmacist-in-charge, there is no authority for the

pharmacy to continue to operate. The board may request the executor of the owner's estate to complete, sign, and submit to the board a Discontinuance of Business (DOB), form 17M-8 along with a copy of the death certificate. The form can be downloaded at www.pharmacy.ca.gov/forms/17m8.pdf.

The original large wall license, the current license renewal certificate, and the inventory of dangerous drugs and devices must be returned to the board with the DOB form.

Answers to Estate Planning Questions Related to Pharmacy

Pharmacy inheritance questions occasionally arise, and the following are examples of questions that have been posed to the board.

Scenario: Smith's Pharmacy has been family owned for 40 years and is currently solely owned by the original pharmacist owner's surviving wife, Mary, who is 83 years old. The family wants to assure that they can maintain ownership of the pharmacy when Mary dies. The family does not intend to sell the pharmacy, nor do they wish to acquire partners. Two sons, John (a licensed pharmacist) and Tom, currently operate the pharmacy and plan to continue to maintain control.

- Q. According to her current estate planning, upon Mary's death all her shares of Smith's Pharmacy, Inc. will pass to the Smith Family Trust, with beneficiaries John and Tom. Will the Board of Pharmacy conclude that a transfer of ownership has occurred?
- A. Yes. The Smith Family Trust would be a new owner and would require a new license. This change needs to be reported as soon as possible when the change occurs, because the Trust is not able to operate the pharmacy as the new owner until the new owner is approved (Title 16, California Code of Regulations, section 1709[c]). It may

See Estate Planning Page 13

Medication Errors Are Preventable

Medication Error Reporting Requirement

Professional errors, including medication errors, resulting in a settlement or an arbitration award of \$3,000 or more for any claim or action for damages or death or personal injury caused by the licensee's negligence, error or omission in practice must be reported to the board, per B&PC section 800. Additional fines of up to \$5,000 may be assessed for failure to report. If the licensee is represented by an insurance company, that company is required to submit the report.

Medication errors account for almost 20 percent of the complaints received and investigated by the California State Board of Pharmacy.

Medication errors are preventable and it is the board's goal to help pharmacists reduce these errors. One of the best ways to avoid medication errors is to provide patients with proper consultation at the time prescriptions are dispensed. Consultation helps identify that the proper medication is being furnished to the proper patient, in the proper dose for the proper diagnosis and that it is compatible with the patient's other medications. Consultation is required by law on all new or changed prescriptions.

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

If a pharmacy makes a medication error, the board strongly encourages the pharmacy to confidentially report errors to programs such as:

United States Pharmacopeial (USP) Practitioner's Reporting Network: http://napra.ca/Content Files/Files/drugerrors.pdf

FDA's MEDWATCH program: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf

Institute of Safe Medication Practices (ISMP): https://www.ismp.org/errorReporting/reportErrortoISMP.aspx

These organizations pool and analyze medication error information obtained from all types of health care practitioners, manufacturers and consumers and alert the profession to error trends. Medication or prescription errors, usually single acts, tare he result of human mistakes and can occur at any point talong he drug therapy course, from prescribing through disposes ibigand administering.

These programs work because thoughtful practitioners report incidents, confident that the purpose of reporting, recording, and tracking medication errors is not to assign blame, but to aid in understanding why the errors occurred and take preventive and corrective action to prevent recurrence.

Examples of common prescription dispensing errors include:

- The wrong drug (inappropriate for the patient's condition) is ordered by the prescriber.
- Incorrect information is entered on the label of the prescription container, as a result the patient is dispensed the wrong drug or wrong dosage.
- A drug is dispensed that is contraindicated if taken with another drug already being taken by the patient.
- A prescription is filled using a drug whose expiration date has passed.
- The medication is furnished to the wrong patient by the pharmacy.

According to the FDA, medication errors are also caused by using trailing zeros and not using leading zeros when writing out doses. The FDA cites as an example that a "5 mg" dose written with the trailing zero as "5.0 mg" can be misread as "50 mg," resulting in a tenfold overdose. Similarly, a "0.5 mg" dose written without the leading zero as ".5 mg" can easily be mistaken for "5 mg," also resulting in a tenfold overdose.

