



## LICENSING COMMITTEE REPORT

Debbie Veale, RPh, Chairperson

Lavanza Butler, RPh

Victor Law, RPh

Greg Lippe, CPA, Public Member

Albert Wong, PharmD

### 1. FOR INFORMATION: Updated on the Evaluation of the Text for Criminal Conviction Questions on Board Applications

#### Background

Currently, the board's applications for individual licenses (e.g., pharmacists, pharmacy technicians) ask:

"Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?"

Check the box next to **"YES"** if you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.

Check the box next to **"NO"** if you have not been convicted of a crime.

In addition, the board encourages (but does not require) applicants to provide certain information along with their application as way to help expedite the review. These items include:

- 1) certified copies of the arresting agency report;
- 2) certified copies of the court documents;
- 3) a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.

The applicant is also advised that failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary."

The Legal Office has asked boards to review these questions and consider changes to ensure consistency with legal requirements.

#### Committee Discussion and Action

The committee discussed briefly the need for review of the application questions used by the board to ascertain arrest and conviction history as part of its process in evaluation an application for licensure. Counsel suggested that this review should include conformance with legal requirements that may have changed since the questions were originally developed.

The committee took no formal action on this item, but directed staff to work with counsel to complete the necessary review and bring the matter back to the committee for further discussion and possible action.

## **2. FOR REVIEW AND DISCUSSION: Update on Discussion of the Pharmacist Intern Hours Requirements from Business and Professions Code Section 4209 and 16 California Code of Regulations Section 1728**

**Attachment 1**

#### Relevant Statutes

Business and Professions Code Section 4209 establishes the requirements for intern pharmacist to earn 1500 hours of experience.

California Code of Regulation Section 1728 further specifies the types of practice environments and experience areas where intern hours that must be earned prior to eligibility for the pharmacist licensure examination.

To confirm compliance with the above requirements, the board uses a pharmacy intern hours affidavit (form 17A-29), which includes two areas where the intern hours earned can be recorded:

- 1) Number of hours of pharmacy practice experience obtained in a pharmacy, and
- 2) Number of hours of pharmacy practice experience substantially related to the practice of pharmacy

#### Background

Periodically, usually in response to inquiries from the public, the board has scheduled discussions on the intern hours requirement and how this information is reported to the board as a requirement for admission to the California pharmacist licensure examination. At the October 2013 Board Meeting, President Weisser requested that intern hours be added to the agenda of the Licensing Committee at the request of Board Member Victor Law.

#### Committee Discussion and Action

The committee discussed the process currently used by board staff to substantiate intern experience and was advised that the board will also accept a letter from the dean of a

school of pharmacy as sufficient documentation of completion of the hours earned under the auspices of the program.

The committee was advised that representatives from California Northstate University have expressed concern about the current process used to verify intern experience, but have not submitted any written information.

The committee discussed the current legal requirements and considered if changes should be made to the current internship requirements or how the board confirms this information.

Public comment received during the meeting included that the board should consider rescinding the affidavit requirement.

The committee did not take formal action on this item, but requested that the topic be included on the agenda for a future meeting. The committee requested that staff extend invitations to the California schools of pharmacy to participate in the discussion and also requested that board staff research internship requirements in other states.

**Attachment 1** includes a copy of Business and Professions Code Section 4209, California Code of Regulations Section 1728 and the intern hour affidavit form.

**2. FOR REVIEW AND DISCUSSION: Update on the Implementation Schedule for SB 809 (DeSaulnier, Chapter 400, Statutes of 2013)**

**Attachment 2**

Relevant Statutes

Health and Safety Code Sections 11165 – 11165.3 establish and define the parameters and use of the CURES Program within the California Department of Justice. Included within these provisions are requirements that have existed for a number of years, including the requirement for prescribers and pharmacies to report dispensing information each week to the CURES system.

Background

In 2013, the CURES Program received additional funding through SB 809 to rebuild and replace its aging computer system and provide minimal, but essential, staffing to support the program in the future. (This funding was needed because CURES had been housed in the DOJ's Bureau of Narcotic Enforcement, a unit that was totally defunded several years ago in response to General Fund budget cuts made by Governor Brown in response to the state's fiscal crisis.)

The new CURES funding source identified for this system is from licensees of several healing arts boards that regulate prescribers and dispensers. Beginning in April 2014, every

practitioner eligible to prescribe (e.g., physicians, nurse practitioners, optometrists, veterinarians, dentists) or dispense (pharmacists, pharmacies), wholesalers and clinics will pay an ongoing fee of \$6 per year fee as part of their renewal. Additionally, before January 1, 2016, every pharmacist (and each of the prescriber classifications) will be required to submit an application to obtain approval to access CURES data as part of the renewal process. This process is intended to ensure widespread eligibility for prescribers and pharmacists to access CURES data on an individual patient – when the practitioners so choose – at the time of prescribing or dispensing.

Additionally, due to a trailer bill to the 2013/14 California State Budget, the board is funding for two years (2013/14 and 2014/15) an additional \$215,000 (in addition to ongoing annual funding of \$92,000 that we have been providing for approximately 10 years) that will be used to replace the aging CURES computer and replace it with a more robust system, capable of providing better access to the state’s prescribers and dispensers, who are checking the controlled substances dispensed to specific patients as part of the prescription drug monitoring program (PDMP). The prescriber boards are also contributing sizeable amounts to secure a new computer system.

Collection of CURES funding from board licensees will begin with renewals due April 1, 2014 and thereafter. The department’s Legal Office has approved the following language to be added to impacted renewal notices from the board:

**FOR BIENNIAL RENEWALS:**

Pursuant to SB 809 (DeSaulnier, Chapter 400, Statutes of 2013), you are assessed \$6 ANNUALLY which is collected at the time of renewal to cover the operation and maintenance of the Controlled Substance Utilization Review and Evaluation System (CURES). The amount of \$12 per renewal cycle is hereby added to the renewal fee.

**FOR ANNUAL RENEWALS:**

Pursuant to SB 809 (DeSaulnier, Chapter 400, Statutes of 2013), you are assessed \$6 ANNUALLY which is collected at the time of renewal to cover the operation and maintenance of the Controlled Substance Utilization Review and Evaluation System (CURES).

Meanwhile, senior board staff members are participating in development of the parameters for the new CURES computer system. They are also involved in establishing a simplified mechanism by which pharmacists will be able to sign up for CURES without needing documents certified by notary publics as part of the approval process.

Committee Discussion and Action

The committee discussed the CURES system and SB 809. The committee did not take action on this item.

**Attachment 2** includes a copy SB 809.

**3. FOR REVIEW AND DISCUSSION: Updated on Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013)**

**Attachment 3**

Background

Senate Bill 493(Hernandez, Chapter 469, Statutes of 2013) establishes an “advanced practice pharmacist” (APP) category of licensure, allowing such pharmacists to perform advanced patient care functions, such as to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers. In addition, this legislation provides for expanded duties all pharmacists can perform.

The APP provisions include the ability to:

- write or issue a prescription in specific settings under 4052.2(a)
- issue an order for controlled substances in specific settings
- Perform patient assessments
- Order and interpret drug therapy related tests
- Refer patients to other health care providers
- Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
- Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter info into patient record shared with the prescriber

Further, depending on the services provided, a pharmacist may require registration with DEA to issue an order for controlled substances.

The law also establishes the following general requirements for an APP including:

- An active CA pharmacist license – in good standing -- as a pharmacist
- Submission of an application and fee (maximum of \$300)
- License good for 2 years, and will be linked to RPh renewal
- An additional 10 units of CE each renewal cycle is required in an area of practice relevant to the pharmacist’s clinical practice
- Satisfy two of the following educational requirements:
  1. Earn certification in relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)

2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management, or health system

Regulations will be needed to implement multiple provisions in SB 493 including the parameters for the education requirements provided above.

As stated above, the legislation also established expanded duties for all pharmacists. Under these provisions a pharmacist may perform all of the following:

- Administer drugs and biological products that have been ordered by a prescriber
- Independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older as specified
- Furnish nicotine replacement products in accordance with a state treatment protocol to be developed jointly by the Pharmacy and Medical boards, provided:
  - Records are retained of drugs and devices furnished for at least 3 years so as to notify health provides or monitoring of the patient
  - The pharmacist notifies the patients primary care provider of drugs and devices furnished or into a patient record -- the pharmacist must complete 1 hour of CE on smoking cessation therapy biennially
- Furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Pharmacy and Medical boards of California pursuant to the guidelines of the CDC.
- Furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications)

Some of these provisions will also require the board to implement regulations.

#### Committee Action and Discussion

The committee discussed the legislation and was provided with a brief presentation by the California Pharmacists Association (CPhA) and California Society of Health System Pharmacists (CSHP). The associations have joined together with some of their members and multiple California schools of pharmacy to develop components to comply with some of the provisions in SB 493. The board is not involved in this process.

The committee was reminded that the board is charged with the implementation of SB 493 and the development of the necessary regulations will need to be done publicly, either in subcommittees or through the Licensing Committee. The committee/board may choose to use the work product of the CPhA/CSHP workgroups as one source of consideration in development of these requirements.

Several participants expressed interest in working with the board and committee as it moves forward with development of the necessary regulations.

The committee did not take formal action on this item, but will reconvene on February 12, 2014, to focus efforts on implementation.

**Attachment 3** is a copy of SB 493.

**4. FOR REVIEW AND DISCUSSION: Update on the Implementation Schedule for SB 294 (Emmerson, Chapter 565, Statutes 2013)**

**Attachment 4**

Background

SB 294 is the board's sponsored legislation to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products – that is, those that are compounded for injection, administration to the eye or for inhalation. The provisions provide for implementation of the requirements beginning July 1, 2014.

Committee Discussion and Action

The committee discussed the legislation and was advised of the implementation efforts being made by staff to ensure full implementation by July 1, 2014 as the legislation calls for. The committee was advised that inspector staff members received specific training and are beginning to complete inspections that are necessary as a condition of licensure. In response to public comment, all in attendance were advised that the board's inspections will include nonresident sterile compounding pharmacies and those located in California, however, the former mentioned inspections may not occur in advance of July 1, 2014.

