



California State Board of Pharmacy

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

DATE: July 30, 2013
TO: Greg Lippe, Chair and
Legislation and Regulation Committee Members

a. LEGISLATION REPORT

The Senate and Assembly are on summer recess. The Assembly returns on August 5, and the Senate returns from recess on August 12.

Legislative measures, related analyses and additional documents are provided for each bill in Attachment 1.

Board-Sponsored Legislation for 2013

Attachment 1

1. SB 294 (Emmerson) Compounded Drug Products

Last Amend: July 3, 2013

Board Position: Support

Status: Set for Hearing: Assembly Health August 6, 2013

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.

Under current law, a sterile compounding pharmacy is not required to possess a specialty permit to compound drug products if they are accredited, or otherwise exempted from the specialty permit. This measure will require all pharmacies – whether accredited or not – to possess a specialty permit from the board if they compound sterile drug products for distribution in California. SB 294 sets the license fee for a sterile compounding permit at \$780 annually, requires nonresident sterile compounding pharmacies to reimburse the board for actual and necessary expenses associated with the yearly inspection of a nonresident pharmacy.

As reflected in the attached analysis, staff has requested amendments to remove references to the Building Standards Commission, as the board does not anticipate the need to implement (on an emergency basis for initial implementation) additional or different building standards.

SB 294 passed the Senate on May 29, 2013, was heard and passed out of the Assembly Committee on Business, Professions and Consumer Protection, and is scheduled for hearing in Assembly Health on August 6th.

2. SB 821 (Senate Comm. on Business Professions and Economic Development) Omnibus

Last Amend: June 27, 2013

Board Position: Support

Status: Re-referred to ASM Appropriations

SB 821 is a Senate Omnibus measure that contains three board-approved proposals, as summarized below. The bill passed the Senate (on consent) on May 28, 2013, and has passed the Assembly Committee on Business, Professions and Consumer Protection. The board's provisions were amended into SB 821 on June 14, as summarized below.

Due to the length of the bill, only the sections relevant to the board's proposals are provided in Attachment 1 (Sections 18-20 of the bill).

Add the Definition of "Correctional Pharmacy" – See SEC. 18 of SB 821

At the April 2013 Board Meeting, the board ratified the language provided to Senate Committee on Business, Professions and Economic Development to specify a definition of "Correctional Pharmacy." The board proposed the definition to be at Section 4066 of the Business and Professions Code. To keep board definitions in alphabetical order, however, Legislative Counsel placed the definition at Section 4021.5. Also, the board suggested that the word "state" be stricken from the definition, so as to broadly apply to any correctional pharmacy. That modification was not accepted as an omnibus provision.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative – See SEC. 19 of SB 821

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. The board's proposal specifies that the one year of paid work experience shall be earned in a licensed facility.

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception – See SEC. 20 of SB 821

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit.

3. SB 305 (Price) Healing Arts Boards

Last Amend: June 19, 2013
Board Position: (none)
Status: Referred to ASM Appropriations (6/25/13)

Staff recommendation: Support

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; some of these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to the B&PC to provide the board with the express authority to receive certified records for this purpose. To address the board's request, and that of other healing arts boards, Senator Price introduced a provision to add Section 144.5 to the Business and Professions Code, applicable to all DCA boards that would authorize boards to request and receive such documents for the purpose of completing applicant and licensee investigations. The board's original proposal included a requirement that upon request, the courts and law enforcement jurisdictions would be required to provide the records being requested. This provision equated to a state mandate, which drew concerns from local jurisdictions. Thus, it was not included in the bill.

Section 144.5 was amended into SB 305 on April 15, 2013, and since that time has passed the Senate. The Assembly Committee on Business, Professions and Consumer Protection passed the measure on June 25th, and the bill was referred to Assembly Appropriations where it awaits hearing.

4. Other Board-Approved Proposals

In May 2012, the board voted to sponsor the addition of a statutory provision to authorize the board to issue a public reprimand for violations that may not warrant license denial or issuance of a probationary license. Any such reprimand issued with a license would constitute discipline, and would be reported to the National Practitioner Data Bank. Staff has not yet secured an author to carry this proposal. A copy of the board-approved language is provided in Attachment 1.

Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

5. AB 1045 (Quirk-Silva) Nonresident Sterile Compounding Pharmacies

Last Amend: June 19, 2013
Board Position: Support
Status: 7/2/13 – Ordered to Senate Third Reading

AB 1045 will allow the board to immediately take action to cancel, revoke, or suspend a nonresident pharmacy license and a nonresident sterile compounding pharmacy permit if the home state license has been canceled, revoked or suspended.

In addition, AB 1045 specifies conditions under which prescribers, pharmacies, and patients shall be notified if a sterile compounding pharmacy issues a recall notice, and where the drug use of or exposure to the recalled drug may cause a serious adverse health consequence or death, and where the recalled drug was dispensed or is intended for use in California. The bill specifies that the board shall be notified within 12 hours of a recall notice.

6. AB 1136 (Levine) Pharmacists: Drug Disclosures (Auxiliary Label)

Last Amend: April 15, 2013

Board Position: Oppose

Status: 7/2/13 – Ordered to Senate Third Reading

Currently, board regulation specifies seven classes of drugs that may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol. That section further defines examples of drugs that may have harmful effects when taken in combination with alcohol, but that may or may not affect a person's ability to operate a motor vehicle.

AB 1136 would require that where a drug is specified by the board to be a drug for which a warning shall be given (i.e., as specified in regulation), that in addition to the requirements of the regulation, on or after July 1, 2014, if the pharmacist exercises his or her professional judgment and determines that the drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written warning on the drug container.

7. SB 204 (Corbett) Prescription Drugs: Labeling (Translations)

Last Amend: June 27, 2013

Board Position: (none)

Status: 6/27/13 – Referred to ASM Health

SB 204 would require that non-English translations of the "directions for use" as published on the board's web site be printed on prescription container labels. SB 204 would permit a pharmacy to use its own translations of the "directions for use" if a trained and qualified translator or translation service is utilized. In addition, SB 204 provides that a pharmacist has not breached his or her legal duty if the pharmacist uses a translation on the board's web site, where the directions contained an error, and where the pharmacist did not know, or have reason to know of the error. SB 204 provides that where a non-English translation is used on a prescription container label, the English directions for use also be provided.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

8. SB 205 (Corbett) Prescription Drugs: Labeling (12-Point Font)

Last Amend: July 1, 2013

Board Position: (none)

Status: 8/13/13 – Set for Hearing in Assembly Business, Professions and Consumer Protection

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and that certain items on the label be printed in at least a 12-point font. Existing regulation at 16 CCR 1707.5 requires that specified “patient-centered” information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient. SB 205 also amends a reference to a facility *licensed* pursuant to Health & Safety Code 1250 to require that the facility be *defined by* that section.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

9. SB 306 (Torres) Automated Dispensing Machines

Last Amend: July 1, 2013

Board Position: (none)

Status: 8/13/13 – Set for Hearing in Assembly Business, Professions and Consumer Protection

Recommendation: Oppose unless amended

SB 306 would provide for board licensure of physician group practices, allow these groups to purchase drugs at wholesale; allow for the use of automated drug delivery systems in these settings for the purpose of providing point-of-care access to prescription medications, without having a pharmacist or consulting pharmacist. To accomplish this, SB 306 proposes to amend Pharmacy Law to allow physician group practices the ability to acquire a board license, own comingled inventories of drugs, and allow all physicians in the group practice, or in a contract with the group practice, to be able to dispense patient medications from that inventory, including controlled substances. In addition, SB 306 will amend current provisions related to automated drug delivery systems to allow non-pharmacists to stock, re-stock and maintain these systems, and ‘designees’ of physicians to have access to the drug stock. SB 306 removes the existing requirement for a pharmacist that maintains an automated drug delivery system to be *‘located’* in California; rather, that a pharmacist be *‘licensed’* in California. Further, this bill would amend existing law to allow an automated drug dispensing system to *not* have 2-way video, if a prescriber provides a (drug) consultation to a patient, as specified in the bill.

The board has provided draft language as a discussion point to the sponsors that would structure a license similar to that of other board-licensed clinics.

10. SB 598 (Hill) Biosimilars

Last Amend: June 20, 2013
Board Position: Oppose
Status: In Assembly Appropriations
Passed out of ASM Health on 7/2/13

SB 598 would add Section 4073.5 to specify conditions under which a pharmacist can exercise professional discretion to substitute a biosimilar where a biologic has been prescribed. For prescriptions filled prior to January 1, 2017, SB 598 requires the pharmacy to notify the prescriber of any substitution made within five business days of the selection. The board opposed SB 598 at the April 2013 Board Meeting stating the board's concerns that the bill may be premature, the burden placed on the pharmacy to provide follow-up notification to a prescriber, as well as the role a pharmacist plays in substitutions. The board noted that once deemed "biosimilar" the board would support an approach similar to the authority that allows the substitution of generics. The board also has conveyed to the author that where there is an adverse event attributed to the use of a biosimilar that such an event be required to be reported to the FDA's "Medwatch."

During a recent policy hearing (ASM Health), the committee made comments in support of pharmacist notification to physicians each time a substitution would be made.

11. SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors

Last Amend: July 3, 2013
Board Position: Support if Amended
Status: 8/13/13 – Set for Hearing in ASM Judiciary

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals, in good faith and not for compensation, to administer an epinephrine auto-injector without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

The board established a position of Support if Amended at the April 2013 Board Meeting, with the suggested amendment to also authorize a pharmacist to approve the requisite training certification and issue the prescription for an epinephrine auto-injector, as specified. Staff has met with the author's staff and sponsor and conveyed the board's request to amend the bill.

12. SB 809 (DeSaulnier) CURES

Last Amend: June 26, 2013
Board Position: Support (4/24/13)
Status: 8/13/13 – Set for Hearing in ASM Business, Professions and Consumer Protection

Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners. SB 809 would establish permanent funding for CURES by increasing fees for specified health care practitioners and also to wholesalers, nonresident wholesalers and veterinary food-animal drug retailers.

Enforcement

13. SB 62 (Price-Liu) Coroners: Reporting Requirements: Prescription Drug Use

Last Amend: June 27, 2013
Board Position: Support
Status: In ASM Appropriations (as of July 15, not yet scheduled for hearing)

Existing law requires a coroner to file a report with the Medical Board and others when findings indicate that a death may be the result of specified health care practitioners' gross negligence or incompetence. SB 62 will require a coroner to also file a report with the Medical Board when the findings of a pathologist indicate that a cause of death is due to a Schedule II, II or IV drug, and further specifies the information that is to be provided. SB 62 provides that following any initial report provided is followed by a final report of investigation, coroner's report, autopsy protocol and other relevant information within 90 days or as soon as possible.

The introduced version of the bill included the Board of Pharmacy as one of the recipients of the reports, but was amended out in April 2013 based on concerns from coroners over having to file reports with multiple agencies. The board has requested amendments to SB 62 to expressly state that the MBC and other boards that receive the reports are authorized to share the information with the Board of Pharmacy.

Licensing

14. AB 258 (Chavez) State Agencies: Veterans

Last Amend: April 23, 2013

Status: As of 7/2/13, on the Senate Floor

SB 258 would standardize the way any state government organization would ask an individual about their veteran status. As amended on April 23, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format:

"Have you ever served in the United States military?"

This item is provided for information only; the board does not have a position on this measure. Please see AB 1057 for related legislation.

15. AB 512 (Rendon) Healing Arts Licensure Exemption

Introduced: February 20, 2013

Status: As of 7/8/13, Passed to the Senate

Position: Support

AB 512 extends the provisions of Section 901 of the Business and Professions Code to provide that until 1/1/18, an individual may be exempt from the licensure and regulation requirements for defined health care practitioners, to offer or provide health care services for which he or she is licensed or certified, through a sponsored event, as defined. The current provisions 'sunset' on 1/1/14. This section also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other requirements, including the payment of a fee as determined by a board.

This item is provided for information only.

16. AB 1057 (Medina) Professions and Vocations: License: Military Experience

Last Amend: June 3, 2013

Status: As of 6/25/13, on the Senate Floor

AB 1057 would require every board on or after January 1, 2015, to inquire on every application for licensure if the applicant is serving in, or has previously served in, the military.

This item is provided for information only; the board does not have a position on this measure. Please see AB 258 for related legislation.

Pharmacy / Other

17. SB 146 (Lara) Workers' Compensation: Medical Treatment: Billing

Last Amend: June 13, 2013

Status: Ordered to Engrossing and Enrolling (7/3/13)

SB 146 is an urgency measure that specifies a copy of a prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement that requires a copy of a prescription for a pharmacy service.

The bill specifies that any request for payment as established by the Division of Workers' Compensation that was denied for not providing a copy of the prescription, may resubmit the bill for payment, until March 31, 2014.

SB 146 also provides that nothing shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

This item is for information only; the board does not have a position on this measure.

18. SB 445 (Price) Pharmacies: Advertising: Controlled Substances

Last Amend: June 13, 2013

Status: Ordered to Engrossing and Enrolling (7/3/13)

Existing Pharmacy Law requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances. Additionally, existing law requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified.

SB 445 would specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

This item is for information only; the board does not have a position on this measure and staff will continue to monitor its movement.

19. Other Legislation Impacting the Practice of Pharmacy

b. REGULATION REPORT

Attachment 2

Recently Noticed Regulations

1. Fee Schedule – Proposal to Amend Title 16 Section 1746

On April 24, 2013, the board approved a proposal to amend Title 16 California Code of Regulations Section 1746 to increase the board's fees to the statutory maximum.

The rulemaking was initiated on June 14, 2013, and the 45-day public comment period will conclude on Monday, July 29. A Regulation Hearing is scheduled for 1:00 p.m. on July 30, 2013. (Note: this item is listed on the Board Agenda as Item VIII.) A copy of the Proposed Text to amend Section 1746 is provided in Attachment 2.

2. Combined Rulemaking - Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partial Fill of Schedule II Prescriptions, Criteria for Rehabilitation, and to Define Unprofessional Conduct

At the February Board Meeting, the board voted to modify the text of its proposal at Section 1762. This is the board's combined rulemaking to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations. Staff is preparing a notice of modified text that will be issued for a 15-day public comment period. The modified language approved by the board is provided in Attachment 2.

Board Approved - Undergoing Administrative Review (Information Only)

3. Proposed Addition of a new Article 5.5, and new Sections 1747 and 1747.1 Related to Pedigree Requirements

The board noticed its proposal to add a new Article 5.5 to Title 16 of the California Code of Regulations related to Pedigree Requirement. The board's proposal to add a new Section 1747 would establish requirements for the "unique identification number" required by Section 4034 of the Business and Professions Code, and the board's proposal to add a new Section 1747.1 would establish requirements for declarations that must be filed with the board, as required by Sections 4163.2 and 4163.5 of the Business and Professions Code.

The board's proposal was initially noticed on September 21, 2012. The board conducted a regulation hearing in conjunction with the December 2012 Board Meeting and subsequently issued two Notices of modified text. Thereafter, the board adopted the final regulation language at the Board Meeting held February 5, 2013, and staff completed the rulemaking file. The rulemaking file was submitted to the department for administrative review in March. Staff recently learned that on July 9, the Business, Consumer Services and Housing Agency approved the regulation and transmitted the file to the Department of Finance for review and sign-off. Upon receipt of the approved file, staff will deliver the rulemaking to the Office of Administrative Law for final review.