Other consistent problems include misinterpreted abbreviations and incomplete medication orders. Also, errors can be caused by poor communication, similarities in product names, ambiguities in directions for use or medical abbreviations, unclear labeling or poor pharmacy procedures or techniques.

Recent medication errors reported to the Board of Pharmacy include:

- Case 1. A patient received a prescription for Desogen, but instead was dispensed Aviane for 12 months.
- Case 2. A prescription order written for vitamin D3 10,000IU was incorrectly verified, ordered and dispensed as vitamin D3 1,000IU.
- Case 3. A prescription written and filled for Nexium 40 mg for patient A was incorrectly dispensed to patient B.
- Case 4. A pharmacy dispensed imiquimod 5% cream with directions to apply packet to affected areas 2 times a day for 6 weeks. The frequency of application was significantly higher than recommended by the manufacturer. The pharmacist failed to contact the prescriber for clarification and dispensed the prescription with irregular directions.

See Med Errors Are Preventable, Page 9

ATTACHMENT 5

APPLICATIONS													
Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	42	63	44	41	38	33	27	31	35	46	59		459
Designated Representatives Vet (EXV)	0	1	0	0	0	0	0	0	0	2	2		5
Designated Representatives-3PL (DRL)	16	19	5	32	14	14	12	18	8	20	8		166
Intern Pharmacist (INT)	59	518	582	302	84	78	102	122	120	164	151		2282
Pharmacist (exam applications)	201	126	109	149	123	100	117	105	146	313	1067		2556
Pharmacist (initial licensing applications)	139	661	107	397	153	139	63	70	101	46	15		1891
Pharmacy Technician (TCH)	596	486	607	558	440	438	424	555	497	490	549		5640
Centralized Hospital Packaging (CHP)	ام	0	0	0	o	0	1	0	0	0	0	l	1
Clinics (CLN)	6	6	17	13	10	9		8	8	6	9		95
Clinics (CLN) Clinics Exempt (CLE)	2	3	4	13	10	0		0	3	2	2		20
Drug Room (DRM)	0	0	0	0	0	0		0	0	_	0		20
Drug Room Exempt (DRE)	0	0	0	0	0	0		0	0		0		1
Hospitals (HSP)	7	0	0	2	0	1	0	2	8	1	7		28
Hospitals - Temp	5	0	0	0	0	0		0	4	0	3		12
Hospitals Exempt (HPE)	0	0	0	0	0	1	0	0	0	1	1		12
Hypodermic Needle and Syringes (HYP)	0	0	1	0	2	3	i i	3	0	2	- 1		14
Hypodermic Needle and Syringes (HTF) Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0		0	0		0		14
Correctional Pharmacy (LCF)	0	0	0	0	0	0		0	1	0	1		3
Pharmacy (PHY)	35	49	49	86	246	61		34	38		41		713
Pharmacy - Temp	55	17	22	60	225	20		11	8	13	10		403
Pharmacy Exempt (PHE)	0	0	0	1	0	20		0	0		3		403
Pharmacy Nonresident (NRP)	12	16	19	12	17	14		14	9		20		155
Pharmacy Nonresident Temp	1	0	2	3	3	3		4	0		6		28
Sterile Compounding (LSC)	10	13	11	11	6	2	6	6	7	5	5		82
Sterile Compounding - Temp	6	5	6	5	2	2	1	1	5		3		36
Sterile Compounding Exempt (LSE)	0	0	0	0	0	3		0	0	-	1		7
Sterile Compounding Nonresident (NSC)	2	3	2	6	4	4	2	5	3	0	4		35
Sterile Compounding Nonresident Temp	0	0	0	1	0	0		1	2	1	0		8
Third-Party Logistics Providers (TPL)	2	2	1	1	0	0		3	1	1	1		13
Third-Party Logistics Providers - Temp	0	0			0	0		0	. 0	. 0	0		.0
Third-Party Logistics Providers Nonresident (NPL)	5	3	2	11	5	2		5	3		4		45
Third-Party Logistics Providers Nonresident Temp	0	0	0	0	0	0		0	0		0		1
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	1	5	0	0	0	. 0	0		6
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	. 0	5	0	0	0	0	0		5
Wholesalers (WLS)	13	7	11	2	9	19	ŭ	2	9	6	7		91
Wholesalers - Temp	4	0	1	1	0	6		0	0	0	. 0		12
Wholesalers Exempt (WLE)	0	0	0		0	0		0	0		0		.2
Wholesalers Nonresident (OSD)	10	13	13	12	1	11		7	6	11	10		103
Wholesalers Norresident - Temp	2	0	2	5	5	3	0	3	1	1	10		23
Total	1181	2011	1617	1712	1389	978	847	1010	1023	1191	1991	0	14950
	All change of locati	on applications ar	re reported under th	ne license type as a	new license is iss	ued effective 11/1/2	2014						