The committee did not take action on this item.

**Attachment 4** is a copy of SB 294.

**5. FOR REVIEW AND DISCUSSION: Report on the New Pharmacy Technician Accreditation Commission**

Relevant Statutes

Business and Professions Code Section 4202 establishes the requirements for licensure as a pharmacy technician.

California Code of Regulations Section 1793.6 further defines the requirements for a training course, which is one of the pathways to licensure.

Background

The board learned that the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) have announced their collaboration to

accredit pharmacy technician education and training programs, beginning in late 2014. The collaboration will result in the creation of the Pharmacy Technician Accreditation Commission (PTAC), which will be tasked with assuring and advancing the quality of pharmacy technician education and training programs.

The PTAC will conduct document reviews and site surveys and advise the ASHP/ ACPE boards of directors, which will then agree on final accreditation actions. The establishment of the PTAC expands upon ASHP's 31-year history as a national accrediting body for pharmacy technician training programs. The ACPE also accredits educational programs involving pharmacy – specifically all schools of pharmacy in the US are accredited by ACPE.

According to information provided to the board, there are currently 258 programs in the ASHP accreditation process. Through the work of its Commission on Credentialing, ASHP will continue to accredit pharmacy technician programs until the PTAC officially begins its work in the fall of 2014. ASHP will also provide ongoing accreditation support for the PTAC.

#### Committee Action/Discussion

The committee briefly discussed this item. No public comment was provided and the committee did not take formal action. They did, however, request that staff research and provide more information at a future meeting about the new ASHP technician program approval process so the committee can determine if action is necessary, including possible changes to CCR 1793.6.

#### **6. Review and Discussion: Report on the Pharmacy Compounding Accreditation Board (PCAB) Pharmacy Technician Certification Requirement Changes**

The board was advised by the Pharmacy Compounding Accreditation Board (PCAB) that as a result of concerns raised by their applicants regarding technician certification, the PCAB's Standards Committee reviewed the interpretation of PCAB Standard 1.20.

Standard 1.20 states:

“The pharmacy provides documentation that all ... technicians ... who are engaged in compounding and dispensing in the pharmacy are ... certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate ... certifying agency...”

After review (apparently) the Standards Committee recommended no change in Standard 1.20 to the PCAB Board of Directors. Instead, the recommendation was to continue with the current interpretation of Standard 1.20 and cancel the pending January 1, 2015, recommended change.

Consequently, a proposed requirement for pharmacy technician certification that had been slated to begin on January 1, 2015, has been eliminated. Thus, PCAB will continue with their current interpretation of Standard 1.20 directing that pharmacy technicians will be

certified or otherwise credentialed by an appropriate certifying agency only when required by the state(s) in which they practice.

Committee Action/Discussion

The item was brought to the committee for informational purposes only. No committee or public comments were provided and the committee took no action.

**7. FOR INFORMATION: Competency Committee Report**

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board expects to release the scores in February 2014, however, will release exam scores more quickly if the review is completed.

Examination Development

The Competency Committee workgroups continued to meet throughout 2013 for examination development. Both Competency Committee workgroups met once during the fall to discuss examination development.

**8. FOR INFORMATION: Licensing Statistics**

**Attachment 5**

Provided in **Attachment 5** is the second quarter's licensing statistics. During the first half of the fiscal year, the board received more than 8,900 applications and issued more than 7,500 licenses. The number of applications received increased almost 14 percent and the number of licenses issued decreased almost 5 percent when compared to the same time periods last fiscal year.

**9. FOR INFORMATION: Second Quarterly Report on the Committee's Goals for 2013/14**

**Attachment 6**

The second quarterly report on the Licensing Committee's goals is provided in **Attachment 6**.

As demonstrated in the quarterly update, the board is meeting the acceptance parameters for Success Indicators 2C – Review Received Deficiency Items to Determine Application Completeness within five working days of receipt and 2E – Update Information Changes to Licensing Records within five working days.

The board is not meeting the acceptance parameters for the following Success Indicators

- 2A – Cashier All Revenue Received within three working days
- 2B – Review Initial Applications within 30 working days
- 2D – Issue Licenses within three working days of Completed Application.

In these success indicators, board staff is working diligently to move towards the goal. It is our hope that as vacancies are filled and training is completed additional progress will be made in these three areas.

**Attachment 7** includes the draft minutes from the Licensing Committee.

# **Attachment 1**

**BUSINESS AND PROFESSIONS CODE - BPC**

**DIVISION 2. HEALING ARTS [500 - 4999.129]** ( *Division 2 enacted by Stats. 1937, Ch. 399.* )

**CHAPTER 9. Pharmacy [4000 - 4426]** ( *Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.* )

**ARTICLE 16. Applications [4200 - 4210]** ( *Article 16 added by Stats. 1996, Ch. 890, Sec. 3.* )

<sup>4209.</sup> (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(*Amended by Stats. 2012, Ch. 799, Sec. 22. Effective January 1, 2013.*)

## **§ 1728. Requirements for Examination.**

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank-Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
 DEPARTMENT OF CONSUMER AFFAIRS  
 GOVERNOR EDMUND G. BROWN JR.

## Pharmacy Intern Hours Affidavit

Completed by the Supervising Pharmacist or Pharmacist-in-Charge

Prior to receiving authorization from the board to take the pharmacist licensure examination required by section 4200 of the Business and Professions Code, applicants shall submit to the California State Board of Pharmacy satisfactory evidence of obtaining 1,500 intern hours of pharmacy practice experience when he or she submits the pharmacist application. This affidavit must be completed by the pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Original affidavits are required. Photocopies or faxes will not be accepted. Any pharmacist alterations or changes must be initialed by the supervising pharmacist or pharmacist-in-charge. All dates must include the month, day, and year in order for the form to be accepted (present or current will not be accepted).

**A. TO BE COMPLETED BY APPLICANT:** (Please print or type)

|                    |                   |             |                     |
|--------------------|-------------------|-------------|---------------------|
| Name of Applicant: | Intern Number     | Date Issued | Expiration Date     |
| Residence Address: | Number and Street | City        | State      Zip Code |

**B. TO BE COMPLETED BY THE SUPERVISING PHARMACIST OR PHARMACIST-IN-CHARGE**

|  |   |                           |                     |
|--|---|---------------------------|---------------------|
| Name of Pharmacy                                       |   | Pharmacy License Number   |                     |
| Address of Pharmacy                                    | Number and Street                           | City                      | State      Zip Code |
| Name of Supervising Pharmacist or Pharmacist-in-charge | Pharmacist Contact Phone Number<br>(      ) | Pharmacist License Number | State Licensed      |

This is to certify that \_\_\_\_\_ was employed or volunteered as an intern pharmacist during the time set forth as follows:

From: \_\_\_\_/\_\_\_\_/\_\_\_\_ to \_\_\_\_/\_\_\_\_/\_\_\_\_  
 (month/day/year) (month/day/year)

A total of 1,500 intern hours is required but does not have to be obtained in one pharmacy location. Please indicate below the number of hours the intern pharmacist obtained while under your supervision.

\_\_\_\_\_ Number of hours of pharmacy practice experience obtained in a pharmacy.

\_\_\_\_\_ Number of hours of pharmacy practice experience substantially related to the practice of Pharmacy. NOTE: A maximum of 600 hours may be granted at the discretion of the board.

I certify under penalty of perjury under the laws of the State of California that all statements given under section "B" of this form herein are true, and that to the best of my knowledge the experience thus gained by this applicant meets the pharmacy practice experience obtained in a pharmacy as required by law. I further certify that my license is not revoked, suspended, or on probation in any state in which I am now or have been registered.

\_\_\_\_\_  
 Pharmacist's Signature  
 17A-29 (6.13)

\_\_\_\_\_  
 Date

# **Attachment 2**



California  
LEGISLATIVE INFORMATION

SB-809 Controlled substances: reporting. (2013-2014)

**Senate Bill No. 809**

CHAPTER 400

An act to add Sections 208, 209, and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section 11165.5 to, the Health and Safety Code, relating to controlled substances.

[ Approved by Governor September 27, 2013. Filed with Secretary of State  
September 27, 2013. ]

LEGISLATIVE COUNSEL'S DIGEST

SB 809, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would, beginning April 1, 2014, require an annual fee of \$6 to be assessed on specified licensees, including licensees authorized to prescribe, order, administer, furnish, or dispense controlled substances, and require the regulating agency of each of those licensees to bill and collect that fee at the time of license renewal. The bill would authorize the Department of Consumer Affairs to reduce, by regulation, that fee to the reasonable cost of operating and maintaining CURES for the purpose of regulating those licensees, if the reasonable regulatory cost is less than \$6 per licensee. The bill would require the proceeds of the fee to be deposited into the CURES Fund for the support of CURES, as specified. The bill would also permit specified insurers, health care service plans, qualified manufacturers, and other donors to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California.

This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled

substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require, by January 1, 2016, or upon receipt of a federal Drug Enforcement Administration registration, whichever occurs later, health care practitioners authorized to prescribe, order, administer, furnish, or dispense controlled substances, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under their care. The bill would require the Department of Justice, in conjunction with the Department of Consumer Affairs and certain licensing boards, to, among other things, develop a streamlined application and approval process to provide access to the CURES database for licensed health care practitioners and pharmacists. The bill would make other related and conforming changes.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** The Legislature finds and declares all of the following:

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable preventive, investigative, and educational tool for health care providers, regulatory agencies, educational researchers, and law enforcement. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support CURES and its Prescription Drug Monitoring Program (PDMP). The CURES PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 800,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.

(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects and serve as a tool for ensuring safe patient care, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

(d) The following goals are critical to increase the effectiveness and functionality of CURES:

(1) Upgrading the CURES PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.

(2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.

(3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.

(4) Upgrading the CURES PDMP so that it is capable of accepting the reporting of electronic prescription data, thereby enabling more reliable, complete, and timely prescription monitoring.