A copy of the Adopted Text is provided in Attachment 2. Once the approvals are received by the board, staff will update the board's website with final rulemaking documents prior to transmitting the file to OAL.

Board Approved – Awaiting Notice

4. Combined Rulemaking – Proposal to Amend Title 16 Sections 1732.2, 1732.5, 1732.05 related to Continuing Education

The board has approved for a 45-day public comment period four proposals: three related to continuing education. At the April 2013 Board Meeting, staff requested and the board approved to not notice with the combined rulemaking a previously approved proposal to amend Section 1751.9 related to Standards for Agencies that Accredited Sterile Injectable Compounding Pharmacies.

Staff is preparing a notice package for the following three provisions. The board-approved proposals are provided in Attachment 2.

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

Proposed amendments to Section 1732.2 would specify additional methods of obtaining board-accredited continuing education. Pharmacists are required to complete 30 hours of continuing education per renewal period. Specifically, the board's proposal would specify that a pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination (CPJE) for pharmacists may annually be awarded up to six (6) hours of CE hours for conducting a review of exam test questions; would specify that a pharmacist or pharmacy technician may be awarded up to six (6) hours of CE for attending a full-day board meeting and up to two (2) hours of CE for attending a full committee meeting of the board; and would specify that an individual may be awarded three (3) hours of CE for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas

The board's proposal would require continuing education in specific content areas for pharmacists. Specifically, the proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

The board's proposal would amend Section 1732.05(a)(2) to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

4. Update on Self-Assessments

On May 15, the board submitted a Section 100 regulatory update to the Office of Administrative Law to revise the board's self-assessment forms. The modifications made to the self-assessment forms reflect changes in Pharmacy Law in the prior legislative session.

Self-Assessment forms are required to be completed by pharmacies by July 1 of every odd-numbered year. The board anticipated having these forms available in advance of the July 1 deadline. However, the Office of Administrative Law indicated to staff that while the new information on the forms may reflect changes to pharmacy Law, the requirement that a pharmacist-in-charge or designated representative-in-charge certify under penalty of perjury as to those items was discretionary, and equated to a new requirement; thus, the proposal would not qualify as a Section 100 update. As a result staff withdrew the request for review.

At the October 2013 meeting, staff will bring to the board for consideration and discussion a formal rulemaking proposal to amend the board's self-assessment forms.

Until that time, however, board staff will make available on the board's website the self-assessment forms prepared for the Section 100 review. Pharmacies may utilize the self-assessment forms last approved by the Office of Administrative Law (Rev. 05/11). The board would also accept the completion of the newly revised self-assessment forms (showing draft revision dates of 07/13) which reflect recent changes in Pharmacy Law. A copy of the newly drafted self-assessment forms are provided in Attachment 2.

c. LEGISLATION AND REGULATION COMMITTEE

Third Quarterly Report - Committee Goals for 2012/13

Since the adoption of the board's new Strategic Plan, the committee has not completed its work to finalize committee goals.

ATTACHMENT 1



Bill Number:	SB 294 (Board-Sponsored)
Introduced	2/15/13
Last Amend:	July 3, 2013
Author:	Senator Bill Emmerson
Topic:	Sterile Drug Products
Position:	SUPPORT

Current Bill Status: 8/13/13 – Set for Hearing: Assembly Health

Affected Sections: Amend the heading of Article 7.5 (Commencing with Section 4127) of the Business and Professions Code (BPC)
Repeal and Add Section 4127 BPC
Amend Sections 4127.1, 4127.2 and 4400 BPC

Board Position: Support

Staff Recommendation: No change to position

SUMMARY:

SB 294 contains board-sponsored provisions to strengthen board's ability to regulate and monitor pharmacies that compound sterile drug products and distribute or ship into California sterile products for injection, for administration to the eye, or for inhalation.

Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies in this state, and requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

Existing law requires California and nonresident pharmacies to obtain a specialty permit from the board, subject to annual renewal, in order to compound injectable sterile drug products for distribution in California. Current law allows a board-licensed pharmacy to be exempt from the requirement to obtain a specialty permit to compound if they have specified accreditation. Also, the board is currently unable to inspect nonresident pharmacies to ensure compliance with California requirements.

SB 294 will expand the board's provisions to require a pharmacy (resident or nonresident) that compounds sterile drug products for injection, administration to the eye or inhalation to obtain a specialty permit (license) from the board. This specialty permit is in addition to the requisite 'pharmacy' permit such an entity must have to receive a specialty permit. The bill sets a fee for a nonresident sterile compounding permit, and requires these entities to reimburse the board for the actual and necessary costs of conducting an annual inspection. Failure to pay the fee will result in the non-issuance or suspension of the nonresident sterile compounding pharmacy license.

RECENT AMENDMENTS:

The most recent amendments specify a license fee of \$780 for a nonresident compounding permit. This fee is consistent with the fee structure of other pharmacies. In addition, amendments related to fees, require the nonresident sterile compounding pharmacy to reimburse the board of r actual and necessary costs of conducting the inspection. Other amendments include the addition of language that requires the board to adopt emergency regulations for the initial implementation of the bill. Finally, the period of time in which a sterile compounding pharmacy notifies the board of any recall of a compounded drug product dispensed in California was changed from 24 to 12 hours.

The board has requested an additional amendment to remove the reference to the Building Standards Commission within the language that authorizes the board to promulgate emergency regulations. The board does not anticipate the need to implement (on an emergency basis as it relates to initial implementation) additional building standards. At this time, existing board regulations incorporate by reference in its sterile compounding regulations the following building standards:

16 CCR 1751 – With regard to the compounding area for sterile injectable compounding, the board's requirements incorporate by reference the clean room and work station requirements (arrangement of the pharmacy, sinks, surfaces, etc.) found in Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations, as well as the ventilation requirements found in Section 505.5 of Title 24, Chapter 5 CCR.

16 CCR 1751.4 – For pharmacies that prepare parenteral cytotoxic agents, existing regulations require that the preparation of these agents be done in accordance with Sections 505.5 and 505.5.1 of Title 24, Chapter 5, of the CCR which specifies requirements for ventilation and laminar flow biological safety cabinetry.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a

Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Section 4400 BPC sets the fees and penalties as it relates to Pharmacy Law.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend the title of Article 7.5 to be "Sterile Drug Products."

Amend, Repeal and Add Section 4127 to require (after July 1, 2014) any pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation to possess a sterile compounding pharmacy license pursuant to Article 7.5 "Sterile Drug Products."

Authorize the board to adopt regulations for the implementation of the provisions; first, emergency regulations to initially implement the provisions; and broad/general rulemaking authority thereafter.

Add and Repeal Section 4127.1 to specify requirements (after July 1, 2014) for pharmacies that compound sterile drug products. These provisions require that a pharmacy must first be licensed as a pharmacy with the board in order to seek a specialty permit to compound sterile drug products, and specify that the license is to be renewed annually. These requirements include:

Require the *board* to:

- Perform an onsite inspection of the premises, and any deficiencies noted are corrected
- Review a current copy of the pharmacy's policies and procedures for sterile compounding
- Review the pharmacy's completed self-assessment form required by 16 CCR § 1735.2
- Is provided with copies of all inspection reports conducted of the pharmacy's premises, including those from a private accrediting agency, conducted in the prior 12 month
- Receives a list of all sterile medications compounded by the pharmacy since the last license renewal

Require the pharmacy licensed pursuant to the section to:

- Provide the board with a copy of any disciplinary or other action taken by another state within 10 days of the action
- Notify the board within 10 days of the suspension of any accreditation held by the pharmacy
- Provide the board, within **12 hours**, any recall notice issued by the pharmacy for sterile drug products it has compounded
- Require that adverse effects reported or potentially attributable to a pharmacy's sterile drug product be immediately reported to the Board and to the FDA's MedWatch program

Amend, Repeal and Add Section 4127.2 to specify requirements for nonresident pharmacies that wish to ship sterile drug products into California. These requirements mirror those found in 4127.1, but as they relate to nonresident pharmacies seeking a specialty permit. The requirements include.

- Restrict a nonresident pharmacy from shipping into California any compounded sterile drug product without obtaining a license pursuant to this section.
- Specify that a license issued pursuant to this section can be issued only to a location that is also licensed with the board as a nonresident pharmacy, and specify requirements for the board and pharmacy

- Sets forth requirements of the board and of the nonresident pharmacy (mirrors requirements in 4127.1), including to advise the board of any complaint it receives from a provider, pharmacy, or patient in California

Amend Section 4400 to specify a fee for a nonresident sterile compounding pharmacy license, and require the payment of travel expenses incurred by the board to inspect a nonresident sterile compounding pharmacy at least once annually. Failure to pay the fee within 30 days shall result in suspension of the nonresident sterile compounding pharmacy license.

FISCAL IMPACT ON THE BOARD:

The board anticipates that staffing needed to inspect, administer and enforce the provisions of the bill (4 inspectors, 1 Associate Analyst, 1 Staff Analyst, 1 Office Technician) will be offset by anticipated revenue, at a cost of approximately \$546,000 annual/ongoing; in addition, the board anticipates one-time costs of approximately \$20,000 for system modifications necessary to track and issue licenses. All costs associated with the annual inspections of nonresident sterile compounding pharmacies are expected to be cost-neutral.

California Pharmacies:

As of June 30, 2013, the board had issued licenses to approximately 6,385 California community and outpatient pharmacies; and approximately 286 permits to compound sterile injectable drug products. In April 2012, the board estimated that there were approximately 293 pharmacies that compound sterile drug products that are accredited in lieu of holding a sterile compounding permit with the board.

Nonresident Pharmacies:

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

History

Date	Action
07/03/13	Read second time and amended. Re-referred to Com. on HEALTH.
07/02/13	From committee: Do pass as amended and re-refer to Com. on HEALTH. (Ayes 10. Noes 3.) (July 2).
06/24/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Coms. on B.,P. & C.P. and HEALTH.
05/30/13	In Assembly. Read first time. Held at Desk.
05/29/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1165.) Ordered to the Assembly.
05/28/13	Read second time and amended. Ordered to third reading.
05/24/13	From committee: Do pass as amended. (Ayes 7. Noes 0. Page 1010.) (May 23).
05/17/13	Set for hearing May 23.
04/22/13	Placed on APPR. suspense file.
04/12/13	Set for hearing April 22.
04/09/13	Set, first hearing. Hearing canceled at the request of author.
04/05/13	Set for hearing April 15.
04/02/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 388.) (April 1). Re-referred to Com. on APPR.
03/19/13	Set for hearing April 1.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

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

As Amended 7/3/13 - Today's Law As Amended

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, including, but not limited to, building standards adopted pursuant to Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code. 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, including, but not limited to, building standards adopted pursuant to Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code.

(c) 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 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 immediately reported to the board and 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 ~~may~~ *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) This section shall become ~~effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127~~; *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 immediately reported to the board and the MedWatch program of the federal Food and Drug Administration.

(g) 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).

~~(t) (u) The fee for issuance or renewal of a retired nongovernmental license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to forty-five dollars (\$45); seven hundred eighty dollars (\$780).~~

~~(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).~~

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.*



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

June 28, 2013

The Honorable Richard S. Gordon, Chair
and Members
Assembly Committee on Business,
Professions and Consumer Protection
State Capitol, Room 4126
Sacramento, CA 95814

RE: Senate Bill 294 – Support

Dear Assembly Member Gordon and Members:

Senate Bill 294 (Emmerson) will soon be before the Assembly Committee on Business, Professions and Consumer Protection, and the Board of Pharmacy respectfully requests your Aye vote to pass this bill to Appropriations.

The Board of Pharmacy regulates the entities and individuals who distribute dangerous drugs and dangerous devices in this state, and SB 294 is necessary to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products to ensure the safety of Californians.

In 2001, the California Legislature first enacted provisions to strengthen state oversight of sterile drug compounding in pharmacies following the death of three people and multiple hospitalizations due to a pharmacy in California that compounded and distributed a cortisone-based injectable drug that was tainted with meningitis bacteria. That legislation resulted in pharmacies within California being required to obtain a specialty license if they performed sterile injectable compounding. Additional provisions required non-resident pharmacies that shipped sterile injectable drugs into California to also be licensed with this board, but the law carved out an exemption for obtaining the specialty license to compound sterile injectable drug products. Current law allows a California or non-resident pharmacy to avoid this specialty license if they are accredited or where, in the case of non-resident pharmacies, regulators (other than the Board of Pharmacy) have oversight. In light of recent events, this exemption is not protecting the health and lives of Californians.

Unfortunately, the tragic incidents that occurred over a decade ago have not ceased. In June of 2012, a licensed sterile injectable pharmacy located in Florida shipped contaminated products into California and patients here were injured. In September 2012, the New England Compounding Center based in Massachusetts shipped contaminated injectable drugs throughout the country, including California, resulting in the death of more than 50 people and in the illness of more than 700 patients. California was fortunate in that while our patients received products, no deaths or injuries have been reported as a result of these contaminated products. However, in both cases, because the board was unable to inspect these non-resident facilities, the board was not able to ensure that the operations met California's regulatory requirements.

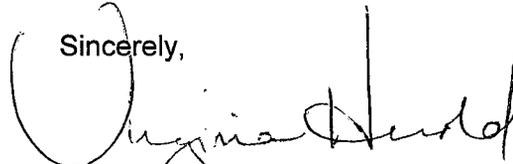
Senate Bill 294 will

- Require annual inspections by the board of pharmacy of specialty pharmacies that want to ship these products into California, to ensure that the operations comply with California's requirements for sterile compounding;
- Expand the types of medications for which a specialty license is required to also include other high-risk types of drugs, such as those administered into the eyes, or inhaled; and
- Ensure California standards are met and enforced for all pharmacies that ship these specialty compounded drug products into California, by requiring board inspections of those who hold a specialty license. In addition to the license fee, the non-resident Pharmacy will also be required to reimburse the board for reasonable / actual costs associated with an out-of-state inspection.

It is time to once again strengthen the state's oversight of pharmacies that compound sterile drug products so that Californians are protected. Senate Bill 294 will provide for such enhanced protection and will ensure that California's standards are enforced and patients are protected.

The Board of Pharmacy respectfully requests your Aye vote to pass SB 294 (Emmerson).

Sincerely,



VIRGINIA HEROLD
Executive Officer

cc: The Honorable Bill Emmerson
Members, Assembly Committee on Business
Professions and Consumer Protection



Bill Number:	SB 821
Introduced	2/22/13
Last Amend:	6/27/13
Author:	Senate Committee on Business, Professions and Economic Development
Topic:	Healing Arts Omnibus Bill
Position:	Support

Current Bill Status: 6/26/13 – Passed ASM Business, Professions & Consumer Protection
Referred to ASM Appropriations

Affected Sections: Add Section 4021.5 to the Business and Professions Code
Amend Section 4053 of the Business and Professions Code
Amend Section 4107 of the Business and Professions Code

Recommendation: Maintain Position of Support

SUMMARY:

SB 821 is a Senate Omnibus measure that contains three board-approved proposals, as summarized below. The bill passed the Senate (on consent) on May 28, 2013, and has passed the Assembly Committee on Business, Professions and Consumer Protection. The board's provisions were amended into SB 821 on June 14.