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APPLICATIONS (continued)													
Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	34	39	36	54	26	27	29	53	31	22	31		382
Designated Representatives Vet (EXV)	0	0	0	0	1	0	0	0	0	0	1		2
Designated Representatives-3PL (DRL)	34	19	19	14	25	8	22	13	6	12	5		177
Intern Pharmacist (INT)	103	222	639	408	105	59	57	40	140	106	108		1987
Pharmacist (initial licensing applications)	146	451	342	223	280	175	68	52	80	83	23		1923
Pharmacy Technician (TCH)	717	592	488	591	633	475	296	413	501	481	326		5513
Centralized Hospital Packaging (CHP)	1	0	0	0	0	0	0	1	1	0	0		3
Clinics (CLN)	12	7	10	9	10	8	7	11	7	10	2		93
Clinics Exempt (CLE)	1	0	0	4	3	2	1	1	0	0	1		13
Drug Room (DRM)	1	0	0	0	0	0	0	0	0	1	0		2
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0		0
Hospitals (HSP)	0	5	1	2	1	0	0	1	1	1	1		13
Hospitals - Temp	1	0	0	0	0	1	0	0	0	0	1		3
Hospitals Exempt (HPE)	0	1	0	0	1	0	0	0	1	1	0		4
Hypodermic Needle and Syringes (HYP)	0	6	1	0	0	0	0	4	0	2	0		13
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0		0
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	1	1	0		2
Pharmacy (PHY)	30	36	38	49	35	282	34	47	30	35	24		640
Pharmacy - Temp	7	2	4	0	9	7	1	5	5	2	2		44
Pharmacy Exempt (PHE)	1	0	1	1	0	1	1	0	1	1	0		7
Pharmacy Nonresident (NRP)	3	9	5	7	6	5	12	9	18	11	10		95
Pharmacy Nonresident Temp	5	5	0	1	0	2	4	1	0	1	0		19
Sterile Compounding (LSC)	3	1	3	4	6	1	2	7	6	5	2		40
Sterile Compounding - Temp	2	6	0	0	4	0	0	0	0	1	0		13
Sterile Compounding Exempt (LSE)	0	0	1	1	0	0	0	0	0	4	1		7
Sterile Compounding Nonresident (NSC)	2	1	3	1	1	3	1	1	0	1	1		15
Sterile Compounding Nonresident Temp	0	0	0	1	0	1	3	1	0	0	0		6
Third-Party Logistics Providers (TPL)	3	1	2	1	2	1	1	0	2	0	2		15
Third-Party Logistics Providers-Temp	0	0	0	1	0	0	0	0	0	0	0		1
Third-Party Logistics Providers Nonresident (NPL)	10	2	6	3	8	2	15	9	1	1	0		57
Third-Party Logistics Providers Nonresident Temp	0	0	0	0	0	0	0	0	0	0	0		0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	5	0		5
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0	0	0		0
Wholesalers (WLS)	7	3	7	4	8	6	6	3	2	7	3		56
Wholesalers - Temp	0	0	0	0	0	0	0	0	0	0	0		0
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0		0
Wholesalers Nonresident (OSD)	11	4	9	8	5	9	9	7	6	8	4		80
Wholesalers Nonresident - Temp	0	0	0	1	0	1	0	0	0	0	0		2
Total	1134	1412	1615	1388	1169	1076	569	679	840	802	548	0	11232