**SEC. 2.** Section 208 is added to the Business and Professions Code, to read:

**208.** (a) Beginning April 1, 2014, a CURES fee of six dollars (\$6) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be

billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars (\$6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Wholesalers and nonresident wholesalers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(3) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(4) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the California Board of Podiatric Medicine to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

**SEC. 3.** Section 209 is added to the Business and Professions Code, to read:

**209.** The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that he or she is applying for licensure or renewing his or her license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to order reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

**SEC. 4.** Section 2196.8 is added to the Business and Professions Code, to read:

**2196.8.** The board shall periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Public Health, the boards and committees specified in subdivision (d) of Section 208, and the Department of Justice in developing the materials to be distributed pursuant to this section.

**SEC. 5.** Section 11164.1 of the Health and Safety Code is amended to read:

**11164.1.** (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy,

if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

**SEC. 6.** Section 11165 of the Health and Safety Code is amended to read:

**11165.** (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

**SEC. 7.** Section 11165.1 of the Health and Safety Code is amended to read:

**11165.1.** (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

**SEC. 8.** Section 11165.5 is added to the Health and Safety Code, to read:

**11165.5.** (a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

(b) For purposes of this section, the following definitions apply:

(1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

# **Attachment 3**



California  
LEGISLATIVE INFORMATION

SB-493 Pharmacy practice. (2013-2014)

**Senate Bill No. 493**

CHAPTER 469

An act to amend Sections 733, 4040, 4050, 4051, 4052, 4052.3, 4060, 4076, 4111, and 4174 of, and to add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210, and 4233 to, the Business and Professions Code, relating to pharmacy.

[ Approved by Governor October 01, 2013. Filed with Secretary of State October 01, 2013. ]

LEGISLATIVE COUNSEL'S DIGEST

SB 493, Hernandez. Pharmacy practice.

The Pharmacy Law provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. The law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber. Pharmacists may also furnish emergency contraception drug therapy pursuant to standardized procedures if they have completed a training program. A violation of the Pharmacy Law is a crime.

This bill, instead, would authorize a pharmacist to administer drugs and biological products that have been ordered by a prescriber. The bill would authorize pharmacists to perform other functions, including, among other things, to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers, as specified. Additionally, the bill would authorize pharmacists to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations, as specified. This bill also would establish board recognition for an advanced practice pharmacist, as defined, would specify the criteria for that recognition, and would specify additional functions that may be performed by an advanced practice pharmacist, including, among other things, performing patient assessments, and certain other functions, as specified. The bill would authorize the board, by regulation, to set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to these provisions, not to exceed \$300.

Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The bill would make other conforming and technical changes.

This bill would incorporate additional changes in Section 4076 of the Business and Professions Code proposed by SB 205, that would become operative only if SB 205 and this bill are both chaptered and become effective on or before January 1, 2014, and this bill is chaptered last.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 733 of the Business and Professions Code is amended to read:

**733.** (a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

**SEC. 2.** Section 4016.5 is added to the Business and Professions Code, to read:

**4016.5.** "Advanced practice pharmacist" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

**SEC. 3.** Section 4040 of the Business and Professions Code is amended to read:

**4040.** (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

**SEC. 4.** Section 4050 of the Business and Professions Code is amended to read:

**4050.** (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

**SEC. 5.** Section 4051 of the Business and Professions Code is amended to read:

**4051.** (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, 4052.3, or 4052.6, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

- (1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient.
- (2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.
- (3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

**SEC. 6.** Section 4052 of the Business and Professions Code is amended to read:

**4052.** (a) Notwithstanding any other law, a pharmacist may:

- (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
- (2) Transmit a valid prescription to another pharmacist.
- (3) Administer drugs and biological products that have been ordered by a prescriber.
- (4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
- (5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.
- (6) Perform procedures or functions as authorized by Section 4052.6.
- (7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.
- (8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.
- (9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.
- (10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):
  - (A) (1) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.
  - (2) Nicotine replacement products, as authorized by Section 4052.9.
  - (3) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.
- (B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.
- (11) Administer immunizations pursuant to a protocol with a prescriber.
- (12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

**SEC. 7.** Section 4052.3 of the Business and Professions Code is amended to read:

**4052.3.** (a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

**SEC. 8.** Section 4052.6 is added to the Business and Professions Code, to read:

**4052.6.** (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

- (1) Perform patient assessments.
  - (2) Order and interpret drug therapy-related tests.
  - (3) Refer patients to other health care providers.
  - (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
  - (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.
- (b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
- (c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
- (d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
- (e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

**SEC. 9.** Section 4052.8 is added to the Business and Professions Code, to read:

**4052.8.** (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

- (1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.
- (2) Be certified in basic life support.
- (3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

**SEC. 10.** Section 4052.9 is added to the Business and Professions Code, to read:

**4052.9.** (a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

**SEC. 11.** Section 4060 of the Business and Professions Code is amended to read:

**4060.** A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

**SEC. 12.** Section 4076 of the Business and Professions Code is amended to read:

**4076.** (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

**SEC. 12.5.** Section 4076 of the Business and Professions Code is amended to read:

**4076.** (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a health facility, as defined in Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section

3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

**SEC. 12.7.** Section 4076 is added to the Business and Professions Code, to read:

**4076.** (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) The information required by paragraphs (1), (2), (3), (7), and (10) of subdivision (a) shall be printed in at least a 12-point typeface.

(c) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(d) If a pharmacist dispenses a dangerous drug or device in a health facility, as defined in Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(e) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(f) This section shall become operative on January 1, 2016.

**SEC. 13.** Section 4111 of the Business and Professions Code is amended to read:

**4111.** (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) 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 person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, 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.

**SEC. 14.** Section 4174 of the Business and Professions Code is amended to read:

**4174.** Notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6.

**SEC. 15.** Section 4210 is added to the Business and Professions Code, to read:

**4210.** (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).

**SEC. 16.** Section 4233 is added to the Business and Professions Code, to read:

**4233.** A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

**SEC. 17.** Sections 12.5 and 12.7 of this bill incorporate amendments to Section 4076 of the Business and Professions Code proposed by both this bill and Senate Bill 205. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2014, (2) each bill amends Section 4076 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 205, in which case Section 12 of this bill shall not become operative.

**SEC. 18.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

# **Attachment 4**



California  
LEGISLATIVE INFORMATION

SB-294 Sterile drug products. (2013-2014)

**Senate Bill No. 294**

CHAPTER 565

An act to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to amend, repeal, and add Sections 4127, 4127.1, 4127.2, and 4400 of, the Business and Professions Code, relating to pharmacy.

[ Approved by Governor October 04, 2013. Filed with Secretary of State  
October 04, 2013. ]

LEGISLATIVE COUNSEL'S DIGEST

SB 294, Emerson. Sterile drug products.

(1) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California. A violation of the Pharmacy Law is a crime.

This bill, commencing July 1, 2014, would expand these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. The bill, commencing July 1, 2014, would specify requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. The bill would require the board to adopt regulations to implement these provisions, and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary, as specified. By adding additional requirements to the Pharmacy Law concerning sterile drug products, the violation of which is a crime, the bill would impose a state-mandated local program.

(2) Existing law specifies the fee for issuance or renewal of a nongovernmental license to compound sterile drug products.

This bill, commencing July 1, 2014, would establish the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license in the amount of \$780 and would require the applicant to deposit a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing an inspection of the nonresident pharmacy location, as specified.

(3) The bill would also require the board to report to the Legislature, on or before January 1, 2018, regarding the regulation of nonresident pharmacies, including, among other things, a detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** The heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

**Article 7.5. Sterile Drug Products**

**SEC. 2.** Section 4127 of the Business and Professions Code is amended to read:

**4127.** (a) The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

(b) The board shall adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to initially implement the provisions of this article that become operative on July 1, 2014. The initial adoption, amendment, or repeal of a regulation authorized by this section is deemed to address an emergency for purposes of Sections 11346.1 and 11346.6 of the Government Code, and the board is hereby exempted for that purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. After the initial adoption, amendment, or repeal of an emergency regulation pursuant to this section, the board may request approval from the Office of Administrative Law to readopt the regulation as an emergency regulation pursuant to Section 11346.1 of the Government Code.

(c) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

**SEC. 3.** Section 4127 is added to the Business and Professions Code, to read:

**4127.** (a) A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

(d) This section shall become operative on July 1, 2014.

**SEC. 4.** Section 4127.1 of the Business and Professions Code is amended to read:

**4127.1.** (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Public Health and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

- (1) The sterile powder was obtained from a manufacturer.
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

**SEC. 5.** Section 4127.1 is added to the Business and Professions Code, to read:

**4127.1.** (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

- (1) Reviews a current copy of the pharmacy's policies and procedures for sterile compounding.
- (2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.
- (3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.
- (4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

- (1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.
- (2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.
- (3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

- (1) The sterile powder was obtained from a manufacturer.
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(h) This section shall become operative on July 1, 2014.

**SEC. 6.** Section 4127.2 of the Business and Professions Code is amended to read:

**4127.2.** (a) A nonresident pharmacy shall not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(3) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(e) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

**SEC. 7.** Section 4127.2 is added to the Business and Professions Code, to read:

**4127.2.** (a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the nonresident pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(4) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

- (1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.
- (2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.
- (3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.
- (4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.
- (f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.
- (g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:
  - (1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.
  - (2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.
  - (3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.
  - (4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.
- (h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.
- (i) This section shall become operative on July 1, 2014.

**SEC. 8.** Section 4400 of the Business and Professions Code is amended to read:

**4400.** The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

- (a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).
- (d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).
- (f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

**SEC. 9.** Section 4400 is added to the Business and Professions Code, to read:

**4400.** The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two

hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become operative on July 1, 2014.

**SEC. 10.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a

crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.





Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

| I. APPLICATIONS (continued)                 | JUL  | AUG  | SEP  | OCT  | NOV  | DEC  | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|------|------|------|------|------|------|-----|-----|-----|-----|-----|-----|------|
| C. Pending                                  |      |      |      |      |      |      |     |     |     |     |     |     |      |
| Pharmacist (exam applications)              | 649  | 281  | 530  | 527  | 466  | 354  |     |     |     |     |     |     | 0    |
| Pharmacist (eligible)                       | 1441 | 268  | 1006 | 1069 | 812  | 785  |     |     |     |     |     |     | 0    |
| Intern pharmacist                           | 157  | 373  | 192  | 147  | 153  | 139  |     |     |     |     |     |     | 0    |
| Pharmacy technician                         | 2636 | 2362 | 2743 | 2623 | 2688 | 2733 |     |     |     |     |     |     | 0    |
| Pharmacy                                    | 150  | 130  | 140  | 129  | 135  | 150  |     |     |     |     |     |     | 0    |
| Pharmacy - Exempt                           | 2    | 2    | 2    | 1    | 1    | 1    |     |     |     |     |     |     | 0    |
| Pharmacy - Temp                             | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Sterile Compounding                         | 25   | 20   | 27   | 25   | 28   | 41   |     |     |     |     |     |     | 0    |
| Sterile Compounding - Exempt                | 2    | 2    | 1    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Sterile Compounding - Temp                  | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Nonresident Sterile Compounding Clinics     | 18   | 17   | 20   | 22   | 22   | 21   |     |     |     |     |     |     | 0    |
| Clinics                                     | 50   | 45   | 46   | 47   | 48   | 43   |     |     |     |     |     |     | 0    |
| Clinics - Exempt                            | 25   | 17   | 8    | 13   | 12   | 14   |     |     |     |     |     |     | 0    |
| Hospitals                                   | 12   | 12   | 10   | 11   | 11   | 10   |     |     |     |     |     |     | 0    |
| Hospitals - Exempt                          | 0    | 1    | 0    | 0    | 0    | 1    |     |     |     |     |     |     | 0    |
| Hospitals - Temp                            | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Drug Room                                   | 0    | 0    | 0    | 0    | 1    | 1    |     |     |     |     |     |     | 0    |
| Drug Room - Exempt                          | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Nonresident Pharmacy                        | 91   | 70   | 91   | 102  | 96   | 94   |     |     |     |     |     |     | 0    |
| Nonresident Pharmacy - Temp                 | 0    | 0    | 0    | 0    |      | 0    |     |     |     |     |     |     | 0    |
| Licensed Correctional Facility              | 0    | 0    | 0    | 0    | 1    | 1    |     |     |     |     |     |     | 0    |
| Hypodermic Needle and Syringes              | 16   | 5    | 16   | 16   | 9    | 9    |     |     |     |     |     |     | 0    |
| Hypodermic Needle and Syringes - Exempt     | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Nonresident Wholesalers                     | 91   | 67   | 43   | 100  | 97   | 77   |     |     |     |     |     |     | 0    |
| Nonresident Wholesalers - Temp              | 0    | 0    | 0    | 0    |      | 0    |     |     |     |     |     |     | 0    |
| Wholesalers                                 | 65   | 47   | 70   | 70   | 70   | 74   |     |     |     |     |     |     | 0    |
| Wholesalers - Exempt                        | 1    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Wholesalers - Temp                          | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer        | 2    | 0    | 2    | 2    | 3    | 2    |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer - Temp | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Designated Representatives                  | 140  | 78   | 112  | 137  | 141  | 153  |     |     |     |     |     |     | 0    |
| Designated Representatives Vet              | 8    | 2    | 0    | 0    | 1    | 1    |     |     |     |     |     |     | 0    |
| Centralized Hospital Packaging              | 0    | 0    | 0    | 0    | 0    | 0    |     |     |     |     |     |     | 0    |
| Total                                       | 5581 | 3799 | 5059 | 5041 | 4795 | 4704 | 0   | 0   | 0   | 0   | 0   | 0   | 0    |

Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

| I. APPLICATIONS (continued)                 | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|
| D. Withdrawn                                |     |     |     |     |     |     |     |     |     |     |     |     |      |
| Pharmacist (exam applications)              | 0   | 0   | 0   | 0   | 98  | 147 |     |     |     |     |     |     | 245  |
| Pharmacist (eligible)                       | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Intern pharmacist                           | 1   | 2   | 0   | 0   | 0   | 17  |     |     |     |     |     |     | 20   |
| Pharmacy technician                         | 5   | 0   | 0   | 1   | 7   | 11  |     |     |     |     |     |     | 24   |
| Pharmacy                                    | 0   | 0   | 0   | 0   | 1   | 1   |     |     |     |     |     | 1   | 2    |
| Pharmacy - Exempt                           | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Pharmacy - Temp                             | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Sterile Compounding                         | 0   | 0   | 0   | 0   | 0   | 1   |     |     |     |     |     |     | 1    |
| Sterile Compounding - Exempt                | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Sterile Compounding - Temp                  | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Sterile Compounding             | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Clinics                                     | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Clinics - Exempt                            | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals                                   | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals - Exempt                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals - Temp                            | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Drug Room                                   | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Drug Room - Exempt                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Pharmacy                        | 1   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 1    |
| Nonresident Pharmacy - Temp                 | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Licensed Correctional Facility              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hypodermic Needle and Syringes              | 1   | 0   | 0   | 0   | 7   | 0   |     |     |     |     |     |     | 8    |
| Hypodermic Needle and Syringes - Exempt     | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Wholesalers                     | 0   | 0   | 0   | 0   | 3   | 4   |     |     |     |     |     |     | 7    |
| Nonresident Wholesalers - Temp              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Wholesalers                                 | 17  | 0   | 0   | 0   | 0   | 2   |     |     |     |     |     |     | 19   |
| Wholesalers - Exempt                        | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Wholesalers - Temp                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer        | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer - Temp | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Designated Representatives                  | 22  | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 22   |
| Designated Representatives Vet              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Centralized Hospital Packaging              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Total                                       | 47  | 2   | 0   | 1   | 116 | 183 | 0   | 0   | 0   | 0   | 0   | 0   | 349  |

Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

| I. APPLICATIONS (continued)                 | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|
| E. Denied                                   |     |     |     |     |     |     |     |     |     |     |     |     |      |
| Pharmacist (exam applications)              | 2   | 0   | 1   | 1   | 1   | 1   |     |     |     |     |     |     | 6    |
| Pharmacist (eligible)                       | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Intern pharmacist                           | 0   | 0   | 0   | 1   | 0   | 1   |     |     |     |     |     |     | 2    |
| Pharmacy technician                         | 3   | 7   | 1   | 3   | 3   | 5   |     |     |     |     |     |     | 22   |
| Pharmacy                                    | 0   | 0   | 0   | 3   | 2   | 0   |     |     |     |     |     |     | 5    |
| Pharmacy - Exempt                           | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Pharmacy - Temp                             | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Sterile Compounding                         | 0   | 1   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 1    |
| Sterile Compounding - Exempt                | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Sterile Compounding - Temp                  | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Sterile Compounding             | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Clinics                                     | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Clinics - Exempt                            | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals                                   | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals - Exempt                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hospitals - Temp                            | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Drug Room                                   | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Drug Room - Exempt                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Pharmacy                        | 0   | 1   | 0   | 1   | 0   | 0   |     |     |     |     |     |     | 2    |
| Nonresident Pharmacy - Temp                 | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Licensed Correctional Facility              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hypodermic Needle and Syringes              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Hypodermic Needle and Syringes - Exempt     | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Wholesalers                     | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Nonresident Wholesalers - Temp              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Wholesalers                                 | 0   | 0   | 0   | 1   | 0   | 0   |     |     |     |     |     |     | 1    |
| Wholesalers - Exempt                        | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Wholesalers - Temp                          | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer        | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Veterinary Food-Animal Drug Retailer - Temp | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Designated Representatives                  | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Designated Representatives Vet              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Centralized Hospital Packaging              | 0   | 0   | 0   | 0   | 0   | 0   |     |     |     |     |     |     | 0    |
| Total                                       | 5   | 9   | 2   | 10  | 6   | 7   | 0   | 0   | 0   | 0   | 0   | 0   | 39   |

Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

**II. RESPOND TO STATUS REQUESTS**

|   | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|
| <b>A. E-mail status requests and inquiries</b>    |     |     |     |     |     |     |     |     |     |     |     |     |      |
| Pharmacist/Intern                                 | 568 | 389 | 286 | 200 | 153 | 153 |     |     |     |     |     |     | 1749 |
| Pharmacy Technicians                              | 523 | 601 | 436 | 534 | 395 | 542 |     |     |     |     |     |     | 3031 |
| Site Licenses (pharmacy, clinic)                  | 307 | 531 | 268 | 388 | 265 | 301 |     |     |     |     |     |     | 2060 |
| Site Licenses (wholesalers)                       | 248 | 375 | 247 | 264 | 207 | 250 |     |     |     |     |     |     | 1591 |
| Pharmacist-in-Charge                              | 215 | 242 | 353 | 326 | 279 | 403 |     |     |     |     |     |     | 1818 |
| Renewals*   | 71  | 145 | 112 | 109 | 92  | 116 |     |     |     |     |     |     | 645  |
| <i>*denotes updates made January 2014</i>         |     |     |     |     |     |     |     |     |     |     |     |     |      |
| <b>B. Telephone status requests and inquiries</b> |     |     |     |     |     |     |     |     |     |     |     |     |      |
| Site Licenses (pharmacy, clinic)                  | 146 | 194 | 137 | 162 | 203 | 148 |     |     |     |     |     |     | 990  |
| Site Licenses (wholesalers)                       | 142 | 195 | 163 | 212 | 134 | 104 |     |     |     |     |     |     | 950  |
| Pharmacist-in-Charge                              | 50  | 91  | 77  | 70  | 175 | 76  |     |     |     |     |     |     | 539  |
| Renewals*   | 492 | 697 | 531 | 609 | 680 | 404 |     |     |     |     |     |     | 3413 |
| <i>*denotes updates made January 2014</i>         |     |     |     |     |     |     |     |     |     |     |     |     |      |