Due to the length of the bill, only the sections relevant to the board's proposals (SEC. 18 – SEC. 20) are provided in Attachment 1.

THIS BILL WOULD:

Add a Definition of "Correctional Pharmacy" – See SEC. 18 of SB 821

At the April 2013 Board Meeting, the board ratified the language provided to Senate Committee on Business, Professions and Economic Development to specify a definition of "Correctional Pharmacy." The board proposed the definition to be at Section 4066 of the Business and Professions Code. To keep board definitions in alphabetical order, however, Legislative Counsel placed the definition at Section 4021.5. Also, the board suggested that the word "state" be stricken from the definition, so as to broadly apply to any correctional pharmacy. That modification was not accepted as an omnibus provision.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative – See SEC. 19 of SB 821

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work

experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. The board's proposal specifies that the one year of paid work experience shall be earned in a licensed facility.

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception – See SEC. 20 of SB 821

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations as a result of this measure.

HISTORY:

Date	Action
06/27/13	Read second time and amended. Re-referred to Com. on APPR.
06/26/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (June 25).
06/19/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1118.) Ordered to the Assembly.
05/22/13	Ordered to special consent calendar.
05/21/13	Read second time. Ordered to third reading.
05/20/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
05/10/13	Set for hearing May 20.
05/07/13	Hearing postponed by committee.
05/03/13	Set for hearing May 13.
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 734.) (April 29). Re-referred to Com. on APPR.
04/23/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
04/03/13	Referred to Com. on B., P. & E.D.
03/21/13	From printer. May be acted upon on or after April 20.
03/20/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Excerpt: Senate Bill No. 821 As Amended June 19, 2013

Sections 18, 19 and 20 related to Pharmacy

(View: Today's Law as Amended)

SEC. 18.

Section 4021.5 is added to the Business and Professions Code, to read:

4021.5.

"Correctional pharmacy" means a pharmacy, licensed by the board, located within a state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.

SEC. 19.

Section 4053 of the Business and Professions Code is amended to read:

4053.

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development *certificate* equivalent.

(2) He or she shall have a minimum of one year of paid work ~~experience, in~~ *experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in* the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

SEC. 20.

Section 4107 of the Business and Professions Code is amended to read:

4107.

(a) The board may not issue more than one site license to a single premises except as follows:

(1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.

(2) To issue a license to compound sterile injectable drugs to a pharmacy pursuant to Section 4127.1.

(3) To issue a centralized hospital packaging license pursuant to Section 4128.

~~The (b) board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy.~~ For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.



Bill Number:	SB 305
Introduced	2/15/13
Last Amend:	6/19/13
Author:	Senator Curren Price
Topic:	Access to Certified Records
Position:	

Current Bill Status: 6/26/13 – Passed ASM Business, Professions & Consumer Protection
Referred to ASM Appropriations

Affected Sections: Add Section 144.5 to the Business and Professions Code

Staff

Recommendation: Support SB 305 as Amended 6/19/13

SUMMARY:

SB 305 contains a version of a board-approved legislative proposal to receive from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation and further specifies that a local or state agency may provide those records upon request.

It is customary for most boards and bureaus to obtain complete arrest, conviction and other related documentation as part of an applicant's or licensee's disciplinary investigation – and the board must rely on local law enforcement agencies to provide them. In response to some requests for certified documents, jurisdictions refused to provide the certified records, citing the board's lack of authority to request them. This has caused delays in the completion of applicant and licensee investigations.

At the October 2012 Board Meeting, the board approved a proposal to add Section 4008.5 to the B&PC to provide the board with the express authority to receive certified arrest, court and probation records for the purpose of completing applicant and licensee investigations. The board's proposal included a requirement that the jurisdiction provide them upon request, and this mandate was not picked up in the bill due to concern of a state mandate, as well as concerns from local jurisdictions.

THIS BILL WOULD:

Authorize the board to request and receive certified records for the purpose of determining if a crime committee by an applicant or licensee is substantially related to the qualifications, functions or duties for which the license is held or sought.

EXISTING LAW:

Business and Professions Code Section 480 specifies criteria for which a board may deny an application for any crime that is substantially related to the qualifications, functions or duties for which the license is issued.

Business and Professions Code Section 490 permits a board to take action against a licensee on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Business and Professions Code Section 493 provides in a proceeding conducted by a board pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the grounds that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and that the board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

Business and Professions Code Section 4301 specifies disciplinary proceedings for any holder of license that is guilty of unprofessional conduct or other specified acts.

Business and Professions Code Section 4202(c) requires the board to conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, as specified.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations as a result of this measure.

HISTORY:

Date	Action
06/25/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (June 25). Re-referred to Com. on APPR.
06/19/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 37. Noes 0. Page 1100.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.

Date	Action
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1011.) (May 23).
05/17/13	Set for hearing May 23.
05/13/13	Placed on APPR. suspense file.
05/03/13	Set for hearing May 13.
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 733.) (April 29). Re-referred to Com. on APPR.
04/25/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/15/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

SB-305 Healing arts: boards. (2013-2014)

As Amended 6/19/13 - Today Law As Amended (Only page 1)

SECTION 1. *Section 144.5 is added to the Business and Professions Code, to read:*

144.5. Notwithstanding any other law, a board described in Section 144 may request, and is authorized to receive, from a local or state agency certified records of all arrests and convictions, certified records regarding probation, and any and all other related documentation needed to complete an applicant or licensee investigation. A local or state agency may provide those records to the board upon request.

SEC. 2. Section 1000 of the Business and Professions Code is amended to read:

1000. (a) The law governing practitioners of chiropractic is found in an initiative act entitled "An act prescribing the terms upon which licenses may be issued to practitioners of chiropractic, creating the State Board of Chiropractic Examiners and declaring its powers and duties, prescribing penalties for violation hereof, and repealing all acts and parts of acts inconsistent herewith," adopted by the electors November 7, 1922.

(b) The State Board of Chiropractic Examiners is within the Department of Consumer Affairs.

(c) Notwithstanding any other law, the powers and duties of the State Board of Chiropractic Examiners, as set forth in this article and under the act creating the board, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 3. Section 2450 of the Business and Professions Code is amended to read:

2450. There is a Board of Osteopathic Examiners of the State of California, established by the Osteopathic Act, which shall be known as the Osteopathic Medical Board of California which enforces this chapter relating to persons holding or applying for physician's and surgeon's certificates issued by the Osteopathic Medical Board of California under the Osteopathic Act.

Persons who elect to practice using the term of suffix "M.D.," as provided in Section 2275, shall not be subject to this article, and the Medical Board of California shall enforce the provisions of this chapter relating to persons who made the election.

Notwithstanding any other law, the powers and duties of the Osteopathic Medical Board of California, as set forth in this article and under the Osteopathic Act, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2018.

SEC. 4. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, ~~2014~~, ~~2018~~, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, ~~2014~~, ~~2018~~, deletes or extends that date. Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to review by the appropriate policy committees of the Legislature.

SEC. 5. Section 2530.2 of the Business and Professions Code is amended to read:

2530.2. As used in this chapter, unless the context otherwise requires:

Proposed Legislation for Issuing Licenses with a letter of reprimand
with changes in underline from Legal Counsel

Add Business and Professions Code section 4310.5 as follows:

- (a) Notwithstanding subdivision (c) Section 4300, the board may issue a license to an applicant who has committed minor violations that the board deems, in its discretion, do not merit the denial of a certificate or require probationary status under Section 4300, and may concurrently issue a public letter of reprimand.
- (b) The letter of reprimand shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
- (c) The letter of reprimand shall inform the licensee that within 30 days of service of the letter of reprimand the licensee may do either of the following:
 - (1) Submit a written request for an office conference to the executive officer of the board to contest the letter of reprimand.
 - (A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
 - (B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of reprimand.
 - (C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
 - (D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of reprimand. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of reprimand.
 - (E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of reprimand.
 - (2) Accept the letter of reprimand. The board shall inform the licensee that the letter of reprimand shall be purged after three years if no letter of admonishment, citation, notice of correction, or disciplinary action is initiated by the board.

- (d) The letter of reprimand shall be served upon the licensee personally or by certified mail at the applicant's address of record with the board. If the applicant is served by certified mail, service shall be effective upon deposit in the United States mail.
- (e) A public letter of reprimand issued concurrently with a board license shall be purged three years from the date of issuance if no letter of admonishment, citation, notice of correction, or disciplinary action is initiated by the board during the three-year period.
- (f) A public letter of reprimand issued pursuant to this section shall be disclosed to an inquiring member of the public and shall be posted on the board's Internet Web site.
- (g) Nothing in this section shall be construed to affect the board's authority to issue an unrestricted license.



Bill Number:	AB 1045 (Quirk-Silva)
Introduced	February 22, 2013
Last Amend:	June 19, 2013
Author:	Assembly Member Sharon Quirk-Silva
Topic:	Nonresident Sterile Compounding Pharmacies; Recall Notices
Position:	Support

Current Bill Status: In Senate Appropriations – as of 7/15/13 no hearing yet set

Affected Sections: Amend Section 4303 of the Business and Professions Code
Add Section 4127.9 to the Business and Professions Code

Board Position: Support (5/10/13)

Recommendation: Ratify the position taken on 5/10/13

SUMMARY:

AB 1045 will strengthen the board's ability to protect Californians in cases where non-resident pharmacies and non-resident sterile compounding pharmacies lose their pharmacy permit in the home state by allowing the board simply to cancel, revoke or suspend the corresponding California non-resident permits. In addition, AB 1045 will require sterile compounding pharmacies to provide notice to a pharmacy, prescriber or patient of a recalled sterile compounded drug that was dispensed, and require the pharmacy to notify the board within 12 hours of a recall notice.

Currently, to revoke a pharmacy permit, the board must take formal disciplinary action to remove the California license where there is no longer regulatory oversight by the home state, unless the non-resident pharmacy requests to cancel its California license. AB 1045 provides for the immediate protection of California's patients by specifying that when the underlying permit in the home state has been canceled, revoked or suspended, the California permit is canceled, revoked or suspended by operation of law.

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Article 19 (Sections 4300-4315) specify disciplinary proceedings that the board may take against a licensee, including grounds for discipline of a nonresident pharmacy (Section 4303).

Article 20 (Sections 4320-4343) specify prohibitions and offenses for which the board is authorized to discipline a license.

Title 16 California Code of Regulations Section 1760 specifies the board's Disciplinary Guidelines.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend Section 4303 to specify that if the home state license of a nonresident pharmacy is canceled, revoked or suspended for any reason, the board shall immediately cancel, revoke or suspend the board-issued license by operation of law.

Add Section 4127.9 to specify that a resident or nonresident pharmacy that holds a sterile compounding permit that issues a recall notice regarding a compounded drug, that the pharmacy shall contact the recipient pharmacy, prescriber or patient of the recalled drug, as well as contact the board within 12 hours, if certain conditions are met, as specified.

FISCAL IMPACT ON THE BOARD:

The board does not anticipate any significant impact should AB 1045 be enacted.

History

Date	Action
07/02/13	Read second time. Ordered to third reading.
07/01/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/19/13	Read second time and amended. Re-referred to Com. on APPR.
06/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 17).
06/06/13	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/06/13	Referred to Com. on B., P. & E.D.
05/23/13	In Senate. Read first time. To Com. on RLS. for assignment.
05/23/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1578.)
05/20/13	Read second time. Ordered to consent calendar.
05/16/13	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 15).
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 30). Re-referred to Com. on APPR.
04/25/13	From committee: Be re-referred to Com. on B.,P. & C.P. Re-referred. (Ayes 8. Noes 0.) (April 25). Re-referred to Com. on B.,P. & C.P.
04/25/13	Re-referred to Com. on RLS. pursuant to Assembly Rule 96.
04/23/13	Re-referred to Com. on B.,P. & C.P.
04/22/13	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/14/13	Referred to Com. on B.,P. & C.P.
02/25/13	Read first time.
02/24/13	From printer. May be heard in committee March 26.
02/22/13	Introduced. To print.



California
LEGISLATIVE INFORMATION

AB-1045 Sterile compounding and nonresident pharmacies. (2013-2014)

As Amended 6/19/13 - Today's Law as Amended

SECTION 1. *Section 4127.9 is added to the Business and Professions Code, to read:*

4127.9. *(a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2, including a pharmacy that is exempt from licensure pursuant to subdivision (d) of Section 4127.1 and subdivision (c) of Section 4127.2, that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:*

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 2. Section 4303 of the Business and Professions Code is amended to read:

4303. *(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.*

*(b) The board may **cancel**, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.*

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

SEC. 3. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB 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 XIIB of the California Constitution.*



Bill Number:	AB 1045 (Quirk-Silva)
Introduced	February 22, 2013
Last Amend:	June 19, 2013
Author:	Assembly Member Sharon Quirk-Silva
Topic:	Nonresident Sterile Compounding Pharmacies; Recall Notices
Position:	Support

Current Bill Status: In Senate Appropriations – as of 7/15/13 no hearing yet set

Affected Sections: Amend Section 4303 of the Business and Professions Code
Add Section 4127.9 to the Business and Professions Code

Board Position: Support (5/10/13)

Recommendation: Ratify the position taken on 5/10/13

SUMMARY:

AB 1045 will strengthen the board's ability to protect Californians in cases where non-resident pharmacies and non-resident sterile compounding pharmacies lose their pharmacy permit in the home state by allowing the board simply to cancel, revoke or suspend the corresponding California non-resident permits. In addition, AB 1045 will require sterile compounding pharmacies to provide notice to a pharmacy, prescriber or patient of a recalled sterile compounded drug that was dispensed, and require the pharmacy to notify the board within 12 hours of a recall notice.

Currently, to revoke a pharmacy permit, the board must take formal disciplinary action to remove the California license where there is no longer regulatory oversight by the home state, unless the non-resident pharmacy requests to cancel its California license. AB 1045 provides for the immediate protection of California's patients by specifying that when the underlying permit in the home state has been canceled, revoked or suspended, the California permit is canceled, revoked or suspended by operation of law.

As of June 30, 2013, the board issued licenses to approximately 488 Nonresident pharmacies, of which approximately 93 held nonresident sterile compounding permits.

EXISTING LAW:

Section 4112 BPC prohibits any pharmacy located outside of California from shipping, mailing, or delivering in any manner, controlled substances, dangerous drugs or dangerous devices into California – pursuant to a prescription - without obtaining a license from the board. The section specifies information that shall be disclosed to the board, and sets forth requirements for recordkeeping, patient consultation, and other requirements related to the license.

Section 4120 BPC prohibits a nonresident pharmacy from selling or distributing dangerous drugs or dangerous devices in California through any person or media other than a board-licensed wholesaler.

Section 4127 BPC requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Related regulations are at Title 16 Cal.Code Reg Article 4.5 (starting at Section 1735) and Article 7 (starting at Section 1751).

Section 4127.1 BPC restricts the compounding of sterile drug products to pharmacies that have obtained a specialty permit (license) from the board to conduct such compounding. Pharmacies that are licensed by the board or are licensed by the California Department of Public Health AND have specified accreditation are exempt from the requirement to obtain this specialty permit.

Section 4127.2 BPC specifies that a nonresident pharmacy shall not compound injectable sterile drug products without a specialty permit (license) issued by the board. These permits may be issued only to those nonresident pharmacies that are licensed by the board as a Pharmacy to ship dangerous drugs and devices into California. This section exempts from the requirement to hold a specialty permit those nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have specified accreditation.