nding	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	228	257	263	24	257	255	249	225	214	218	239	
Designated Representatives Vet (EXV)	3	4	2	2	2	2	2	1	1	2	3	
Designated Representatives-3PL (DRL)	120	109	95	92	78	72	63	68	73	77	77	
Intern Pharmacist (INT)	102	384	313	184	146	162	175	263	230	243	252	
Pharmacist (exam applications)	905	805	750	824	849	828	826	873	941	1044	1637	
Pharmacist (eligible exam)	1981	1709	1501	1259	1013	873	854	817	784	844	1237	
Pharmacy Technician (TCH)	1228	992	1130	1081	879	852	824	929	1068	918	1237	
Centralized Hospital Packaging (CHP)	16	16	16	13	13	13	13	12	9	9	9	
Clinics (CLN)	66	72	74	73	73	77	75	71	68	69	72	
Clinics Exempt (CLE)	10	11	15	14	12	10	11	9	12	14	16	
Drug Room (DRM)	1	1	1	2	3	3	5	5	4	5	6	
Drug Room Exempt (DRE)	0	0	0	1	1	1	1	0	0	0	0	
Hospitals (HSP)	22	14	14	14	12	10	12	14	21	18	20	
Hospitals Exempt (HPE)	4	4	4	3	2	3	3	3	2	2	3	
Hypodermic Needle and Syringes (HYP)	14	8	8	9	10	13	12	10	10	10	11	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	1	1	0	1	
Pharmacy (PHY)	210	208	207	182	424	196	197	178	169	159	172	
Pharmacy Exempt (PHE)	4	5	4	4	4	5	5	6	4	5	6	
Pharmacy Nonresident (NRP)	203	204	212	215	226	233	223	223	177	151	145	
Sterile Compounding (LSC)	44	44	49	53	48	46	46	46	44	43	45	
Sterile Compounding - Exempt (LSE)	6	7	6	5	5	8	8	8	7	5	6	
Sterile Compounding Nonresident (NSC)	38	40	41	42	46	42	39	41	39	41	40	
Third-Party Logistics Providers (TPL)	12	13	11	10	8	8	8	11	10	11	9	
Third-Party Logistics Providers Nonresident (NPL)	52	54	49	56	54	51	38	34	35	37	40	
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	1	1	6	6	7	7	2	2	
Wholesalers (WLS)	57	61	65	61	63	77	74	74	76	74	78	
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0	
Wholesalers Nonresident (OSD)	73	83	86	88	95	96	98	102	100	98	108	
Total	5400	5106	4917	4312	4324	3942	3867	4031	4106	4099	5471	-

APPLICATIONS (continued)													
Vithdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	1	5	2	2	2	7	4	6	14	5	3		5
Designated Representatives Vet (EXV)	0	0	2	0	0	0	0	1	0	0	0		
Designated Representatives-3PL (DRL)	0	0	1	0	0	1	0	0	1	0	2		
Intern Pharmacist (INT)	0	0	0	0	0	0	0	1	0	0	0		
Pharmacist (exam applications)	0	1	0	0	0	1	1	0	0	0	0		
Pharmacist (initial licensing applications)	0	0	0	0	0	0	0	0	0	0	0		
Pharmacy Technician (TCH)	132	53	11	13	16	10	11	13	0	6	9		27
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0	0	0	2	0	0		
Clinics (CLN)	0	1	0	3	0	0	0	0	1	0	0		
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0	0	0		
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0		
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0		
Hospitals (HSP)	0	4	0	0	0	0	0	0	0	0	0		
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0	0	0		
Hypodermic Needle and Syringes (HYP)	4	0	0	0	0	0	2	1	0	1	0		
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0		
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0	0	0		
Pharmacy (PHY)	0	1	3	4	8	1	1	3	4	3	2		3
Pharmacy Exempt (PHE)	0	0	0	0	0	0	0	0	0	0	0		
Pharmacy Nonresident (NRP)	20	1	2	3	0	0	4	2	34	23	17		10
Sterile Compounding (LSC)	1	4	1	0	3	2	0	1	4	0	0		1
Sterile Compounding Exempt (LSE)	0	0	0	0	0	0	0	0	1	0	0		
Sterile Compounding Nonresident (NSC)	0	0	1	1	0	1	1	0	3	2	1		1
Third-Party Logistics Providers (TPL)	0	0	1	0	0	0	0	0	0	0	0		
Third-Party Logistics Providers Nonresident (NPL)	0	0	1	1	0	0	0	0	1	0	2		
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	0	0		
Wholesalers (WLS)	1	0	0	2	0	0	1	1	2	1	0		
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0		
Wholesalers Nonresident (OSD)	0	2	1	1	0	2	2	0	2	2	1		
Total	159	72	26	30	29	25	27	29	69	43	37	0	54
	The number of te												