**III. UPDATE LICENSING RECORDS**

|   | JUL  | AUG  | SEP  | OCT  | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | FYTD |
|---|------|------|------|------|-----|-----|-----|-----|-----|-----|-----|-----|------|
| <b>A. Change of Pharmacist-in-Charge***</b> |      |      |      |      |     |     |     |     |     |     |     |     |      |
| Received                                    | 97   | 95   | 103  | 94   | 114 | 138 |     |     |     |     |     |     | 641  |
| Processed                                   | 16   | 105  | 152  | 337  | 89  | 68  |     |     |     |     |     |     | 767  |
| Pending                                     | 1023 | 1013 | 964  | 275  | 296 | 309 |     |     |     |     |     |     | 0    |
| <b>B. Change of Exemptee-in-Charge***</b>   |      |      |      |      |     |     |     |     |     |     |     |     |      |
| Received                                    | 13   | 10   | 19   | 14   | 9   | 14  |     |     |     |     |     |     | 79   |
| Processed                                   | 0    | 7    | 23   | 13   | 12  | 10  |     |     |     |     |     |     | 65   |
| Pending                                     | 249  | 252  | 248  | 37   | 43  | 49  |     |     |     |     |     |     | 0    |
| <b>C. Change of Permits</b>                 |      |      |      |      |     |     |     |     |     |     |     |     |      |
| Received                                    | 46   | 45   | 50   | 39   | 64  | 124 |     |     |     |     |     |     | 368  |
| Processed                                   | 54   | 54   | 48   | 93   | 78  | 176 |     |     |     |     |     |     | 503  |
| Pending                                     | 450  | 441  | 443  | 389  | 320 | 161 |     |     |     |     |     |     | 0    |
| <b>D. Discontinuance of Business***</b>     |      |      |      |      |     |     |     |     |     |     |     |     |      |
| Received                                    | 31   | 27   | 22   | 5    | 19  | 22  |     |     |     |     |     |     | 126  |
| Processed                                   | 16   | 9    | 43   | 12   | 18  | 18  |     |     |     |     |     |     | 116  |
| Pending                                     | 253  | 271  | 250  | 149  | 153 | 153 |     |     |     |     |     |     | 0    |
| <b>E Requests processed</b>                 |      |      |      |      |     |     |     |     |     |     |     |     |      |
| Address/Name Changes                        | 1250 | 1200 | 1065 | 1030 | 891 | 764 |     |     |     |     |     |     | 6200 |
| Off-site storage                            | 56   |      | 46   |      |     |     |     |     |     |     |     |     | 102  |
| Transfer of intern hours                    | 13   | 11   | 6    | 8    | 5   | 7   |     |     |     |     |     |     | 50   |
| License verification                        | 162  | 168  | 93   | 170  | 190 | 123 |     |     |     |     |     |     | 906  |

Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

**IV. AVERAGE PROCESSING TIMES**

|   | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| A. Average days to process initial applications |     |     |     |     |     |     |     |     |     |     |     |     |
| Pharmacist (exam application)                   | 25  | 23  | 20  | 23  | 17  | 12  |     |     |     |     |     |     |
| Pharmacy Intern                                 | 9   | 4   | 4   | 6   | 4   | 4   |     |     |     |     |     |     |
| Pharmacy Technician                             | 31  | 41  | 30  | 46  | 36  | 24  |     |     |     |     |     |     |
| Pharmacies                                      | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Non-Resident Pharmacies                         | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Wholesaler                                      | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Veterinary Drug Retailers                       | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Designated Representatives                      | 24  | 24  | 16  | 24  | 9   | 24  |     |     |     |     |     |     |
| Out-of-State Distributors                       | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Clinics   | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Hypodermic Needle & Syringe Distributors        | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Sterile Compounding                             | 24  | 24  | 16  | 24  | 14  | 24  |     |     |     |     |     |     |
| Change of Permit                                | 58  | 45  | 59  | 23  | 19  | 10  |     |     |     |     |     |     |
| Change of Pharmacist-in-Charge                  | 27  | 22  | 38  | 21  | 18  | 17  |     |     |     |     |     |     |
| Change of Designated Representative-in-Charge   | 0   | 9   | 24  | 47  | 19  | 19  |     |     |     |     |     |     |
| Discontinuance of Business                      | 68  | 13  | 51  | 6   | 19  | 19  |     |     |     |     |     |     |

B. Average days to process deficiency documents

|  |   |   |   |   |   |   |  |  |  |  |  |  |
|--|---|---|---|---|---|---|--|--|--|--|--|--|
| Pharmacist (exam application)            | 3 | 3 | 4 | 3 | 3 | 4 |  |  |  |  |  |  |
| Pharmacy Intern                          | 3 | 3 | 2 | 3 | 4 | 3 |  |  |  |  |  |  |
| Pharmacy Technician                      | 2 | 2 | 1 | 1 | 1 | 1 |  |  |  |  |  |  |
| Pharmacies                               | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Non-Resident Pharmacies                  | 5 | 5 | 5 | 6 | 5 | 4 |  |  |  |  |  |  |
| Wholesaler                               | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Veterinary Drug Retailers                | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Designated Representatives               | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Out-of-State Distributors                | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Clinics                                  | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Hypodermic Needle & Syringe Distributors | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |
| Sterile Compounding                      | 5 | 5 | 5 | 6 | 8 | 4 |  |  |  |  |  |  |

Board of Pharmacy Licensing Statistics - Fiscal Year 2013/14

**IV. AVERAGE PROCESSING TIMES (cont.)**

C. Average days to issue a license after all deficiencies are corrected

|  | JUL | AUG | SEP | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN |
|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Pharmacist (initial licensing)           | 3   | 4   | 3   | 3   | 3   | 2   |     |     |     |     |     |     |
| Pharmacy Intern                          | 3   | 3   | 3   | 3   | 2   | 2   |     |     |     |     |     |     |
| Pharmacy Technician                      | 10  | 4   | 4   | 2   | 2   | 2   |     |     |     |     |     |     |
| Pharmacies                               | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Non-Resident Pharmacies                  | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Wholesaler                               | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Veterinary Drug Retailers                | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Designated Representatives               | 20  | 10  | 18  | 15  | 4   | 4   |     |     |     |     |     |     |
| Out-of-State Distributors                | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Clinics                                  | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Hypodermic Needle & Syringe Distributors | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |
| Sterile Compounding                      | 10  | 10  | 18  | 15  | 17  | 13  |     |     |     |     |     |     |



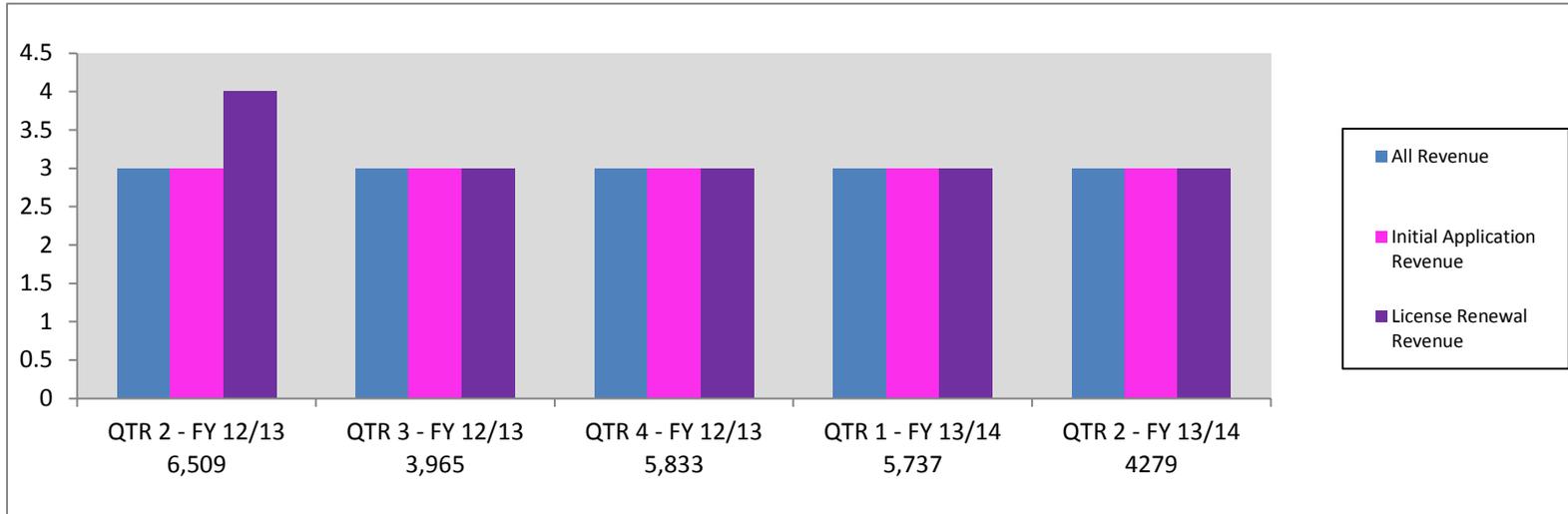


# **Attachment 6**

### Strategic Planning: Licensing

| Success Indicators |  | Related Performance Measures |  Acceptance Parameters | Actual Percentage Green Light Status | Average Processing Time | Explanation   |
|--------------------|--|------------------------------|--|--------------------------------------|-------------------------|---|
| 2A                 | Cashier all revenue received within 3 working days.  | [EF]                         | <input type="radio"/> 90%<br><input type="radio"/> 86%<br><input checked="" type="radio"/> 85%           | 63%                                  | 3.28                    | *93% cashiered within 5 days or less.<br>* 82% cashiered within 4 days or less.<br>*Staff vacancy at the initial application cashiering desk.         |
| 2B                 | Review intial applications within 30 working days.   | [PC, EF]                     | <input type="radio"/> 90%<br><input type="radio"/> 86%<br><input checked="" type="radio"/> 85%           | 36%                                  | 30                      | *87% reviewed with 45 days or less.<br>*Staff training at the TCH processing desk   |
| 2C                 | Review received deficiency items to determine application completeness within 5 working days of receipt. | [PC, EF, RC]                 | <input checked="" type="radio"/> 90%<br><input type="radio"/> 86%<br><input type="radio"/> 85%           | 94%                                  | 1.96                    |   |
| 2D                 | Issue licenses within 3 working days of completed application.   | [PC, EF]                     | <input type="radio"/> 90%<br><input type="radio"/> 86%<br><input checked="" type="radio"/> 85%           | 81%                                  | 3.30                    | *93% issued within 5 days or less.<br>*90% issued within 4 days or less.<br>*Staff Vacancy at the Site Analyst desk responsible for issuing licenses. |
| 2E                 | Update information changes to licensing records within 5 working days.                                   | [EF]                         | <input checked="" type="radio"/> 90%<br><input type="radio"/> 86%<br><input type="radio"/> 85%           | 99.7%                                | 1.71                    |   |

**2A. Cashier all revenue received three three working days.  
(Reported with number of items cashiered.)**



**All Revenue** - Includes all revenue reported in License Renewal Revenue and Initial Application Revenue as well as the following revenue categories: citations and fines, pharmacist scholarship fund, fingerprint fees, dishonored checks, change of permits, license verifications, change of ownerships, change of pharmacist-in-charge, change of designated representative-in-charge, retired licenses, regrades for examinations, and temporary permits.