Article 19 (Sections 4300-4315) specify disciplinary proceedings that the board may take against a licensee, including grounds for discipline of a nonresident pharmacy (Section 4303).

Article 20 (Sections 4320-4343) specify prohibitions and offenses for which the board is authorized to discipline a license.

Title 16 California Code of Regulations Section 1760 specifies the board's Disciplinary Guidelines.

AS AMENDED 7/3/13 THIS BILL WILL:

Amend Section 4303 to specify that if the home state license of a nonresident pharmacy is canceled, revoked or suspended for any reason, the board shall immediately cancel, revoke or suspend the board-issued license by operation of law.

Add Section 4127.9 to specify that a resident or nonresident pharmacy that holds a sterile compounding permit that issues a recall notice regarding a compounded drug, that the pharmacy shall contact the recipient pharmacy, prescriber or patient of the recalled drug, as well as contact the board within 12 hours, if certain conditions are met, as specified.

FISCAL IMPACT ON THE BOARD:

The board does not anticipate any significant impact should AB 1045 be enacted.

History

Date	Action
07/02/13	Read second time. Ordered to third reading.
07/01/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
06/19/13	Read second time and amended. Re-referred to Com. on APPR.
06/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 17).
06/06/13	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/06/13	Referred to Com. on B., P. & E.D.
05/23/13	In Senate. Read first time. To Com. on RLS. for assignment.
05/23/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1578.)
05/20/13	Read second time. Ordered to consent calendar.
05/16/13	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 15).
04/30/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 30). Re-referred to Com. on APPR.
04/25/13	From committee: Be re-referred to Com. on B.,P. & C.P. Re-referred. (Ayes 8. Noes 0.) (April 25). Re-referred to Com. on B.,P. & C.P.
04/25/13	Re-referred to Com. on RLS. pursuant to Assembly Rule 96.
04/23/13	Re-referred to Com. on B.,P. & C.P.
04/22/13	From committee chair, with author's amendments: Amend, and re-refer to Com. on B.,P. & C.P. Read second time and amended.
03/14/13	Referred to Com. on B.,P. & C.P.
02/25/13	Read first time.
02/24/13	From printer. May be heard in committee March 26.
02/22/13	Introduced. To print.



California
LEGISLATIVE INFORMATION

AB-1136 Pharmacists: drug disclosures. (2013-2014)

As Amended 4/15/13 - Today's Law As Amended

SECTION 1. Section 4074 of the Business and Professions Code is amended to read:

4074. (a) *A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:*

~~(a) (1) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug~~ *The drug* poses substantial risk to the person consuming the drug when taken in combination with alcohol or ~~if~~ the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, ~~and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.~~ *applicable.*

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

~~(b) (c)~~ The board may by regulation require additional information or labeling.

~~(e) (d)~~ This section shall not apply to ~~drugs~~ *a drug* furnished to ~~patients~~ *a patient* in conjunction with treatment or emergency services provided in *a health facilities facility* or, except as provided in subdivision ~~(d)~~ *(e)*, to ~~drugs~~ *a drug* furnished to ~~patients~~ *a patient* pursuant to subdivision (a) of Section 4056.

~~(d) (e)~~ A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each ~~medication drug~~ *medication drug* given at the time of discharge and each ~~medication drug~~ *medication drug* given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each ~~medication;~~ *drug*, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other ~~provision of~~ law shall be construed to require that only a pharmacist provide this consultation.

SEC. 2. *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.*



Bill Number:	SB 204
Introduced	2/8/13
Last Amend:	6/27/13
Author:	Senator Ellen Corbet
Topic:	Prescription Drugs: Labeling (Translations)
Position:	<i>(none)</i>

Current Bill Status: 8/13/13 – Hearing in Assembly Health

Affected Sections: Add Section 4076.3 to the Business and Professions Code

THIS BILL WOULD:

Add a new Section 4076.3 to the Business and Professions Code, where the provisions become operative on January 1, 2016 to:

- Require that the translations of the directions for use in non-English languages published on the board’s web site shall be used when labeling a prescription container label.
- Permit English language directions for use to be translated into additional non-English languages so long as a trained and qualified translator or translation service is utilized to complete the translations
- Permit a pharmacy to use its own translations of the directions for use as established by board regulation, if a trained and qualified translator or translation service is utilized.
- Allow a pharmacist to use the English language directions for use if the pharmacist reasonably believes that a translation of the directions for use contains an error due to software or equipment malfunction, as specified
- Provide that a pharmacist has not breached his or her legal duty if the published translations on the board’s website contain an error, where the pharmacist used the translation and did not know, or have reason to know of the error.
- Specify that the English language directions for use be provided in each instance when a non-English translation of the directions for use is used
- Define “translation,” and “trained and qualified translator or translation service.

EXISTING LAW:

Section 4076 of the Business and Professions Code (BPC) specifies requirements for the labeling of a prescription container dispensed to a patient, to include:

- The manufacturer’s trade name of the drug or the generic name and the manufacturer
- ***The directions for use of the drug***
- The name of the patient
- The name of the prescriber
- The date of issue

- The name and address of the pharmacy, and prescription number or other means of identifying the prescription
 - The strength of the drug or drugs dispensed
 - The quantity of the drug or drugs dispensed
 - The expiration date of the effectiveness of the drug dispensed
 - The condition or purpose for which the drug was prescribed, if indicated on the prescription
 - The physical description of the dispensed medication, as specified (exemptions specified)
- Section 4075 further specifies requirements for unit dose medications in specified settings; and other requirements as it relates to the dispensing of a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code.

Section 4076.5 BPC was enacted in 2012 (SB 472, Corbett) to require the board to promulgate regulations to standardize “patient-centered” prescription drug labels, and further specified various factors that the board would consider in developing the regulations. Two of the many factors the board was to consider were improved directions for use, and the needs of patients with limited English proficiency. This resulted in the promulgation of 16 CCR § 1707.5.

Section 11 BPC specifies for purposes of the Code that “writing includes any form of recorded message capable of comprehension by ordinary visual means. Whenever any notice, report, statement, or record is required by this code, it shall be made in writing in the English language unless it is otherwise expressly provided.”

Title 16 CCR 1707.5 specifies requirements for patient-centered labels for prescription drug containers, to include

- Clustering of specified information, printed in at least 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface
- A requirement that the board publish on its website *translations of directions for use* into at least five languages other than English to facilitate the use thereof by California pharmacies
- A requirement that the board collect and publish on its website examples of labels that conform to the stated requirements
- A requirement that pharmacies have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label; and further specifies the minimum content for the policies and procedures
- A requirement that the board re-evaluate the requirements of the regulation by December 2013; and
- Define “appropriate dosage form” for purposes of the section

Background

As reflected in the board’s regulation at 16 CCR § 1707.5, pharmacies are required ensure the labels on drug containers dispensed to Californians conform to the format specified in the regulation. One of the clustered “patient-centered” elements is the directions for use. The regulation specifies multiple standard phrases to use for the “directions for use” if it is applicable to the prescription. For example, a prescriber writes a prescription “Take 1 pill at

bedtime.” The regulation at 1707.5(a)(D)(4)(A) specifies the phrase “Take 1 [insert appropriate dosage form] at bedtime.” Thus the label would include the language as stated in the regulation.

The board maintains on its website ¹translations in five languages of the various “directions for use” as enumerated at 1707.5(a)(D)(4).

STAFF COMMENTS:

The Public Education and Communications Committee began the board’s review of the patient-centered labeling requirements in April 2013, which is to be completed by December 31, 2013.

The board has not taken a position on the bill, as it is in the process of re-evaluating the requirements of the patient centered regulations.

It may be necessary to clarify through regulations what a “trained and qualified translator or translation service” is or would include.

FISCAL IMPACT ON THE BOARD:

The board may need to promulgate regulations, which would be absorbed within existing staff resources.

¹ <http://www.pharmacy.ca.gov/publications/translations.shtml>

Senate Bill 204

Prescription Drug Label Translations Senate Majority Leader Ellen M. Corbett

SUMMARY

Senate Bill 204 requires pharmacists to use the translated standard directions for use currently available on the California Board of Pharmacy (Board) website when providing patients with translated directions in Spanish, Chinese, Vietnamese, Korean, and Russian on their prescription medication labels.

The bill also requires pharmacists to use certified translation services if they choose to provide translations in languages other than the five provided on the website.

BACKGROUND

Title VI of the federal Civil Rights Act of 1964 and The Dymally-Alatorre Bilingual Services Act both require language access and the right to translation services for limited English proficient individuals.

In 2010, as a result of SB 472 (Corbett, 2007,) the Board adopted regulations that require it to publish translations of directions for use on its website and require pharmacies to provide interpretive services to patients, when available. Senator Corbett has actively worked to get more comprehensive assistance for limited English proficient Californians through the regulation process. SB 204 was introduced to ensure that limited English proficient Californians get the same assistance that all other Californians receive.

In October 2012, the U.S. Pharmacopeial Convention (USP) released labeling standards which recommend that pharmacies print the directions for use on a prescription label in the patient's preferred language using a high-quality translation process. This bill adopts the translation standard that the USP recommends.

PROBLEM

The Centers for Disease Control and Prevention recommend that adults follow medication directions to reduce the risk of harm from their medicine.

An estimated 7 million Californians are limited English proficient. It is troubling that studies show only about 2/3 of California pharmacies are providing translated directions, upon request. Patients cannot follow directions

if they cannot read them. This large population of Californians is in danger of accidentally misusing their prescription medications because the directions are provided in a language they cannot read.

With the increased number of limited English proficient Californians who will have access to health coverage and prescription medication through the Affordable Care Act, the state could incur additional costs whenever a person is harmed or hospitalized due to incorrect medication use.

When someone has been harmed by a medicine, they have had an adverse drug event. Preventing this harm saves both lives and money. Adverse drug events cause over 700,000 emergency room (ER) visits around the country every year, and every year almost 120,000 patients are hospitalized after an ER visit for adverse drug events. Depending on the size, hospitals around the country are already spending up to \$5.6 million a year due to adverse drug events. It is safer and more cost-effective to prevent this harm in the first place.

SOLUTION

Many medication disasters can be avoided simply by printing translated directions onto prescription medication labels so limited English proficient patients can read them. This bill corresponds with the standards released by the USP in 2012, and it coincides with the Board's goal of ensuring that pharmacists exhibit greater cultural awareness with respect to primary language in this increasingly diverse state.

SB 204 aims to assist limited English proficient patients in understanding the directions on their prescription labels to reduce the opportunity for errors.

SUPPORT

California Pan-Ethnic Health Network (Sponsor)

STATUS

April 22nd hearing in Senate Business, Professions, and Economic Development Committee.

CONTACT

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California
LEGISLATIVE INFORMATION

SB-204 Prescription drugs: labeling. (2013-2014)

Today's Law As Amended

SECTION 1. *Section 4076.3 is added to the Business and Professions Code, to read:*

4076.3. *(a) Translations of the directions for use in non-English languages published on the board's Internet Web site shall be used, as applicable, when labeling a prescription container pursuant to Section 4076.*

(b) The English language directions for use established by regulation of the board may be translated into additional non-English languages if a trained and qualified translator or translation service is utilized to complete the additional translations.

(c) Notwithstanding subdivision (a), a pharmacy may use its own translations of the directions for use established by regulation of the board in the non-English languages published on the board's Internet Web site when labeling a prescription container pursuant to Section 4076 if a trained and qualified translator or translation service is utilized.

(d) If a pharmacist reasonably believes that a translation of the directions for use contains an error due to software or equipment malfunction, he or she may use the English language directions for use established by regulation of the board when labeling a prescription container pursuant to Section 4076.

(e) A pharmacist that reasonably uses the translations of the directions for use in non-English languages published on the board's Internet Web site has not breached his or her legal duty if the published translations contain an error and the pharmacist did not know, or did not have reason to know, of the error.

(f) The English language directions for use established by regulation of the board shall be provided in each instance in which a non-English translation of the directions for use is used pursuant to this section.

(g) For purposes of this section, "translation" means the conversion of written text to the corresponding written text in a different language.

(h) For purposes of this section, "trained and qualified translator or translation service" means any of the following:

(1) An individual certified by the American Translators Association or any other nationally accredited or state-approved program the board deems satisfactory.

(2) An individual trained in translation who has been assessed as competent by a company specializing in translation that employs, or has a contractual relationship with, the individual.

(3) An individual employed by a pharmacy who meets all of the following requirements:

(A) He or she has written proficiency in both English and a non-English language.

(B) He or she commits to abide by the American Translators Association's Code of Professional Conduct and Business Practices.

(C) He or she exhibits sufficient knowledge and understanding of required health care vocabulary and terminology related to the practice of pharmacy.

A pharmacy shall establish internal policies to determine and document an individual's qualifications pursuant to subparagraphs (A) to (C), inclusive, of this paragraph.

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

SEC. 2. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB 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.



Bill Number:	SB 205
Introduced	2/8/13
Last Amend:	July 1, 2013
Author:	Senator Ellen Corbett
Topic:	Prescription Drugs: Labeling (12-pt font)
Position:	(none)

Current Bill Status: 8/13/13 – Hearing in ASM Business, Professions & Consumer Protection

Affected Sections: Amend Section 4076 of the Business and Professions Code

Staff Comment: Should the board take a position on SB 205 before the review of patient-centered label requirements is complete?

SUMMARY

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and that certain items on the label be printed in at least a 12-point font. Existing regulation at 16 CCR 1707.5 requires that specified “patient-centered” information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

THIS BILL WOULD:

Amend Section 4076 to

- Add a new subdivision (b) that would specify that the name of the patient, the name and strength of the drug, the directions for use, and the condition or purpose for which the drug is prescribed (if indicated on the Rx) be printed in at least a 12-point typeface; and
- With regard to the dispensing of a dangerous drug or device in a health facility, as defined, the bill removes a reference to a “licensed” facility (pursuant to HSC 1250), and instead references a health facility “defined” in HSC 1250.

EXISTING LAW:

Section 4076 of the Business and Professions Code (BPC) specifies requirements for the labeling of a prescription container dispensed to a patient, to include:

- The manufacturer’s trade name of the drug or the generic name and the manufacturer
- The directions for use of the drug
- The name of the patient
- The name of the prescriber
- The date of issue

- The name and address of the pharmacy, and prescription number or other means of identifying the prescription
 - The strength of the drug or drugs dispensed
 - The quantity of the drug or drugs dispensed
 - The expiration date of the effectiveness of the drug dispensed
 - The condition or purpose for which the drug was prescribed, if indicated on the prescription
 - The physical description of the dispensed medication, as specified (exemptions specified)
- Section 4075 further specifies requirements for unit dose medications in specified settings; and other requirements as it relates to the dispensing of a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code.

Section 4076.5 BPC was enacted in 2012 (SB 472, Corbett) to require the board to promulgate regulations to standardize “patient-centered” prescription drug labels, and further specified various factors that the board would consider in developing the regulations. One of the many factors the board was to consider was improved font types and sizes. This resulted in the promulgation of 16 CCR § 1707.5.