APPLICATIONS (continued)													
Denied	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	1	0	0	0	0	0	0	0	0	0	0		1
Designated Representatives Vet (EXV)	0	0	0	0	0	0	0	0	0	0	0		(
Designated Representatives-3PL (DRL)	0	0	0	0	0	0	0	0	0	0	0		(
Intern Pharmacist (INT)	0	0	0	1	0	1	1	1	0	0	0		1
Pharmacist (exam applications)	2	0	0	1	0	3	2	0	1	0	0		٤
Pharmacist (initial licensing applications)	0	0	0	0	1	0	0	0	0	0	0		
Pharmacy Technician (TCH)	3	8	10	2	4	7	2	4	7	1	11		59
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0	0	0	0	0	0		
Clinics (CLN)	0	0	0	0	0	0	0	0	0	0	0		
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0	0	0		
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0		
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0		
Hospitals (HSP)	0	0	0	0	0	0	0	0	0	0	0		
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0	0	0		
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0	0	0	0	0	0	0		
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0		
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0	0	0		
Pharmacy (PHY)	1	6	0	0	2	0	1	1	1	2	2		16
Pharmacy Exempt (PHE)		0	0	0	0	0				0	0		
Pharmacy Nonresident (NRP)	0	1	0	0	0	0	0	0	0	0	0		-
Sterile Compounding (LSC)	0	0	0	0	0	0	0	0	0	0	0		
Sterile Compounding Exempt (LSE)	0	0	0	0	0	0	0	0	0	0	0		
Sterile Compounding Nonresident (NSC)	0	0	0	0	0	0	0	0	1	0	0		
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0	0	0		(
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	0	0	0	0	0		-
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	0	0		
Wholesalers (WLS)	0	0	0	0	0	0	0	0	0	0	0		- (
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0		
Wholesalers Nonresident (OSD)	0	0	0	0	0	0	0	0	0	0	0		
Total	7	15	10	4	7	11	6	6	10	3	13	0	92
	, i	10	10	-	,	<u>''</u>	ı	<u> </u>	10	3	10		JE