**Initial Application Revenue** - Includes initial applications for all license types.

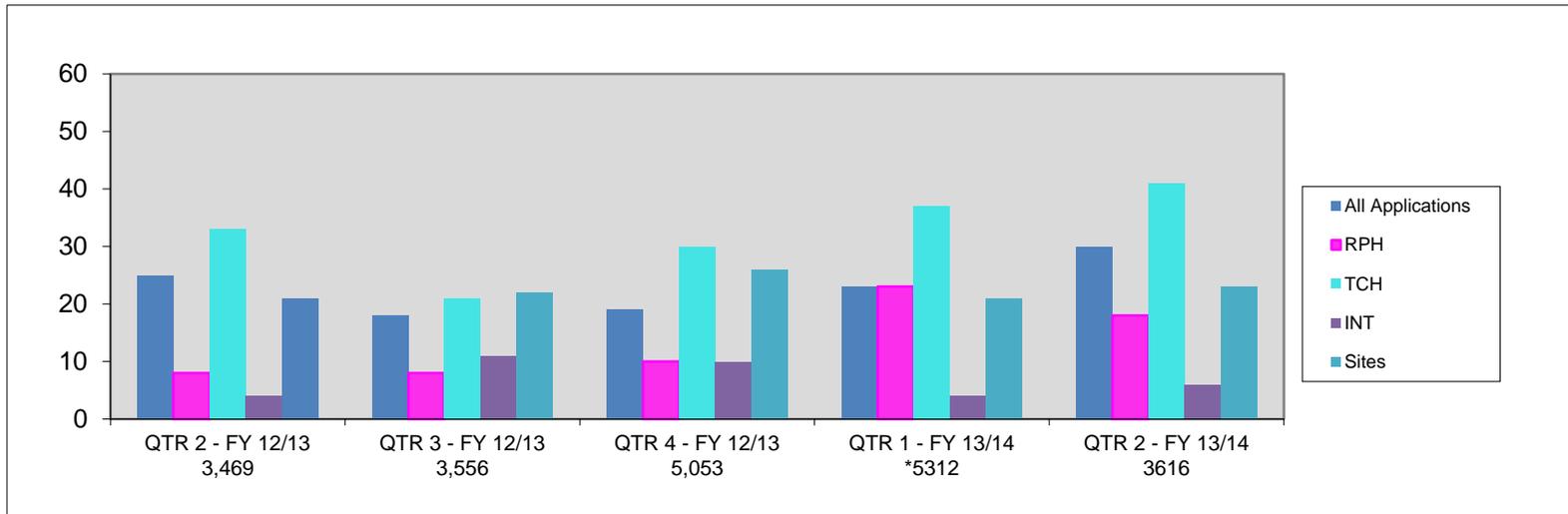
**License Renewal Revenue** - Includes all licensee renewal applications.

Notes:

Averages reported in working days excluding holidays.

**2B. Review initial applications within 30 days.**

**(Reported with Number of All Application Types, Pharmacist Applications and Pharmacy Technician Applications Received)**



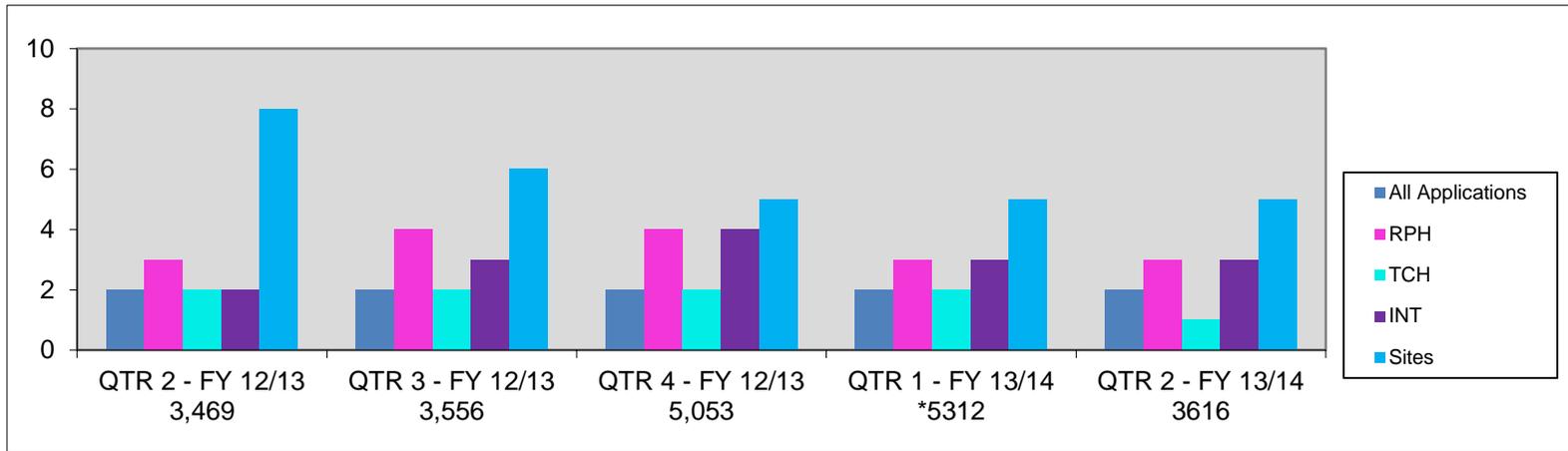
**Notes:**

Averages reported in working days excluding holidays.

Data does not include applicants where their application fee was paid by another entity.  
number updated to include Exempt site applications received.

\* Total

**2C. Review deficiency items to determine a complete application within five working days of receipt.  
(Reported with number of applications received)**



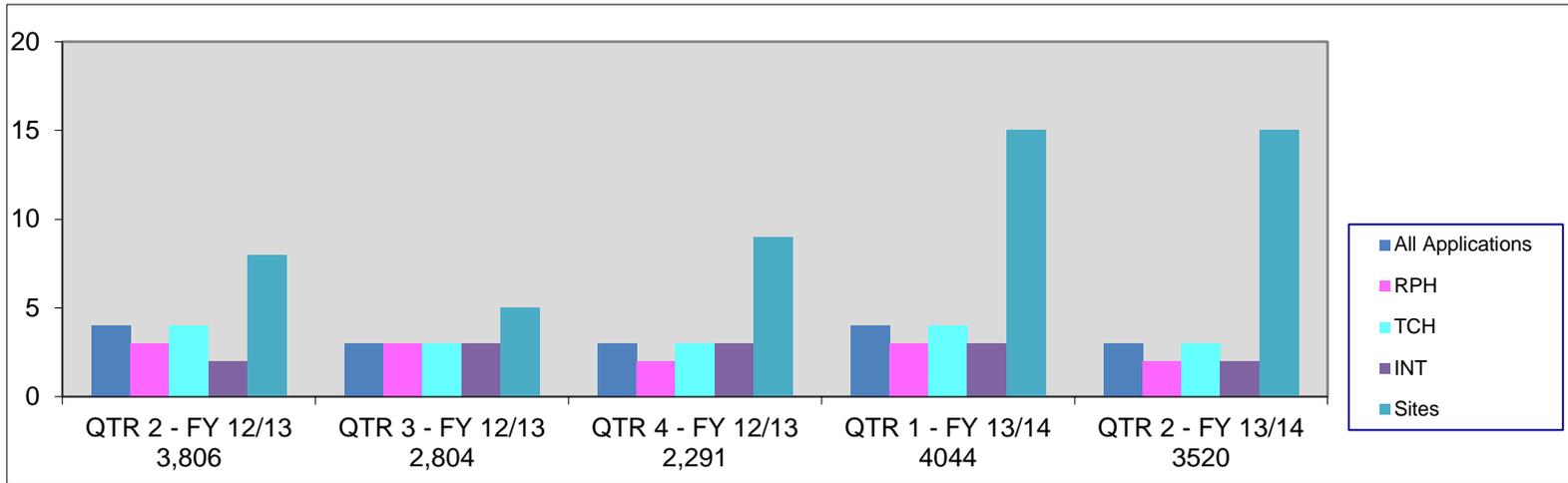
**Notes:**

Averages reported in working days excluding holidays.

Data does not include applicants where their application fee was paid by another entity.

Average issue time for site applications determined without inspection time.