Title 16 CCR 1707.5 specifies requirements for patient-centered labels for prescription drug containers, to include

- Clustering of specified information, printed in at least 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface
- A requirement that the board publish on its website translations of directions for use into at least five languages other than English to facilitate the use thereof by California pharmacies
- A requirement that the board collect and publish on its website examples of labels that conform to the stated requirements
- A requirement that pharmacies have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label; and further specifies the minimum content for the policies and procedures
- A requirement that the board re-evaluate the requirements of the regulation by December 2013; and
- Define “appropriate dosage form” for purposes of the section

Background

As reflected in the board’s regulation at 16 CCR § 1707.5, pharmacies are required to print certain “patient-centered” elements on a prescription drug label in a 12-point sans serif typeface, if requested by the patient. Thus, under the current regulation requirements, pharmacies have the capacity to print the ‘clustered’ elements of the prescription label in 12-point sans serif typeface.

Also, and as specified in the regulation, the board has begun to re-evaluate the requirements of the patient-centered prescription drug labels. This review was initiated through the board’s Communication and Public Education Committee.

STAFF COMMENTS:

Staff is inquiring as to the intent or purpose of removing the reference to a facility “licensed” pursuant to Section 1250 of the Health and Safety Code. Removing the requirement that the facility be “licensed” may cause confusion.

FISCAL IMPACT ON THE BOARD:

If enacted the board would need to update its regulation at 16 CCR § 1707.5 to remove references to the printing in 10-point typeface. Any such update would be absorbed within the board's existing resources.

HISTORY

Date	Action
07/01/13	Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/27/13	From committee: Do pass as amended and re-refer to Com. on B.,P. & C.P. (Ayes 12. Noes 6.) (June 25).
05/28/13	Referred to Coms. on HEALTH and B.,P. & C.P.
05/16/13	In Assembly. Read first time. Held at Desk.
05/16/13	Read third time. Passed. (Ayes 23. Noes 9. Page 944.) Ordered to the Assembly.
05/15/13	Read second time. Ordered to third reading.
05/14/13	From committee: Do pass. (Ayes 5. Noes 0. Page 936.) (May 13).
05/07/13	Set for hearing May 13.
05/06/13	Hearing postponed by committee.
04/26/13	Set for hearing May 6.
04/24/13	Read second time and amended. Re-referred to Com. on APPR.
04/23/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 6. Noes 0. Page 638.) (April 22).
04/05/13	Set for hearing April 22.
02/21/13	Referred to Com. on B., P. & E.D.
02/11/13	From printer. May be acted upon on or after March 13.
02/11/13	Read first time.
02/08/13	Introduced. To Com. on RLS. for assignment. To print.

As of 7/15/13

Senate Bill 205

12 Point Font Prescription Drug Labels Senate Majority Leader Ellen M. Corbett

SUMMARY

Senate Bill 205 requires pharmacists to print all required items on a prescription label in at least 12 point, sans serif typeface to make it easier for patients to read.

BACKGROUND

The California Department on Aging reports that from 1990 to 2020, California's elderly population of the 60 and over age group will increase by 112 percent, over 200 percent in some counties. Even more drastic is the increase in population of the 85 and older age group, which will see an increase of 143 percent from 1990 to 2020. Several counties will even see an increase of 300 to over 400 percent in this age group.

In 2007, SB 472 (Corbett) required the Board of Pharmacy (Board) to standardize the prescription drug label to make it patient-centered. As part of that effort, the Board conducted a survey in 2009 which found that 60% of participants believed that larger or bolder print would make prescription labels easier to read.

Accordingly, 12 point font was proposed to be adopted at the Board's January 20, 2010 meeting. However, due to a last minute appointment to the Board by then-Governor Schwarzenegger, the Board adopted 10 point font as the standard and made 12 point font available only upon request, despite over 1,000 public comment letters opposing the change to a smaller font size.

PROBLEM

The Centers for Disease Control and Prevention recommend that adults read and follow directions to reduce the risk of harm from their medication.

Seniors are having difficulty reading the small print on their prescription labels, and for those who take multiple medications, their inability to read the label puts them in serious danger.

Medications that are taken incorrectly or mixed with other medications can cause dangerous reactions that can lead to injury and death.

SOLUTION

The Board acknowledges that seniors frequently have diminished eyesight and usually take more medication. For prescription labels to meet the needs of California's seniors, the words must be large enough to read.

Patients shouldn't have to struggle to read their prescriptions or worry about harming themselves just by taking their medication. SB 205 aims to make font size larger on prescription labels to make them more patient-centered and to help avoid disasters that occur because of easily preventable medication errors.

SUPPORT

California State Retirees, Chapter 1
California Alliance for Retired Americans (CARA)
California Pan-Ethnic Health Network (CPEHN)

OPPOSITION

California Pharmacists Association
National Association of Chain Drug Stores
California Board of Pharmacy
California Grocers Association

STATUS

April 22nd Hearing in Senate Business, Professions, and Economic Development Committee

CONTACT

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California
LEGISLATIVE INFORMATION

SB-205 Prescription drugs: labeling. (2013-2014)

Today's Law As Amended

SECTION 1. 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 where 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 either Section 4052.1 or 4052.2 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 either Section 4052.1 or 4052.2.

(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.

~~(b)~~ (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.

~~(e)~~ (d) If a pharmacist dispenses a dangerous drug or device in a ~~facility licensed pursuant to~~ 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 either Section 4052.1 or 4052.2.

~~(d)~~ (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.

SEC. 2. *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.*



Bill Number: SB 306
Introduced
Last Amend: June 20, 2013
Author: Senator Norma Torres
Topic: Automated Drug Delivery Systems
(Sponsor: Molina / InstyMeds)
Position:

Current Bill Status: Hearing: August 13 – ASM Business, Professions and Consumer Protection

Affected Sections: Amend Section 4170 (Article 12. Prescriber Dispensing)
Amend Section 4180 (Article 13. Nonprofit or Free Clinics)
Amend Section 4186 re: Automated Drug Delivery Systems

Staff Recommendation: Oppose Unless Amended

BILL HISTORY:

SB 306 was introduced in the Senate on February 15, 2013, related to the Chiropractic Act. On June 20, 2013 – after passing the policy and fiscal committees of the Senate and passed on to the Assembly – the bill was gutted and provisions related automated drug delivery systems were introduced. The bill has been scheduled for its first policy hearing in the Assembly on August 13.

EXISTING LAW:

Existing Pharmacy Law provides for the licensure of sites and individuals involved in the practice of pharmacy; that is, those settings in which controlled substances, dangerous drugs and dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, and repackaged and from which they are furnished, sold or dispensed; and individuals licensed to practice/work in those settings. These settings include community and retail pharmacies, hospital pharmacies, and nonresident pharmacies. (Article 7 – Pharmacies, commencing with § 4110.)

Existing law specifies entities and individuals to which a pharmacy may furnish dangerous drugs.

Existing law provides for the licensure of wholesalers – to include those who act as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or dangerous device. Licensed wholesalers must have a designated representative-in-charge, subject to approval by the board, who is responsible for the wholesaler's compliance with state and federal laws related to wholesalers.

Existing law (§ 4170) authorizes a prescriber to dispense dangerous drugs and devices in his or her office, so long as specified conditions are met

Existing law provides for board licensure of various ¹clinics, including

- Nonprofit or free clinics
- Surgical clinics
- Primary care clinics owned by a county
- Clinics operated by a federally recognized Indian tribe or tribal organization
- Student health center clinics operated by public institutions of higher education, and others

Existing law (§ 1204 of the Health and Safety Code) provides for the licensure of clinics by the California Department of Public Health. This section provides for the licensing of clinics operated by a tax-exempt, nonprofit corporation, as well as specialty clinics, as specified.

Eligible clinics may purchase drugs for wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as specified. Further, the dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs.

Existing law specifies requirements for ⁱⁱⁱautomated delivery device systems, which may be located in any Nonprofit or Free clinic that is licensed by the board.

Only upon authorization by a pharmacist may drugs be removed from an automated drug delivery system, and they shall be provide to the patient by a health professional licensed pursuant to Division 2 of the Business and Professions Code. Only a pharmacist shall restock an automated delivery device system.

Existing law defines a ²dangerous drug or dangerous device to be one that can be dispensed only upon a valid prescription.

Section 4037 defines a “pharmacy” as any area, place, or premise licensed by the board in which the profession of pharmacy is practiced to include any area, place, or premise where controlled substances, dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold or dispensed at retail.

Section 4040 defines a “prescription” as that which is given individually for a person or persons for whom it is ordered (i.e., patient-specific), and that is issued by a prescriber, as specified. That section further specifies additional requirements for the content of a valid prescription.

Section 4076 specifies requirements for labeling of a prescription, and 16 CCR § 1707.6 specify additional patient-centered labeling requirements.

Section 4111 places restrictions on physician ownership of a pharmacy.

Existing law at Health and Safety Code § 1206 specifies those entities that are **exempt from licensure** as a clinic by the California Department of Public Health. These exempt clinics include, but are not limited to

- “Free clinics” that are owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession.

¹ See Article 13 - Nonprofit or Free Clinics, commencing with § 4180, and Article 14 – Clinics, commencing with § 4190.

² Business and Professions Code § 4022.

- Community clinics, Tribal clinics, and clinics conducted, operated, or maintained as outpatient departments of hospitals.
- Clinics operated by a nonprofit corporation exempt from federal income taxation, as specified.
- A clinic that provides health care services to patients covered under Medicare, or through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time to direct patient care activities for which charges for professional services are paid.
- A freestanding clinic, as specified

Existing law at Health and Safety Code § 1375.4 specifies requirements for contracts between a health care service plan and a ^{iv}risk-bearing organization, and defines a “risk-bearing organization.”

THIS BILL WOULD:

Amend Section 4170 (Prescriber Dispensing) to

- Remove the restriction that specifies that a nurse or physician attendant do not furnish the physician’s drugs or devices to a patient, and instead allow health care professional or a physician’s designee to physically furnish the drug or device to the patient. (“Designees” are not defined, and there is no criterion for which the individual must abide.) This section specifically states that an automated drug delivery system may be utilized.
- Removes the restriction that a prescriber not use an automated dispensing device unless he or she personally owns the device, and the drugs that are within the device.
- Specify that the prescriber identified by the manufacturer or wholesaler on invoices, bills of lading, etc., is the recipient of and responsible for the safe and secure storage of drugs and devices. (There is no requirement that the responsible prescriber be located at the location in which an automated drug dispensing system is housed.)
- Add a requirement that when a physician dispenses a dangerous drug or device, that the physician provide the patient with an oral consultation regarding *issues that the physician deems necessary* and other items required by board regulation, to ensure the safe and effective use of the drug or device.
- Specifies conditions under which a physician group practice can own an inventory of dangerous drugs and devices, and dispense from those drugs and devices, to include
 - Each prescriber dispenses drugs or devices only to patients seen or treated at the group practice, and that all drugs or devices packaged, labeled, and that all recordkeeping requirements of pharmacy law are met.
 - The group identifies a “responsible provider” within the group that shall be named by the drug manufacturer or wholesaler as the recipient of drugs and devices, and who shall be responsible for the record-keeping and storage of the drug inventory.
 - Requires that records be maintained by each provider to identify the patient, and the name, strength, quantity and directions for use for each drug dispensed.
 - Require that a daily log or some other paper or electronic record is created each day to document the daily inventory of all drugs that are jointly owned by the group, and the name, strength and quantity of all drugs dispensed by each prescriber.
- Authorizes a prescriber that is employed by the group, or under contract to the group, to dispense drugs out of the group practice drug inventory.
- Specifies that dangerous drugs are ‘owned’ if they are ‘delivered’ to the possession of the prescriber, clinic, or group practice. Subdivision (f) further specifies that each prescriber, clinic or group practice has the responsibility for the security and recordkeeping associated with the possession of the dangerous drugs, regardless of the person or entity responsible for payment of the drug inventory.
- Defines “group practice” to be more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in the Knox-Keene Health Care Service Plan Act of 1975.

Amend Section 4180 (Clinics that can purchase drugs at wholesale) to

- Allow a group practice, licensed by Section 4170, to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, or other prescriber when permitted by law, to patients registered for care at a clinic.
- Make conforming changes to provisions that currently require clinics to notify the board of address changes, and the requirement to maintain records of drug inventory for three years.

Amend Section 4186 (Automated Drug Delivery systems) to

- Allow a clinic or group practice (specified in Section 4180) to have an automated drug delivery system.
- Require a physician group practice that utilizes an automated drug delivery system to develop and implement written policies and procedures. This provision specifies that all prescribers who dispense drugs from the system, and *all health care professionals and delegated personnel* authorized to stock, refill or retrieve the drugs from the system have to comply with the written policies and procedures.
- Strikes the requirement that only a pharmacist stock an automated drug delivery system and, in a physician group practice, allow a prescriber *or designee of a prescriber* to stock an automated drug delivery system.
- Amend provisions that require an automated drug delivery system to maintain 2-way audio and video, to allow for only two-way audio where a consultation is provided by the prescriber in a physician group practice.
- Amends provisions that require a pharmacist that operates an automated drug delivery system to be located in California; rather, that they be licensed in California.
- Amends the definition of an automated drug delivery system to specify that if it is used to facilitate prescriber dispensing, that the system
 - Be located within a clinic or office of the group practice, and the contents be secure from access or removal from unauthorized individuals.
 - That a policy and procedure manual be developed and maintained, and shall include information related to the system and provisions related to security, drug stocking, etc.
 - Requirements to ensure the security of the system to prevent unauthorized access to the drugs within the system.
 - Specify requirements for the stocking or filling of the system by a pharmacist, prescriber, or other person designated by the pharmacist or prescriber, and that certain requirements be met.
 - Maintain electronic or hard copy records of medications in the system.
 - Maintain readily retrievable electronic records to identify all persons involved in the dispensing of a drug.
 - Be able to comply with product recalls.
 - Specify records of transactions be available to board inspectors.
 - Provide patients with telephonic access to consultation by a California-licensed pharmacist, unless the prescriber provides a consultation.
 - Specify that a prescriber or designee reconstitute any medication that requires reconstitution.
- Authorizes the board to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient, and that any such regulations be based, in part, on the board's assessment of the safety of the systems.

Discussion

Staff has met with the sponsors of the bill on a couple of occasions and as a starting point for discussion, in June provided draft language that would reflect a licensing structure similar to that which was crafted for the licensure of surgical clinics (i.e., those authorized by SB 1095 (Rubio), 2012). A copy of the draft language offered is provided in Attachment 1. This licensing structure allows clinics, with a consulting pharmacist, to purchase drugs at wholesale, where a comingled drug supply is utilized by physicians at the surgical clinic for administration to patients at the clinic.

Staff is concerned where a Pharmacist is taken out of the picture where inventories of dangerous drugs and dangerous devices, including controlled substances, are maintained and where multiple prescribers dispense from this drug stock.

Staff is concerned about provisions that remove the requirement for a pharmacist, located in California, to maintain an automated drug delivery system. Staff is also concerned where those other than pharmacists or physicians and surgeons have full access to a comingled drug stock and where "designees" can stock, re-stock and retrieve dangerous drugs and dangerous devices from an automated drug delivery system.

The provisions of SB 306 may conflict with Business and Professions Code Section 4111, which place restrictions on prescriber ownership of a pharmacy.