RESPOND TO STATUS REQUESTS													
A. Email Inquiries	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist/Intern Received	633	520	433	546	387	294	326	417	506	492	522		507
Pharmacist/Intern Responded	550	452	400	455	361	285	273	360	392	441	390		4359
Pharmacy Technician Received	29	31	107	248	229	179	220	238	338	300	363		2282
Pharmacy Technician Responded	36	41	72	167	251	190	214	121	292	213	267		1864
Pharmacy Received	480	458	429	548	444	441	575	619	759	729	693		6175
Pharmacy Responded	384	370	404	381	320	204	369	376	357	660	241		4066
Sterile Compounding Received	187	190	167	204	154	263	155	313	401	384	276		2694
Sterile Compounding Responded	88	129	135	125	112	160	119	261	365	315	238		2047
Wholesale/Clinic/Hypodermic/3PL Received	255	260	428	306	315	344	446	545	651	502	303		435
Wholesale/Clinic/Hypodermic/3PL Responded	164	468	296	240	416	240	310	512	518	429	367		396
Pharmacist-in-Charge Received	245	186	162	210	148	118	178	138	163	115	169		1833
Pharmacist-in-Charge Responded	190	150	139	143	98	68	126	102	114	80	111		132
Change of Permit Received	272	399	502	555	348	379	396	421	318	398	407		439
Change of Permit Responded	355	287	329	381	250	280	323	321	212	317	319		3374
Renewals Received	127	202	170	255	201	165	289	227	214	245	263		2358
Renewals Responded	109	186	157	213	129	104	220	136	172	162	176		1764
B. Telephone Calls Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist/Intern	204	191	141	112	121	117	93	102	191	157	92		1521
Pharmacy	348	185	132	134	115	96	92	105	113	115	73		1508
Sterile Compounding	72	39	21	70	27	22	22	24	24	49	68		438
Wholesale/Clinic/Hypodermic/3PL	109	120	134	136	96	133	122	113	124	128	116		1331
Pharmacist-in-Charge	91	64	76	132	90	74	69	90	91	85	84		946
Change of Permit	32	60	79	85	50	22	35	61	53	57	81		61
Renewals	631	655	650	788	477	611	706	620	682	551	557		6928
UPDATE LICENSING RECORDS													
A. Change of Pharmacist-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	177	181	218	165	219	231	177	209	163	197	213		2150
Processed	196	233	208	197	86	142	229	253	287	225	190		2246
Pending	284	246	114	225	332	429	402	356	207	198	240		240
B. Change of Desig. Representative-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	18	18	14	15	15	16	9	16	11	14	10		156
Processed	20	25	11	15	16	8	15	13	16	14	9		162
Pending	51	56	50	52	39	46	42	42	29	22	20		20
C. Change of Responsible Manager	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	0	0	0	0	0	0	0	0	0	0	1		
Processed	0	0	0	0	0	0	0	0	0	0	0		(
Pending	0	0	0	0	0	0	0	0	0	0	1		
D. Change of Permits	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	164	77	142	149	112	95	167	171	145	273	195		1690
Processed	152	311	56	83	73	273	3	103	357	200	285		1896
Pending	621	403	459	583	601	513	651	688	680	842	783		783
E. Discontinuance of Business	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	33	43	46		30	29	33	27	42	23	46		39
Processed	34	29	51	37	12	40	30	35	35	44	36		38:
Pending	78	88	82	93	87	95	112	114	104	86	103		103
F. Requests Approved	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Address/Name Changes	1053	1209	1022	1027	832	878	959	1001	1036	908	972		1089
Off-site Storage		52			50			29			15		146
Transfer of Intern Hours	3	7	5	3	1	5	8	12	9	5	1		59
License Verification	139	116	121	115	231	151	123	304	155	226	178		1859

Revenue Received													
A. Revenue Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Applications	203,149	282,959	383,966	293,075	380,040	369,048	171,101	214,960	113,716	260,674			\$2,672,687
Renewals	843,082	1,573,955	1,016,429	2,287,772	973,220	1,134,359	948,319	1,015,399	1,122,330	1,232,078			\$12,146,944
Cite and Fine	93,883	97,483	193,670	147,727	176,949	271,973	144,563	152,659	177,211	171,913			\$1,628,031
Probation/Cost Recovery	61,591	84,166	200,259	39,882	41,522	16,753	104,439	46,985	36,624	80,797			\$713,018
Request for Information/Lic. Verification	1,640	1,740	2,705	1,978	4,230	3,660	2,965	6,570	1,735	3,300			\$30,523
Fingerprint Fee	7,595	6,811	7,203	9,212	5,710	8,428	6,321	8,526	5.978	12,201			\$77.985
										·			
B. Licenses Renewed	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	173	245	208	195	178	212	156	228	244	246	199		2284
Designated Representatives Vet (EXV)	12	5	5	2	1	5	2	5	4	7	5		53
Designated Representatives-3PL (DRL)	0	0	0	0	0	0	0	0	3	8	25		36
Pharmacist (RPH)	1648	1629	1895	1739	1525	1830	1483	1543	1687	1924	1512		18415
Pharmacy Technician (TCH)	2569	2531	2708	2481	2329	2532	2358	2440	2774	2975	2229		27926
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0	0	0	0	0	0		0
Clinics (CLN)	83	78	68	69	54	59	91	99	86	89	102		878
Clinics Exempt (CLE)	2	4	85	96	5	5	2	1	7	0	5		212
Drug Room (DRM)	2	0	2	0	1	2	2	2	3	3	2		19
Drug Room Exempt (DRE)	0	2	2	7	2	0	0	0	0	0	0		13
Hospitals (HSP)	19	16	26	82	21	30	42	32	32	27	29		356
Hospitals Exempt (HPE)	0	8	42	24	3	1	1	0	0	1	1		81
Hypodermic Needle and Syringes (HYP)	18	18	21	24	31	19	22	26	26	20	14		239
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0		0
Correctional Pharmacy (LCF)	0	2	30	20	0	0	0	0	1	0	0		53
Pharmacy (PHY)	213	338	171	1489	279	644	485	458	736	952	177		5942
Pharmacy Exempt (PHE)	0	7	76	34	1	0	1	2	0	0	2		123
Pharmacy Nonresident (NRP)	29	30	25	31	38	32	39	30	30	26	31		341
Sterile Compounding (LSC)	57	35	50	156	44	51	52	79	57	53	58		692
Sterile Compounding Exempt (LSE)	0	1	11	95	0	2	0	0	0	1	4		114
Sterile Compounding Nonresident (NSC)	7	6	5	7	6	8	6	5	5	10	3		68
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0	0	0		0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	2	0	0	0	10		12
Veterinary Food-Animal Drug Retailer (VET)	3	4	4	3	1	2	1	0	3	1	0		22
Wholesalers (WLS)	44	51	41	37	24	37	18	40	33	39	36		400
Wholesalers Exempt (WLE)	0	2	0	3	2	1	0	0	0	0	0		8
Wholesalers Nonresident (OSD)	59	50	58	52	54	47	36	36	56	54	48		550
Total	4938	5062	5533	6646	4599	5519	4799	5026	5787	6436	4492	0	58837