**2D. Issue license within three working days of a complete application.  
(Reported with number of licenses issued)**



**Notes:**

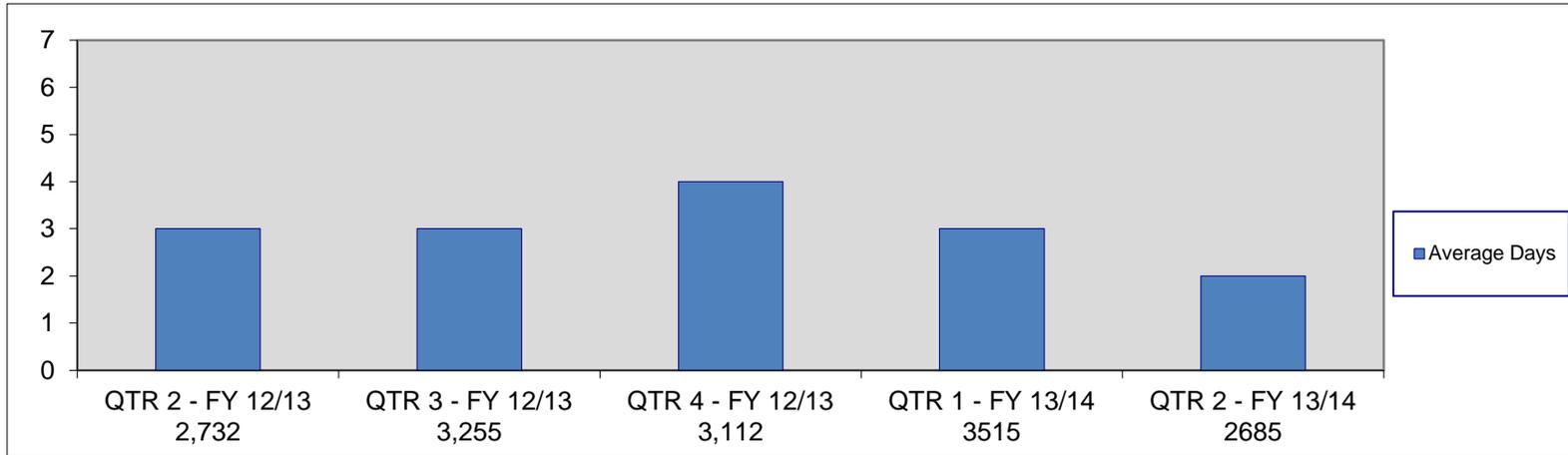
Averages reported in working days excluding holidays.

Data does not include applicants where their application fee was paid by another entity.

Average issue time for site applications determined without inspection time.

Site applications that have been determined to meet licensing requirements but have future opening dates that will impact average processing times as they are issued closer to the opening date.

**2E. Update information changes to licensing records within five working days  
(Reported by number of changes made)**



Notes:  
Averages reported in working days.

# **Attachment 7**



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
LICENSING COMMITTEE MEETING MINUTES**

**DATE:** December 11, 2013

**LOCATION:** Department of Consumer Affairs  
First Floor Hearing Room  
1625 N. Market Boulevard  
Sacramento, CA 95834

**COMMITTEE MEMBERS  
PRESENT:** Deborah Veale, RPh, Chair  
Victor Law, RPh  
Lavanza Butler, PharmD  
Stanley C. Weisser, RPh, Board President

**COMMITTEE MEMBERS  
NOT PRESENT:** Greg Lippe, Public Member  
Albert C.M. Wong, PharmD

**STAFF  
PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Carolyn Klein, Manager  
Kristy Shellans, DCA Staff Counsel  
Michael Santiago, DCA Staff Counsel  
Debbie Damoth, Administration and Regulation Manager  
Amber Dillon, Licensing Manager  
Laura Hendricks, Associate Analyst

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**Call to Order**

Chair Veale called the meeting to order at 10:01 a.m.

Chair Veale provided instructions for meeting attendees interested in receiving continuing education credit to sign in at the sign in sheet at the back of the room.

Chair Veale conducted a roll call. Committee Members Lavanza Butler and Victor Law were present. President Weisser attended and participated in the meeting.

Licensing Committee Meeting Minutes  
December 11, 2013

**1. Text for Criminal Conviction Questions on Board Applications**

Background

The board's applications for individual licenses (e.g., pharmacists, pharmacy technicians) ask:

"Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?"

Check the box next to "**YES**" if you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.

Check the box next to "**NO**" if you have not been convicted of a crime.

You may wish to provide the following information in order to assist in the process of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary."**

The Legal Office requested the committee review these questions and modify the verbiage to conform to the format used by other boards and bureaus in the department.

Discussion

Chair Veale reviewed and referenced the language provided in the meeting materials and asked committee members for comments.

Department of Consumer Affairs (DCA) Staff Counsel Kristy Shellans further explained a letter was sent to DCA clients regarding the conviction related questions. There was some concern with the scope and breadth of the questions used. Specifically, the questions do not identify the questions that the board cannot consider when making a licensing decision. The committee discussed concerns of ensuring the language is clear and easy for all applicants to read and understand.

Board staff indicated it would be beneficial to work with both DCA counsel and Attorney General (AG) counsel as the later would be defending board licensing decisions when an appeal of an application denial occurred.

Licensing Committee Meeting Minutes  
December 11, 2013

Chair Veale requested board staff continue to work with counsel to bring a draft back to the committee.

Chair Veal asked for public comment. No public comment was provided.

**Agenda Items 2 and 3 Combined**

2. **Pharmacist Intern Hours Requirements from Business and Professions Code Section 4209 and 16 California Code of Regulations Section 1728**
3. **Pharmacy Intern Hours Affidavit Form 17A-29**

Relevant Statutes and Regulations

Business and Professions Code section 4209:

- (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
- (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
- (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.
- (c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

Board regulations at 16 California Code of Regulations Section 1728 then goes on to specify:

1728. Requirements for Examination

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
  - (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
    - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
    - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
    - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
    - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

Licensing Committee Meeting Minutes  
December 11, 2013

- (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
- (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
- (4) A signed copy of the examination security acknowledgment.
- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.
- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination

Background

Periodically, usually in response to inquiries from the public, the board has scheduled discussions on the number of intern hours earned and reported to the board as a requirement for admission to the California pharmacist licensure examination. At October 2013 Board Meeting, President Weisser requested that intern hours be added to the agenda of the Licensing Committee at the request of Board Member Victor Law.

The Pharmacy Intern Hours Affidavit (form 17A-29) has two areas where the intern hours earned can be recorded:

- 1) Number of hours of pharmacy practice experience obtained in a pharmacy, and
- 2) Number of hours of pharmacy practice experience substantially related to the practice of Pharmacy. NOTE: A maximum of 600 hours may be granted at the discretion of the board.

The board requests that the hours earned by a pharmacist intern while in school that are not obtained in a pharmacy but substantially related to pharmacy be recorded on line two of the Pharmacy Intern Hour Affidavit form. The board will also accept a letter from the School of Pharmacy on school letterhead "certifying that the student has accumulated 600 hours of internship through the experiential activities of the Doctor of Pharmacy curriculum in the School of Pharmacy" signed by the dean.

California Northstate University has expressed concern to the board's licensing staff about the appropriateness of the forms being completed by the colleges in California. However, there is no written statement from the school.

Discussion

Chair Veale referenced the language provided in the meeting materials and suggested that item 2 and 3 be discussed together then asked if committee members or the public had any questions or concerns.

Mr. Victor Law stated that the concern was brought forth by California Northstate University. Committee members discussed the issue. Some members of the committee indicated that changes to the current requirements are not required and indicated that the intent of the requirements are to protect the consumers and pharmacy students need real life experience such as consultation with the patients. Executive Officer Virginia Herold indicated she would like to hear from the California schools of pharmacy. Ms. Herold also reminded the committee of the requirement for the foreign graduates to complete 1500 hours of intern experience.

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Chair Veale asked for public comment.

Dennis McAllister, representing the Accreditation Council for Pharmacy Education (ACPE), provided the committee with the intern requirements for accredited pharmacy degree programs and shared that as part of their process the ACPE also requires that the preceptors obtain annual training.

Chief Executive Officer John Roth for California Pharmacist Association (CPhA) expressed concern of the requirement for the intern hour affidavit and asked that the form be rescinded for all the hours required by the board.

Chair Veale recommended that the board place the topic on the agenda for the next meeting and invite the California schools of pharmacy to discuss the regulation and affidavit requirements. Board staff was directed to contact the NABP and survey intern hour requirements for other states.

#### **4. Implementation Schedule for SB 809 (DeSaulnier, Chapter 400, Statutes of 2013)**

##### Relevant Statutes

Health and Safety Code Sections 11165 – 11165.3 establish and define the parameters and use of the CURES Program within the California Department of Justice. For a number of years, prescribers and pharmacies have been required to report each week to DOJ every Schedule II, III, and IV prescription dispensed.

##### Background

In 2013, the CURES Program received additional funding through SB 809 to rebuild and replace its aging computer system and provide minimal but essential staffing to support the program in the future. This support was needed because CURES had been housed in the Department of Justice's (DOJ) Bureau of Narcotic Enforcement, a unit that was totally defunded several years ago in response to General Fund budget cuts made by Governor Brown in response to the state's fiscal crisis.

The new CURES funding source is now the regulatory boards in the Department of Consumer Affairs that license prescribers and dispensers. Beginning in April 2014, every practitioner eligible to prescribe (e.g., physicians, nurse practitioners, optometrists, veterinarians, dentists) or dispense (pharmacists, pharmacies), wholesalers and clinics will pay an ongoing fee of \$6 per year fee as part of their renewal. Additionally before January 1, 2016, every pharmacist (and each of the prescriber classifications) will be required to submit an application to obtain approval to access CURES data as part of the renewal process. This process is intended to ensure widespread eligibility for prescribers and pharmacists to access CURES data on an individual patient -- when the practitioners so choose -- at the time of prescribing or dispensing.

Additionally, due to a trailer bill to the 2013/14 California State Budget, the board is funding for two years (2013/14 and 2014/15) an additional \$215,000 (in addition to ongoing annual funding of \$92,000 that we have been providing for approximately 10 years) that will be used to replace the aging CURES computer and replace it with a more robust system, capable of providing better access to the state's prescribers and dispensers who are checking the controlled substances dispensed to specific patients as part of the

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prescription drug monitoring program (PDMP). The dispenser boards are also contributing sizeable amounts to secure a new computer system.