Related to automated drug delivery systems,

- Should automated drug delivery systems be authorized outside of a pharmacy or clinic?
- Should only a pharmacist be authorized to stock and re-stock the device? Should a physician, a "designee" of the physician, and/or a wholesaler be authorized to stock and restock an automated drug delivery system?
- Should a pharmacist that operates an automated drug delivery system be "located in" California (current law), or just licensed to practice in California?
- Would the provisions of the bill that specify the drugs are "owned" upon delivery, regardless of who pays for them, comply with e-Pedigree requirements?
- Is it necessary to retain existing provisions that provide for 2-way telephonic and video at an automated drug delivery system, even if the physician provides a consultation to a patient?
- Should each automated drug delivery system be separately registered, and tied back to a board licensee?

FISCAL IMPACT ON THE BOARD:

A physician group practice would require the board to develop a new license category, applications, etc. for the processing of these entities.

The board may experience challenges in establishing a new "license type" in the existing licensing tracking system.

The board may experience a one-time cost of up to \$20,000 to develop a new licensing category in the BreEZe system.

SUPPORT:

Molina Healthcare of California (Sponsor)

OPPOSITION:

California Pharmacists Association (copy of letter provided)

HISTORY:

Date	Action
06/20/13	From committee with author's amendments . Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/14/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 38. Noes 0. Page 1100.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1011.) (May 23).
05/21/13	Set for hearing May 23.
05/20/13	Placed on APPR. suspense file.
05/10/13	Set for hearing May 20.
05/07/13	Read second time and amended. Re-referred to Com. on APPR.
05/06/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 733.) (April 29).
04/18/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
04/05/13	Set for hearing April 29.
02/28/13	Referred to Com. on B., P. & E.D.
02/19/13	From printer. May be acted upon on or after March 21.
02/15/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.

ⁱ Wholesalers. See Article 11, commencing with § 4160. A wholesaler permit is required before any firm or organization that sells for resale or negotiates for distribution, may distribute, broker or transact the sale or return of dangerous drugs or dangerous devices in California. Wholesalers sell and distribute dangerous drugs and dangerous devices (also called "legend" items or prescription-required drugs and devices) to other business entities that are authorized by law to purchase the items or sell to licensed health care providers who are authorized by law to possess the dangerous drugs and dangerous devices. Wholesalers are not authorized to sell or distribute these items directly to patients unless the wholesaler is delivering dialysis drugs and devices to home dialysis patients in case(s) or full shelf package lots (see section 4054 of the California Business & Professions Code).

ⁱⁱ Prescribers are defined at B&PC Section 4170(c) as a person who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, as specified. Article 12 prohibits a prescriber from keeping a pharmacy, open shop, or drug store for the retailing of dangerous drugs, dangerous devices, or poisons. Prescribers are authorized to distribute dangerous drugs or dangerous devices to their own patients; these drugs or devices are not to be furnished by a nurse or physician attendant. There is no restriction on a prescriber dispensing to his or her patient a controlled substance. A prescriber must ensure that dangerous drugs dispensed by the prescriber meet specified conditions:

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- The drugs and devices are dispensed to the prescriber's own patient, and they are not furnished by a nurse or physician attendant.
 - The drugs and devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
 - The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
 - The prescriber fulfills all of the label requirements imposed upon pharmacists, as specified.
 - The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and that any drugs dispensed therefrom are packaged and labeled in accordance with pharmacy laws.
 - The prescriber offers a written prescription to the patient, so that the patient may elect to have the prescription filled at a pharmacy.
 - The prescriber provides the patient with a written disclosure that the patient has the choice of obtaining the prescription from the dispensing prescriber, or from a pharmacy of the patient's choice.
 - Those authorized to hand a prescription to the patient include: certified nurse-midwife, nurse practitioner, physician assistant, or a naturopathic doctor

ⁱⁱⁱ Automated Drug delivery systems are defined at § 4186(h) as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing or distribution of pre-packaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

^{iv} H&SC § 1375.4 (g) (1) For purposes of this section, a "risk-bearing organization" means a professional medical corporation, other form of corporation controlled by physicians and surgeons, a medical partnership, a medical foundation exempt from licensure pursuant to subdivision (l) of Section 1206, or another lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services, but does not include an individual or a health care service plan, and that does all of the following:

(A) Contracts directly with a health care service plan or arranges for health care services for the health care service plan's enrollees.

(B) Receives compensation for those services on any capitated or fixed periodic payment basis.

(C) Is responsible for the processing and payment of claims made by providers for services rendered by those providers on behalf of a health care service plan that are covered under the capitation or fixed periodic payment made by the plan to the risk-bearing organization. Nothing in this subparagraph in any way limits, alters, or abrogates any responsibility of a health care service plan under existing law.

(2) Notwithstanding paragraph (1), risk-bearing organizations shall not be deemed to include a provider organization that meets either of the following requirements:

(A) The health care service plan files with the department consolidated financial statements that include the provider organization.

(B) The health care service plan is the only health care service plan with which the provider organization contracts for arranging or providing health care services and, during the previous and current fiscal years, the provider organization's maximum potential expenses for providing or arranging for health care services did not exceed 115 percent of its maximum potential revenue for providing or arranging for those services.

Increasing Patient Access to Vital Medication



PURPOSE

This measure would expand access to prescription medication for patients and improve medication compliance, potentially saving the health care system millions of dollars. The bill would allow physicians in a group practice to jointly own and dispense from a single inventory of drugs and authorize the use of automated dispensing machines, under rigorous controls, so that California patients can receive prescription medications for acute conditions at their doctor's offices.

PROBLEM

More than 30 percent of all prescriptions written never get filled. This statistic has been documented in studies as well as in clinical experience. The failure to fill these prescriptions increases health care costs because patients often wind up in emergency rooms and hospitals as a result. Some reports estimate that 10 percent of patients will subsequently require hospital care due to noncompliance with medication therapy and that medication noncompliance leads to 125,000 premature deaths. The costs of medication non-compliance are estimated at more than \$4 billion for California's health care system annually.

The lack of point-of-care access to prescription medication is the primary reason prescriptions go unfilled. Getting to an offsite pharmacy is particularly difficult for the poor, the elderly, the disabled, caregivers with sick children, patients with limited transportation options or ill patients who cannot drive.

Existing California law, however, makes it difficult for physicians to dispense medications in their offices. Physicians, physician assistants and nurse

practitioners are permitted to dispense prescription medication to their patients. However, current statute requires these medical practitioners to personally own the medication and the dispensing equipment. The tracking, storage, inventory control and payment processing requirements, coupled with the need for safe and appropriate dispensing and labeling, make physician ownership and dispensing of drugs at the point of care difficult. In addition, current law prohibits health care providers in a group practice from jointly owning and dispensing medication from a single inventory.

Moreover, California law does not permit a physician group practice to jointly own an inventory of drugs, so that the group practice could take advantage of the efficiencies management of an inventory by the practice as a whole. Though advanced technologies exist to solve this problem through automated dispensing machines that handle tracking, labeling, dispensing, and inventory control, California law does not clearly permit the use of these machines by group practices.

SOLUTION

This measure would amend existing law pertaining to the ownership and dispensing of prescription medications that hinder the use of automated dispensing machines in group practices. The proposed legislation would amend existing law to permit group practices to own the medication and equipment, provided they are licensed by the Board of Pharmacy and comply with rigorous requirements for safety and security pertaining to use of automated dispensing machines. This legislation will expand access to prescription medication for millions of Californians who currently don't fill prescriptions and the millions who will soon receive services under the ACA.

It has been proven that providing prescription medication at the point-of-care increases the rates of prescription filling from 70 percent to 95 percent because patients can quickly and conveniently get their medication without having to go to another facility. These dramatic increases in fill rates reduce the chance of noncompliance with medication therapy and the associated costs of additional treatment.

As a result of implementation of the ACA, about 4.7 million more Californians will be eligible for health insurance starting in 2014. Many newly insured Californians will have a pent-up demand for services and will create even more pressure on the already stressed health care system, particularly in medically underserved areas. In these areas, it's not uncommon for patients to wait 8 hours or more to fill a prescription. Higher patient demand will increase wait times resulting in greater medication noncompliance.

BACKGROUND ON AUTOMATED PRESCRIPTION DISPENSING

Automated prescription medication dispensing at the point-of-care has been available for over 10 years and has safely and accurately dispensed more than 2 million prescriptions in 28 states. The dispensing system consists of an ATM-style, secure machine and HIPAA compliant software to write medication orders, control dispensing, adjudicate costs, receive payment, and track and report on all transactions.

After the patient sees the physician, physician assistant or nurse practitioner, a medication order form is issued and printed with patient drug education material. The practitioner consults with the patient about the medication therapy and answers any questions. The health care professional or his or her designee then takes the order form to the dispenser, which is located in the provider's office, and uses the touch-screen to enter in the order's one-time, unique

access code along with the patient's birthday. If the patient has insurance, the claim will be processed and the cost or insurance co-pay is calculated. The dispenser accepts a variety of forms of payment. Public insurance plans are also accepted, including Medicare, Medicaid and other government programs. If desired, the health care facility can elect to provide the medications at no cost to the patient.

After payment is processed, precision robotics locate the proper medication in the dispenser using a triple barcode check system to ensure accuracy while eliminating handwriting errors. A label with all required information is printed and affixed to the container, and the medication is dispensed directly to the patient. A telephone located on the dispenser with direct dialing to a call center, including a licensed pharmacist, may be used if questions arise. The patient takes the medication and receipt, and is on his or her way in minutes.

CONCLUSION

Other states have recognized these advances in dispensing technology and taken advantage of them implementing regulations that ensure safety and appropriate prescribing. This legislative proposal will allow Californians to improve their health and reduce health care costs by providing medication at the point of care. Californians deserve this expanded access to prescription medication offered by safe, efficient advanced dispensing technology.

SPONSOR

Molina Healthcare of California



California

LEGISLATIVE INFORMATION

SB-306 Pharmacy: dangerous drugs and dangerous devices: automated drug delivery systems.

(2013-2014)

As Amended June 20, 2013 - Today's Law As Amended

SECTION 1. *Section 4170 of the Business and Professions Code is amended to read:*

4170. (a) No prescriber shall dispense *dangerous* drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own ~~patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.~~ *patient. A health care professional who is licensed as described in this section, or his or her designee, shall physically furnish the dangerous drug or device to the patient.*

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) ~~The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).~~ *Unless the prescriber is employed by or under contract to a clinic or group practice that is licensed by the board pursuant to Section 4180, the prescriber is identified by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs and identified by name and registration number as the recipient in all invoices, bills of lading, state or federal order forms, and other documentation. As the recipient of the drugs, the prescriber is responsible for ensuring that the drugs are securely and safely stored prior to dispensing and is responsible for maintaining all required records regarding the receipt, storage, and dispensing or other disposition of all drugs and devices.*

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) The prescriber provides the patient with an oral consultation regarding issues that the prescriber, in his or her professional judgment, deems necessary to ensure the safe and effective use of the prescribed drug or device. The oral consultation shall include all subjects that pharmacists are required to discuss pursuant to regulations adopted by the board pursuant to Section 4005.

~~(8)~~ *(9) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, a registered nurse who functions pursuant to Section 2725.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist. Nothing in this section shall preclude the use of an automated drug delivery system described in Section 4186.*

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a ~~person, who~~ *person who is licensed to prescribe and dispense dangerous drugs and devices, including, but not limited to, a person who* holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

(d) This section shall not prevent a group practice, licensed pursuant to Section 4180, from owning an inventory of dangerous drugs and devices and dispensing the drugs and devices from the inventory owned by the group practice provided that the following conditions are met:

(1) Each prescriber dispenses dangerous drugs or devices only to the patients seen or treated by that prescriber, and not to the patient of any other prescriber in the group practice, and the drugs or devices are packaged, labeled, and recorded in accordance with paragraph (4) of subdivision (a).

(2) The group practice identifies a responsible prescriber within the group practice who shall be named by the drug manufacturer or wholesaler supplying the drugs as the recipient of the drugs on all invoices, bills of lading, state or federal order forms, and other documentation, and who shall be responsible for the record-keeping and storage of the drug inventory.

(3) Records are maintained by each prescriber to identify the identity of the patient and the name, strength, quantity, and directions for use for each dangerous drug dispensed by the prescriber to his or her patient.

(4) A daily dispensing log or some other paper or electronic record is created each day, and maintained by the group practice, to identify both of the following:

(A) A daily starting inventory of all dangerous drugs that are jointly owned by the prescribers who comprise the group practice.

(B) The name, strength, and quantity of all dangerous drugs dispensed by each prescriber.

(e) A prescriber employed by, or under contract to, a clinic or group practice licensed under Section 4180 may dispense drugs that are owned by the clinic or group practice.

(f) (1) For purposes of this section, a dangerous drug is owned if it is delivered to the possession of a prescriber, clinic, or group practice, and each prescriber, clinic, or group practice has responsibility for the security and recordkeeping associated with possession of the dangerous drugs, regardless of the person or entity responsible for payment for the dangerous drug inventory.

(2) For the purposes of this section, "group practice" means more than one prescriber practicing under a single professional corporation or license, including a medical group or risk-bearing organization as defined in 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).

SEC. 2. *Section 4180 of the Business and Professions Code is amended to read:*

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following *clinics entities* may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, *or other prescriber when permitted by law*, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(G) A group practice, as defined in Section 4170, that uses an automated drug delivery system, as described in Section 4186.

(2) The clinic *or group practice* shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic *or group practice* shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic *or group practice* shall notify the board of any change in the ~~clinic's address~~ *address of the clinic or group practice* on a form furnished by the board.

SEC. 3. *Section 4186 of the Business and Professions Code is amended to read:*

4186. *(a) An automated drug delivery system, as defined in subdivision (i), may be located in any clinic or group practice licensed by the board as described in Section 4180.*

~~(a) (b) Automated (1) drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180.~~ If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(2) If an automated drug delivery system is located in a group practice, the group practice shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All prescribers who will be dispensing drugs from the automated drug delivery system and all health care professionals and delegated personnel authorized to stock, refill, or retrieve the drugs inventory from the automated drug delivery system shall be required to comply with the policies and procedures developed by the group practice. All policies and procedures shall be maintained at the location where the automated drug system is being used.

~~(b) (c)~~ Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist *or prescriber* after the pharmacist *or prescriber* has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this ~~division~~ *division or an individual operating under the supervision of the prescriber*.

~~(c) (d)~~ The stocking of an automated drug delivery system shall be performed by a ~~pharmacist~~ *pharmacist or, in a clinic or group practice, by a prescriber or a designee of the prescriber*.

~~(d) (e)~~ Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the ~~clinic~~ *clinic in a clinic setting or by the responsible prescriber in a group practice*. The review shall be conducted on a monthly basis by a pharmacist *or responsible prescriber* and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

~~(e) (f)~~ The automated drug delivery system used at the clinic *or group practice* shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and ~~video~~ *video, unless a consultation is provided by the prescriber pursuant to paragraph (8) of subdivision (a) of Section 4170*.

~~(f) (g)~~ ~~The~~ A pharmacist operating the automated drug delivery system shall be ~~located~~ *licensed* in

California.

~~(g)~~ (h) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

~~(h)~~ (i) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a ~~pharmacist~~ *pharmacist, or, if used to facilitate prescriber dispensing by a prescriber*, that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and ~~accountability~~. *accountability and shall meet all of the following requirements:*

(1) The system shall be located within the clinic or office of the group practice, and its contents shall be secure from access or removal by unauthorized individuals.