ent Licensees													
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	3080	3121	3159	3204	3235	3016	3066	3096	3127	3148	3018		
Designated Representatives Vet (EXV)	69	69	69	69	70	65	65	65	65	65	63		
Designated Representatives-3PL (DRL)	45	66	85	97	123	130	161	165	171	183	188		
Intern Pharmacist (INT)	6305	6166	6459	6586	6420	6378	6391	6389	6456	6501	6591		
Pharmacist (RPH)	42638	43100	43294	43472	43744	43822	43819	43818	43831	43839	43813		4
Pharmacy Technician (TCH)	74728	74875	74664	74656	74863	74561	74306	74059	73875	73769	73542		7
			_1	-1	-1	-1	-1	-1	-1	-1	-1		
Centralized Hospital Packaging (CHP)	5	5	5	3	3	3	3	3	8	8	8		
Clinics (CLN)	1168	1168	1170	1175	1182	1188	1193	1200	1200	1200	1078		
Clinics Exempt (CLE)	244	243	247	247	249	252	251	252	252	247	234		
Drug Room (DRM)	25	25	25	25	24	24	24	23	24	23	23		
Orug Room Exempt (DRE)	14	14	13	13	13	13	13	14	14	14	13		
Hospitals (HSP)	400	400	399	398	398	398	398	399	399	399	397		
Hospitals Exempt (HPE)	85	86	86	86	86	86	86	85	86	86	86		
Hypodermic Needle and Syringes (HYP)	278	281	281	281	281	281	282	283	282	284	284		
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0		
Correctional Pharmacy (LCF)	53	53	53	53	53	53	53	53	54	55	55		
Pharmacy (PHY)	6451	6439	6453	6463	6445	6454	6472	6486	6485	6486	6432		
Pharmacy Exempt (PHE)	124	124	124	124	124	125	126	124	124	124	124		
Pharmacy Nonresident (NRP)	456	455	458	462	468	470	479	487	498	500	502		
Sterile Compounding (LSC)	816	816	810	810	809	804	805	812	813	809	806		
Sterile Compounding Exempt (LSE)	121	121	121	121	120	120	118	117	117	120	121		
Sterile Compounding Nonresident (NSC)	91	91	94	95	95	97	98	98	97	96	93		
Third-Party Logistics Providers (TPL)	3	4	6	8	10	11	12	12	14	14	16		
Third-Party Logistics Providers Nonresident (NPL)	10	14	18	21	29	33	50	57	58	59	59		
/eterinary Food-Animal Drug Retailer (VET)	24	24	24	24	24	24	23	23	23	23	23		
Wholesalers (WLS)	626	623	622	622	628	629	628	629	625	621	552		
Wholesalers Exempt (WLE)	16	16	16	16	16	16	16	16	16	16	16		
Wholesalers Nonresident (OSD)	833	826	819	818	815	820	817	811	809	811	718		
Total	138708	139225	139574	139949	140327	139873	139755	139576	139523	139500	138855	0	1