Specifically, SB 809 provides the following goals for this computer system:

- (1) Upgrading the CURES PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.
- (2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.
- (3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.
- (4) Upgrading the CURES PDMP so that it is capable of accepting the reporting of electronic prescription data, thereby enabling more reliable, complete, and timely prescription monitoring.

Board staff is participating in development of the parameters for the new CURES computer system. They are also involved in establishing a simplified mechanism by which pharmacists will be able to sign up for CURES without having to have documents certified by notary publics as part of the approval process.

Discussion

Chair Veale reviewed and referenced the language provided in the meeting materials.

Virginia Herold stated the intent is to make a more user friendly Prescription Drug Monitoring Program and advised the committee that the board will start collecting fees April 2014 consistent with the legislation. Ms. Herold noted that an upgraded system is necessary to fully implement the provisions of SB 809.

Mr. Law underscored the need for the new system to be user friendly and was advised that board staff is participating in the development along with the Department of Justice. Ms. Herold also noted that the DOJ will also be seeking input from stakeholders on system requirements as part of the development effort for the new system.

Chair Veale asked for public comment.

Darlene Fujimoto with the American Society of Consultant Pharmacists questioned whether the provisions of SB 809 apply to nurses as well. Ms. Herold recommended that Dr. Fujimoto consult with the Board of Registered Nursing.

**5. Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013)**

Background

Senate Bill 493 establishes an “advanced practice pharmacist” category of licensure, allowing such pharmacists to perform advanced patient care functions, such as to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue

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medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

Specifically: SB 493:

- Creates a new license category of Advanced Practice Pharmacist who may practice advanced practice pharmacy within or outside a pharmacy (*CA B&P 4016.5*)
- Allows an APP to write or issue a prescription in specific settings under 4052.2(a) (*CA B&P 4040, 4051, 4076*)
- Allows an APP to issue an order for controlled substances in specific settings (*CA B&P 4060*)
- Also, an APP may:
  - Perform patient assessments
  - Order and interpret drug therapy related tests
  - Refer patients to other health care providers
  - Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
  - Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter info into patient record shared with the prescriber
  - require registration with DEA for prescribing APP
  - tests ordered by APP in coordination with and notification to patient's diagnosing physician (*CA B&P Code section 4052.6* )
- APP Requirements:
  - Hold an active CA pharmacist license – in good standing -- as a pharmacist
  - File an application with the board & pay fee (\$300 max)
  - License good for 2 years, and will be linked to RPh renewal
  - An additional 10 units of CE each renewal cycle is required in an area of practice relevant to the pharmacist's clinical practice (*CA B&P 4210, 4233*)

Regulations will be needed to implement multiple provisions in SB 493: for example

To qualify as an APP, a licensed pharmacist must possess 2 of the 3 below:

1. Earn certification in relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)
2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management, or health system (*CA B&P 4210*)

Additional provisions of the bill affect all pharmacists, including those who do not become licensed as APPs. Some of these provisions will also require the board to implement regulations. Senate Bill 493:

- Allows a pharmacist to administer drugs and biological products that have been ordered by a prescriber (*CA B&P Code section 4052*)

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- Allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older. To initiate immunizations, a pharmacist must:
  - complete an immunization training program endorsed by the CDC
  - be certified in basic life support
  - comply with all state and federal recordkeeping requirements, provide info to patient's primary care physician and into the CDPH's immunization registry.
  - Be able to initiate and administer epinephrine or diphenhydramine by injection (*CA B&P 4052.8*)
- Permits a pharmacist to furnish nicotine replacement products in accordance with a state treatment protocol to be developed jointly by the Board and Medical Board, provided:
  - Records are retained of drugs and devices furnished for at least 3 years so as to notify health providers or monitoring of the patient
  - The pharmacist notifies the patients primary care provider of drugs and devices furnished or into a patient record -- the pharmacist must complete 1 hour of CE on smoking cessation therapy biennially (*CA B&P sections 4052 and 4052.9*)
- Permits a pharmacist to furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Board and the Medical Board of California pursuant to the guidelines of the CDC. (*CA B&P Section 4052, 4052.3*)
- Also a pharmacist may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications) (*CA B&P section 4052*)

The California Pharmacists Association and California Society of Health System Pharmacists have joined together with some of their members and multiple California schools of pharmacy to develop components to comply with some of the provisions in SB 493. The board was not involved in this process.

Discussion

Chair Veale reviewed the agenda item. Ms. Veale iterated that the board will work with the public and stakeholders. Ms. Herold advised the committee that the Medical Board will also have a designee to assist with the development of some protocols required by this legislation. Ms. Herold suggested that a draft protocol could be provided for the Medical Board for consideration during is May 2014 Board Meeting if the draft is ready.

Ms. Veale suggested that the board identified existing protocols and programs that may already exist, to leverage that information and identified the Centers for Disease Control as one possible source.

The committee also heard a brief presentation by representatives of CPhA and CSHP. The presentation discussed a collaborative effort being undertaken by the two associations to develop a certificate program that would comply with the requirements of SB 493. The representatives also expressed interest in working with the board to develop the necessary elements to achieve full implementation of SB 493.

Several meeting attendees also expressed interest in working with the board.

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Chair Debbie Veale requests that the committee reconvene early February 2014 to allow groups the opportunity to bring forward protocols for committee review as well as allow board staff to complete research.

**6. Implementation Schedule for SB 294 (Emmerson, Chapter 565, Statutes 2013)**

Background

SB 294 is the board's sponsored legislation to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products – that is, those that are compounded for injection, administration to the eye or for inhalation. The provisions provide for implementation of the requirements beginning 7/1/2014.

Discussion

Chair Veale provided an overview of the agenda item. Virginia Herold informed the committee that the board has a go live date of July 1, 2014. The board is not authorized to hire staff or have the funds to implement SB 294. The board is working with legal for implementing. Board inspectors have undergone training for at least 53 hours. The board is still completing inspections as this continues to be a public health issue. The board would like to have the hospitals licensed as soon as possible or they will not be able to compound as of 7/1/14 without a board license for sterile compounding. If they are licensed as outsourcing, they will still need to be licensed with the board.

Chair Veale asked for public comment.

Public comment on this item included an inquiry about the board's ability to inspect nonresident sterile compounding pharmacies that are shipping products in to California. Ms. Herold advised all present that the board will be inspecting such facilities.

**7. New Pharmacy Technician Accreditation Commission**

Relevant Statutes

**4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline**

**(a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:**

- (1) Has obtained an associate's degree in pharmacy technology.
- (2) Has completed a course of training specified by the board.**
- (3) Has graduated from a school of pharmacy recognized by the board.
- (4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a).

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Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(e) Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

**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) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(1) Knowledge and understanding of different pharmacy practice settings.

(2) 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) 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) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

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.

Background

The board has learned from an outside source that the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) have announced their collaboration to accredit pharmacy technician education and training programs, beginning in late 2014. The collaboration will result in the creation of the Pharmacy Technician Accreditation Commission (PTAC), which will be tasked with assuring and advancing the quality of pharmacy technician education and training programs.

The PTAC will conduct document reviews and site surveys and advise the ASHP/ ACPE boards of directors, which will then agree on final accreditation actions. The establishment of the PTAC expands upon ASHP's 31-

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year history as a national accrediting body for pharmacy technician training programs. The ACPE also accredits educational programs involving pharmacy – specifically all schools of pharmacy in the US are accredited by ACPE.

According to information provided to the board, there are currently 258 programs in the ASHP accreditation process. Through the work of its Commission on Credentialing, ASHP will continue to accredit pharmacy technician programs until the PTAC officially begins its work in the fall of 2014. ASHP will also provide ongoing accreditation support for the PTAC.

The formation of the new review structure will require the need for the board to reevaluate and possibly modify its regulation at 16 California Code of Regulation section 1793.6 regarding approved courses of training for pharmacy.

Discussion

Chair Veale provided an overview of the agenda item.

No public comment was provided.

Chair Veale requested that this item be placed on a future meeting agenda of this committee for staff to provide more information on the new ASHP technician program approval process so the committee can make a decision about how to proceed.

**8. Pharmacy Compounding Accreditation Board (PCAB) Pharmacy Technician Certification Requirement Changes**

Background

The board has been advised by the Pharmacy Compounding Accreditation Board that as a result of concerns raised by their applicants regarding technician certification, the PCAB's Standards Committee reviewed the interpretation of PCAB Standard 1.20.

After review the Standards Committee recommended no change in Standard 1.20 to the PCAB Board of Directors. Instead the recommendation was to continue with the current interpretation of Standard 1.20 and cancel the pending January 1, 2015, recommended change.

Consequently, a proposed requirement for pharmacy technician certification that had been slated to begin on January 1, 2015, has been eliminated. Thus PCAB will continue with their current interpretation of Standard 1.20 directing that pharmacy technicians will be certified or otherwise credentialed by an appropriate certifying agency only when required by the state(s) in which they practice.

Discussion

Chair Veale provided an overview of the agenda item and determined that the proposed changes have been eliminated.

No committee or public comment was provided.

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**9. Competency Committee Report**

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means there will be a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board expects to release the scores in February 2014.

Examination Development

The Competency Committee workgroups continued to meet throughout 2013 for examination development. Both Competency Committee workgroups met once during the fall to discuss examination development.

No additional committee or public comment was provided.

**10. Licensing Statistics**

Chair Veale provided a summary of some of the licensing statistics for July 2013-October 2013. During the first four months of fiscal year, the board has received over 6,700 applications and issued over 5,600 licenses. The number of applications received has increased when compared to the same period last year by about 7.6 percent. Additionally, there is a slight increase (0.8 percent) in the number of licenses issued.

No additional committee or public comment was provided.

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

No public comment was provided.

Chair Veale adjourned the meeting at 1:02 p.m.