(2) A policy and procedure manual shall be developed and maintained and shall include the type or name of the system including a serial number or other identifying nomenclature and a description of the security provisions, stocking processes, and other documentation practices of the clinic or group practice.

(3) The system shall have a method to ensure security of the system to prevent unauthorized access to dangerous drugs or devices contained within the system. The method may include the use of electronic passwords, biometric identification, including optic scanning or fingerprint, or other coded identification.

(4) The clinic or group practice shall employ a process of filling and stocking the system with drugs. The stocking or restocking of a drug shall only be completed by a pharmacist, prescriber, or personnel designated by the pharmacist or prescriber and all of the following shall apply:

(A) The cartridges or containers to be stocked or restocked shall be provided by a licensed wholesale drug distributor or repackaged by the pharmacy or prescriber in compliance with state and federal law. The licensed wholesale drug distributor shall have a method of receiving and disposing of rejected, expired, or unused medications consistent with state or federal law.

(B) The individual cartridge or container shall be transported to the dispensing site in a secure, tamper-evident package.

(C) The system shall use a bar code verification, electronic verification, weight verification, radio frequency identification, or similar process to ensure that the cartridge or container is accurately stocked or restocked into the automated system. The system shall provide for alerts to the responsible pharmacist or prescriber if a cartridge or container is not recorded in the automated system.

(D) The pharmacist or prescriber responsible for the dispensed drug shall be responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(5) The system shall maintain an electronic or hard copy record of medication filled into the system, including the product identification, lot number, and expiration date.

(6) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, prescribers, and all other personnel involved in the dispensing of a drug.

(7) The system shall be able to comply with product recalls generated by any manufacturer or distributor and shall have a process in place to isolate affected lot numbers.

(8) The record of transactions conducted through the automated drug delivery system shall be available to authorized agents of the board. The record of transactions shall, only to the extent authorized or permitted by state or federal law, include the following:

(A) Name of the patient.

(B) Name, strength, and dosage form of the drug product dispensed.

(C) Quantity of drug dispensed.

(D) Date and time of dispensing.

(E) Prescription number or other unique serial number assigned to the transaction.

(F) Name of prescriber.

(G) Identity of the pharmacist who approved the prescription, or of the prescriber.

(H) Identity of the person to whom the drug was released.

(9) Unless the prescriber provides consultation pursuant to regulations adopted by the board pursuant to Section 4005, the system shall provide patients with telephonic access to consultation by a California-licensed pharmacist.

(10) In the case of dangerous drugs that require reconstitution, the prescriber or his or her designee shall reconstitute the medication for the patient.

(j) The board is authorized to adopt regulations authorizing the use of an automated drug delivery system that delivers dispensed medications directly to a patient. The regulations shall be based, in part, upon the board's assessment of the safety of the systems.

SEC. 4. *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.*

Article 14.5 Medical Professional Corporations Licensed as Clinics

4197

- (a) A professional corporation comprised of physicians may apply for a clinic permit under this article provided at least 75 percent of the patients served by the corporation are provided medical services funded through a MediCal Managed Care Program.
- (b) No entity shall be entitled to the benefits of this article until it has obtained a license from the board.
- (c) A separate license shall be required for each clinic location. No clinic may be located in a home. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board at least 30 days in advance of a move.
- (d) The license shall be renewed annually.
- (e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensed premises shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.
- (f) If at any time during the year the percentage of MediCal patients being served by the corporation decreases below 75 percent of all patients served, the corporation shall notify the board and shall have 90 days to resume serving MediCal Managed Care patients in a proportion that is at least 75 percent of all patients served. If the percentage of MediCal Managed Care patients stays below 75 percent for more than three consecutive months, the medical professional corporation is no longer eligible for a clinic permit under this section, and the permit may be cancelled by the board.

4197.1

A clinic licensed under this article may purchase prescription drugs and devices at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic.

- (a) Prior to the issuance of a clinic license authorized under Section 4197, the clinic shall comply with all applicable laws and regulations of the board relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the

- promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.
- (b) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.
 - (c) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel, including the board.
 - (d) Each clinic that makes an application for a license under Section 4197 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this article shall prohibit the consulting pharmacist from visiting more frequently than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
 - (e) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.
 - (f) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director.
 - (g) Clinics licensed under this article shall notify the board within 30 days of any change in professional director on a form furnished by the board.
 - (h) The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law

4197.2 No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal

Program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

- 4197.3 No Schedule II controlled substance shall be dispensed by the clinic. The board shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.
- 4197.4 (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4197. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.
- (b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided only to a patient and only by a health professional licensed pursuant to this division.
- (c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
- (d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
- (e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
- (f) The pharmacist operating the automated drug delivery system shall be located in California.
- (g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Sections 4076 and 4076.5.
- (h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all

transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4197.5 The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

No clinic holding a license pursuant to this article shall offer drugs for sale or shall charge or bill for professional services for the dispensing or administering of drugs.

No Schedule II controlled substance shall be dispensed in the clinic. This limitation does not prohibit a physician from dispensing a Schedule II drug to the extent permitted by subdivision (b) of Section 11158 of the Health and Safety Code and all other provisions of law, nor does it prevent the lawful administration of Schedule II drugs on the premises of the clinic.



June 27, 2013

The Honorable Norma Torres
California State Senate
State Capitol, Room 3056
Sacramento, CA 95814

Re: **SB 306 – OPPOSE**

Dear Senator Torres:

The California Pharmacists Association (CPhA) must respectfully **oppose your bill, SB 306**. This bill would make a number of changes to the Pharmacy Law to allow physician group practices to purchase prescription drugs as a group and dispense those drugs through automated dispensing machines without important oversight and safeguards.

Pharmacists share your interest in improving medication adherence among patients and we appreciate your intent in this regard. However, as currently structured, this bill takes an inappropriate path to achieving that goal. The scheme proposed by this bill completely cuts pharmacists out of the equation, effectively exempts physician group practices from numerous safeguards with which pharmacies and clinics that dispense drugs must currently comply, and increases the risk of diversion of controlled substances by allowing unlicensed staff to handle medications and allowing all schedules of controlled substances to be dispensed.

This bill significantly expands the existing authority for prescriber dispensing in multiple ways. The proposal allows prescribers operating in group practice to commingle drugs and essentially operate as a pharmacy under the prescriber dispensing authority without the appropriate Board of Pharmacy oversight. Under existing law, prescriber dispensing authority has numerous limitations and requirements—including that the prescriber not be operating a pharmacy. When significant amounts of drugs are dispensed (for example, in a clinic or outpatient surgical center), it is considered to be operating as a pharmacy and the facility must be licensed by the Board of Pharmacy. However, SB 306 would allow group practices to dispense drugs, as if they are a pharmacy, under the prescriber dispensing authority.

This bill also seeks to simultaneously expand the use of and relax the regulation of automated dispensing machines. Dispensing machines are currently allowed to be used by nonprofit clinics. However, each individual site is licensed by both the Department of Public Health and the Board of Pharmacy, all prescriptions must be reviewed by a pharmacist prior to being dispensed to ensure the safety of the prescribed drug, and numerous other safeguards must be in place to ensure the safety and security of the drugs. By contrast, this bill does not require review by a pharmacist, does not require each site to be licensed, does not provide clear

inspection authority by the Board of Pharmacy, and allows unlicensed personnel to operate the dispensing machine and handle drugs.

In general, existing practice and California law require prescription drugs to be prescribed by a licensed healthcare provider with prescriptive authority and then be dispensed by a licensed pharmacist working in a pharmacy, hospital pharmacy, or clinic pharmacy. The pharmacist is responsible for reviewing the prescription for contraindications and for the appropriateness of the therapy. In outpatient settings, nearly half of preventable adverse drug events occur because of prescription errors. The secondary review by a pharmacist helps catch many medication errors before they happen. By cutting pharmacists completely out of the equation, this bill eliminates this important step to protect patients' health and safety.

Again, we share your concerns regarding the number of patients who do not take their medications as prescribed. There are a number of factors leading to medication non-adherence and we would be pleased to work with you on comprehensive solutions to this problem. If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,



Brian Warren
Director, Government and Professional Affairs

cc: Members, Assembly Business, Professions, and Consumer Protection Committee
Sarah Huchel, Consultant, Assembly BPCP Committee
Ted Blanchard, Assembly Republican Caucus



Bill Number:	SB 598
Introduced	2/22/13
Last Amend:	June 20, 2013
Author:	Senator Jerry Hill
Topic:	Biosimilars
Position:	Oppose (4/24/13)

Current Bill Status: Referred to ASM Appropriations
7/2/13 - Passed out of ASM Health

Affected Sections: Add Section 4073.5 to the Business and Professions Code

SUMMARY:

SB 598 would add Section 4073.5 to specify conditions under which a pharmacist can exercise professional discretion to substitute a biosimilar where a biologic has been prescribed. For prescriptions filled prior to January 1, 2017, SB 598 requires the pharmacy to notify the prescriber of any substitution made within five business days of the selection.

The board opposed SB 598 at the April 2013 Board Meeting stating the board's concerns that the bill may be premature, the burden placed on the pharmacy to provide follow-up notification to a prescriber, as well as the role a pharmacist plays in substitutions. The board noted that once deemed "biosimilar" the board would support an approach similar to the authority that allows the substitution of generics. The board also has conveyed to the author that where there is an adverse event attributed to the use of a biosimilar that such an event be required to be reported to the FDA's "Medwatch."

During a recent policy hearing (ASM Health), the committee made comments in support of pharmacist notification to physicians each time a substitution would be made.

EXISTING LAW:

U.S. Food and Drug Administration

The Patient Protection and Affordable Care Act (Affordable Care Act) amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the *Biologics Price Competition and Innovation Act* (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

(<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>)

According to the Biosimilar User Fee Act (BsUFA)

A “¹biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Some products that meet the drug definition or both the drug and device definitions, and that also meet the definition of biological product, might be classified as biological products, rather than as devices or drugs, and be subject to licensure under the PHS Act². The FDA’s Office of Combination Products provides guidance as to whether a product meets the definition of biological product.

Pharmacy Law***Article 4 – Requirements for Prescriptions***

Section 4073 of the B&PC authorizes pharmacists filling prescription orders for drug products prescribed by their trade or brand names to substitute generic drugs for orders if the generic contains the same active chemical ingredients of equivalent strength and duration of therapy, subject to a patient notification and bottle labeling requirement, unless the prescriber specifies that a pharmacist may not substitute another drug product by either indicating on the form submitted for the filling of the prescription drug orders “Do not substitute” or words of similar meaning or selecting a box on the form marked “Do not substitute.”

Article 3 – Scope of Practice and Exemptions

Section 4052.5 of the B&PC authorizes pharmacists filling prescription orders for drug products prescribed by their trade or brand names to substitute a drug product with a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy, subject to a patient notification and bottle labeling requirement, unless the prescriber specifies that a pharmacist may not substitute another drug product by either indicating on the form submitted for the filling of the prescription drug orders “Do not substitute” or words of similar meaning or selecting a box on the form marked “Do not substitute.”

Section 4059 of the B&PC specifies requirements regarding the dispensing and furnishing of dangerous drugs and devices

¹ Section 351(i) (as amended by the Biologics Price Competition and Innovation Act of 2009, title VII of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002 (2010))

² http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm#_ftn4

THIS BILL WOULD:***In Article 4 "Requirements for Prescriptions"***

Add Section 4073.5 to the Business and Professions Code to specify conditions under which a pharmacist may exercise professional discretion to substitute a ***biosimilar*** for a prescribed ***biological*** product, if:

- The biosimilar is approved by the FDA, as specified, and has been determined to be interchangeable with the prescribed biological product;
- The prescriber does not indicate "Do not substitute";
- The pharmacist notifies the prescriber or enters appropriate information in a patient record system shared by the prescriber within five days of the selection (the method of notification is not specified);
- The pharmacy retains a written record of the biosimilar selection, as specified.
- The pharmacist shall communicate to the patient the substitution;
- Require the board to maintain on its website a link to a current list, if available, of biosimilar products determined by the FDA to be interchangeable;
- Define terminology, including "biological product," "biosimilar," "Interchangeable," "prescription" and "351(k) pathway."

FISCAL IMPACT ON THE BOARD:

As introduced, SB 598 will have an unknown fiscal impact on the board to

- Create and maintain on its website a link to an FDA approved list of interchangeable biosimilars. As of 4/5/13, staff has been unable to allocate such a link.
- Update its self-assessment forms for pharmacies.

.As of 7/15/2013

The 6/28/13 analysis by the Assembly Committee on Health lists wide support, and many in opposition to the measure.

HISTORY:

Date	Action
06/25/13	From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 12. Noes 0.) (June 25). Re-referred to Com. on HEALTH.
06/20/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/17/13	Referred to Coms. on B.,P. & C.P. and HEALTH.
05/24/13	In Assembly. Read first time. Held at Desk.
05/24/13	Read third time. Passed. (Ayes 29. Noes 4. Page 1044.) Ordered to the Assembly.
05/21/13	Read second time. Ordered to third reading.
05/20/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
05/10/13	Set for hearing May 20.
05/07/13	Hearing postponed by committee.
05/03/13	Set for hearing May 13.
05/02/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 6. Noes 1. Page 791.) (May 1). Re-referred to Com. on APPR.
04/23/13	Set for hearing May 1.
04/16/13	Read second time and amended. Re-referred to Com. on HEALTH.

Date	Action
04/15/13	From committee: Do pass as amended and re-refer to Com. on HEALTH. (Ayes 10. Noes 0. Page 464.) (April 8).
03/21/13	Set for hearing April 8.
03/11/13	Referred to Coms. on B., P. & E.D. and HEALTH.
02/25/13	Read first time.
02/23/13	From printer. May be acted upon on or after March 25.
02/22/13	Introduced. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

SB-598 Biosimilars. (2013-2014)

As Amended 6/20/13 - Today's Law As Amended

SECTION 1. *Section 4052.55 is added to the Business and Professions Code, to read:*

4052.55. *(a) In addition to the authority allowed under Section 4073.5, a pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if all of the following conditions are met:*

(1) The product selected as a biosimilar has been approved by the federal Food and Drug Administration (FDA) under the 351(k) pathway of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)) and has been determined to be interchangeable with the prescribed biological product.

(2) The prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning, pursuant to subdivision (b).

(3) For prescriptions filled prior to January 1, 2017, the pharmacy notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection.

(4) For prescriptions filled prior to January 1, 2017, the pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biosimilar as would be incurred in filling a prescription for a biosimilar using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient.

(f) The board shall maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable, as provided in paragraph (1) of subdivision (a).

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) "Prescription," with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(3) "351(k) pathway" refers to the licensure of a biological product as a biosimilar or an interchangeable biosimilar by the FDA pursuant to Section 351(k) of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)).

(h) Nothing in this section prohibits the administration of immunizations, as permitted in Section 4052.

SEC. 2. *Section 4073.5 is added to the Business and Professions Code, to read:*

4073.5. *(a) A pharmacist filling a prescription order for a prescribed biological product may select a biosimilar only if all of the following conditions are met:*

(1) The product selected as a biosimilar has been approved by the federal Food and Drug Administration (FDA) under the 351(k) pathway of the federal Public Health Service Act (42 U.S.C. Sec. 262(k)) and has been determined to be interchangeable with the prescribed biological product.

(2) The prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning in the manner provided in subdivision (b).

(3) For prescriptions filled prior to January 1, 2017, the pharmacy notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection.

(4) For prescriptions filled prior to January 1, 2017, the pharmacy retains a written record of the biosimilar selection for a period of at least three years.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on selection be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the biosimilar to be dispensed pursuant to this section shall assume the same responsibility for substituting the dispensed biological product as would be incurred in filling a prescription for a biosimilar using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist substitute a biological product pursuant to this section unless the biological product selected costs the patient less than the prescribed biological product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a selection is made pursuant to this section, the substitution of a biosimilar shall be communicated to the patient.

(f) The board shall maintain on its public Internet Web site a link to the current list, if available, of biosimilar products determined by the FDA to be interchangeable, as provided in paragraph (1) of subdivision (a).

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) "Prescription," with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(3) "351(k) pathway" refers to the licensure of a biological product as a biosimilar or an interchangeable biosimilar by the FDA pursuant to Section 351(k) of the federal Public Health Service Act.

(h) Nothing in this section prohibits the administration of immunizations, as permitted in Section 4052.

SEC. 3. *No reimbursement is required by this act pursuant to Section 6 of Article XIIB 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.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 10, 2013

The Honorable Jerry Hill
Member, California State Senate
State Capitol, Room 5064
Sacramento, CA 95816

RE: SB 598 - Oppose

Dear Senator Hill:

I regret to advise you that the Board of Pharmacy has taken an oppose position on your SB 598. This proposal would specify conditions under which a pharmacist may substitute a biosimilar where a biological product has been initially prescribed.

The board believes that SB 598 is premature in that no biosimilar products have yet been approved by the U.S. Food and Drug Administration (FDA). Nevertheless, the board applauds your effort to provide a pathway for biosimilar substitution. We share your belief that one day such substitution will be important to patient health care. However, we see no need to rush to secure statutory authorization before such determinations have been made.

The board suggests that once the FDA approves the lawful substitution of a biosimilar product would be the appropriate time to make such changes to California law. We also note that once deemed "biosimilar," we would support an approach like that which currently exists for substituting generic drugs, whereby the pharmacist can substitute a biosimilar without prescriber approval, unless the prescriber indicates 'do not substitute.'

Please do not hesitate to contact me at (916) 574-7913 if you have any questions. You may also contact the board's Executive Officer Virginia (Giny) Herold at (916) 574-7911.

Sincerely,


CAROLYN KLEIN, Manager
Legislation and Regulations



July 9, 2013

The Honorable Jerry Hill
California State Senate
State Capitol, Room 5064
Sacramento, CA 95814

Re: SB 598 (Hill) – Oppose

Dear Senator Hill:

The California Pharmacists Association (CPhA) must respectfully **oppose your bill, SB 598**. This bill would authorize a pharmacist to substitute a biologic drug product with an interchangeable biosimilar drug product, provided certain procedures are followed. The substitution process established by this bill closely mirrors that for substituting name brand drugs with generic drugs, except this bill requires the pharmacist to send notification to the prescriber upon dispensing either the prescribed biologic or an interchangeable biosimilar.

As the medication experts, pharmacists strongly support efforts to improve access and adherence to life saving medications. One of the most frequently cited reasons for patients not taking their medications is the high cost of drugs. To that end, pharmacists support the use of less expensive generic medications when available and medically appropriate. With the increasing use of biologics in the treatment of diseases, we look forward to the approval and availability of interchangeable biosimilars as a means of increasing patient access and affordability while reducing the overall cost of delivering healthcare.

CPhA supports appropriate communication and sharing of information between providers; this is why we had previously been neutral on SB 598. However, we strongly believe that pharmacists and other healthcare providers must be allowed to work together, using their professional judgment to ensure optimal medication therapy for their patients, unhindered by burdensome or unnecessary statutory frameworks. Amendments to SB 598 taken in the Assembly Committee on Health establish new and unnecessary notification requirements that will place a burden on pharmacists without any obvious benefit to providers or patients. For this reason, we must respectfully oppose SB 598.

If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Brian Warren'.

Brian Warren
Director, Government and Professional Affairs



Bill Number:	SB 669
Introduced	2/22/13
Last Amend:	July 3, 2013
Author:	Senate Republican Leader Bob Huff
Topic:	Emergency Medical Care: Epinephrine Auto-Injectors
Position:	Support If Amended

Current Bill Status: 8/13/13 – Set for Hearing in ASM Judiciary

Affected Sections: Add Section 4119.3 to the Business and Professions Code
Add Section 1714.23 to the Civil Code
Add Section 1797.197(a) to the Health and Safety Code

SUMMARY:

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals, in good faith and not for compensation, to administer an epinephrine auto-injector without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

The board established a position of Support if Amended at the April 2013 Board Meeting, with the suggested amendment to also authorize a pharmacist to approve the requisite training certification and issue the prescription for an epinephrine auto-injector, as specified in the bill.

To that end, staff recently met with the author's staff and sponsor and conveyed the board's request to amend the bill, as noted.

EXISTING LAW:

Section 4022 of the Business and Professions Code defines a Dangerous Drug or Dangerous Device (i.e., Rx, and one that can be dispensed only upon a valid prescription).

Section 4040 of the Business and Professions Code defines a "prescription" as that which is given individually for a person or persons for whom it is ordered (i.e., patient-specific), and that is issued by a prescriber, as specified. That section further specifies additional requirements for the content of a valid prescription.

Section 4076 of the Business and Professions Code specifies requirements for labeling of a prescription, and 16 CCR § 1707.6 specifies additional patient-centered labeling requirements.

Title 16 CCR § 1761 limits the dispensing of an erroneous or uncertain prescription.

THIS BILL WOULD:

Add Section 4119.3 to Pharmacy Law to authorize a pharmacy to dispense epinephrine auto-injectors to specified persons, in accordance with Section 1797.197a of the Health and Safety Code, provided specified requirements are met, including

- The prescription shall specify that the dispensed auto-injector is for “EMS Purposes Only” and that the named recipient is a “Section 1797.197a Responder.”
- Require a new prescription for additional epinephrine auto-injectors required.
- Require specified labeling of a prescription dispensed pursuant to this section.

Add Section 1714.23 to the Civil Code to

- Define “anaphylaxis” and “epinephrine auto-injector”;
- Grant immunity to an individual who administers epinephrine to another in good faith, at the scene of an emergency situation, in accordance with the provisions of the bill; and
- Provide immunity from alleged civil damages those organizations or others who provide or develop standards for training programs or standards.

Add Section 1797.197 to the Health and Safety to

- Establish definitions, to also include “anaphylaxis” and “epinephrine auto-injector” and others;
- Authorize a health care provider to issue a prescription for an epinephrine auto-injector to a person, as defined, upon presentation of current certification demonstrating that the person is trained and qualified to administer the auto-injector;
- Authorize specified (defined) persons to render emergency care to another person, so long as specified requirements are met; and
- Specify minimum training requirements for the use of epinephrine auto-injectors by the California Emergency Medical Services (EMS) Authority

STAFF COMMENTS

According to the author, SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals to administer the auto-injectors without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

Staff is continuing to discuss the board’s request for amendment with the author’s staff in advance of the August hearing in Assembly Judiciary.

FISCAL IMPACT ON THE BOARD:

Staff has not identified any specific fiscal impact on the board or its operations.

According to the 6/28/13 Analysis of the ASM Committee on Business, Professions and Consumer Protection, the following are in Support of the bill:

SUPPORT:

Conference of California Bar Associations (sponsor)
 California Association of Joint Powers Authorities
 California Hospital Association
 California Medical Association
 Civil Justice Association of California
 Food Allergy Research and Education

Hospital Corporation of America

Opposition
None on file.



California
LEGISLATIVE INFORMATION

SB-669 Emergency medical care: epinephrine auto-injectors. (2013-2014)

As Amended 7/3/13 - Today's Law As Amended

SECTION 1. *Section 4119.3 is added to the Business and Professions Code, to read:*

4119.3. *(a) Notwithstanding any other law, a pharmacy may dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay rescuer for the purpose of rendering emergency care in accordance with Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:*

(1) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed to a person described in subdivision (b) of Section 1797.197a of the Health and Safety Code. The physician and surgeon may issue the prescription only upon presentation of a current certificate demonstrating that the person is trained and qualified under Section 1797.197a of the Health and Safety Code to administer an epinephrine auto-injector to another person in an emergency situation. The prescription shall specify that the dispensed epinephrine auto-injector is for "EMS Purposes Only" and that the named recipient is a "Section 1797.197a Responder." A new prescription shall be written for any additional epinephrine auto-injectors required.

(2) (A) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:

(i) The name of the person to whom the prescription was issued.

(ii) The designations "Section 1797.197a Responder" and "EMS Purposes Only."

(iii) The dosage, use, and expiration date.

(B) Each dispensed prescription shall include the manufacturer's product information sheet for the epinephrine auto-injector.

(b) The person described in subdivision (b) of Section 1797.197a of the Health and Safety Code receiving epinephrine auto-injectors pursuant to this section shall make and maintain a record for five years reflecting dates of receipt, use, and destruction of each auto-injector dispensed, the name of any person to whom epinephrine was administered using an auto-injector, and the circumstances and manner of destruction of any auto-injectors.

(c) The epinephrine auto-injectors dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.

SEC. 2. *Section 1714.23 is added to the Civil Code, to read:*

1714.23. *(a) For purposes of this section, the following definitions shall apply:*

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(b) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code who

administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.

(c) The protection specified in subdivision (b) shall not apply in a case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care treatment by the use of an epinephrine auto-injector.

(d) (1) In order to encourage training of persons described in subdivision (b) of Section 1797.197a of the Health and Safety Code in the emergency administration of epinephrine auto-injectors, and to encourage that emergency care, a local agency, entity of state or local government, or other public or private organization that sponsors, authorizes, supports, finances, or supervises the training of those persons, or develops standards in accordance with Section 1797.197a of the Health and Safety Code, including, but not limited to, the California Emergency Medical Services (EMS) Authority, the local emergency medical system agency, the county department of health, the State Department of Public Health, the American Academy of Allergy, Asthma & Immunology, the American Academy of Pediatrics, the American Heart Association, the American Red Cross, and the California Medical Association, shall not be liable for civil damages alleged to result from those training programs or standards.

(2) The protection specified in paragraph (1) shall not apply when it is alleged that the personal injury or wrongful death was proximately caused by an authorized training provider's failure to meet the minimal statutory training requirements and standards established pursuant to subdivision (c) of Section 1797.197a of the Health and Safety Code, or it is alleged that the authorized training provider otherwise demonstrated gross negligence in the training or certification of an individual whose subsequent actions caused personal injury or wrongful death in the rendering of emergency care treatment by the use of an epinephrine auto-injector.

(e) Nothing in this section relieves a manufacturer, designer, developer, distributor, or supplier of an epinephrine auto-injector of liability under any other applicable law.

SEC. 3. *Section 1797.197a is added to the Health and Safety Code, to read:*

1797.197a. *(a) For purposes of this section, the following definitions shall apply:*

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.

(2) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.

(3) "First responder" means a police officer, firefighter, rescue worker, or any other person who provides emergency response, first aid care, or other medically related assistance either in the course of the person's occupational duties or as a volunteer.

(4) "Lay rescuer" means any person who has met the training standards and other requirements of this section but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.

(5) "Prehospital emergency medical care person" has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.

(b) A prehospital emergency medical care person, first responder, or a lay rescuer may use an epinephrine auto-injector to render emergency care to another person if all of the following requirements are met:

(1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care provider. An authorized health care provider may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person, upon

presentation of current certification demonstrating that person is trained and qualified pursuant to this section to administer an epinephrine auto-injector as a prehospital emergency medical care person, first responder, or lay rescuer.

(2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to address the conditions described in subparagraph (A) of paragraph (1) of subdivision (a).

(3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer's instructions for that product.

(4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as described in subdivision (c), and has current certification of training issued by the provider.

(c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the California Emergency Medical Services (EMS) Authority. The authority may designate existing training standards for the use and administration of epinephrine auto-injectors by first responders and prehospital emergency medical care personnel to satisfy the requirements of this section.

(2) The minimum training and requirements shall include all of the following components:

(A) Techniques for recognizing circumstances, signs, and symptoms of anaphylaxis.

(B) Standards and procedures for proper storage and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including activation of the Emergency Medical System, by calling the emergency 911 telephone number or otherwise alerting and summoning more advanced medical personnel and services.

(D) Compliance with all regulations governing the training, indications, use, and precautions concerning epinephrine auto-injectors.

(E) Written material covering the information required under this provision, including the manufacturer product information sheets on commonly available models of epinephrine auto-injectors.

(F) Completion of a training course in cardiopulmonary resuscitation and the use of an automatic external defibrillator (AED) for infants, children, and adults that complies with regulations adopted by the EMS Authority and the standards of the American Heart Association or the American Red Cross, and a current certification for that training.

(3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.

(d) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.

(e) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.

SEC. 4. *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.*



Bill Number:	SB 809
Introduced	2/22/13
Last Amend:	June 26, 2013
Author:	Senator Mark DeSaulnier
Topic:	CURES Funding (Sponsor: Attorney General)
Position:	Support

Current Bill Status: 8/13/13 – Set for Hearing in ASM Business, Professions and Consumer Protection

Affected Sections: Add Sections 805.8 and 2196.7 to the Business and Professions Code
Amend Sections 11164.1, 11165 and 11165.1 of the Health and Safety Code
Add Section 11165.4 to the Health and Safety Code

EXISTING LAW:

Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners.

THIS BILL WOULD:

- Establish the CURES Fund
- Modernize the existing CURES Program within the California Department of Justice, and specify dedicated funding mechanisms
- Require specified health care practitioner fees to be increased by up to 1.16 percent to provide dedicated funds to sustain CURES, and
- Require the Board of Pharmacy to increase fees charge to wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers by up to 1.16 percent to be deposited into the CURES Fund for sustaining the CURES Program

FISCAL IMPACT ON THE BOARD:

Currently, the board through an interagency agreement with the Department of Justice provides CURES with \$92,000 a year (FY 11/12 – FY 13/14), for a total deposit of \$276,000 for the three years. The board does not receive any itemization or other detailed accounting from the DOJ related to actual maintenance costs for the CURES system. The DOJ contracts with Atlantic Associates (believed to be approximately \$1,000,000 year) who collects and cleans the data in the system.

As proposed, SB 809 would increase application and renewal fees of specified by licensees by up to 1.16 percent. Preliminary estimates indicate this 1.16% increase may result in approximately \$60,000 per year deposited into the CURES Fund from the following licensing categories, based on a 3-year average of the following licensee populations at the current statutory maximum fee:

	Current Statutory Max (Fee)
Pharmacist Applicants/Exam (4400d)	260.00
Pharmacist License (4400e)	195.00
Pharmacist Renewals (4400e)	195.00
Wholesalers (4400f)	780.00
Nonresident Wholesalers (4400j)	780.00
Veterinary Food-Animal Drug Retailers (4400s)	425.00
Vet Food-Animal Drug Retailer Renewal (4400s)	325.00

HISTORY:

Date	Action
06/26/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/26/13	From committee: Do pass and re-refer to Com. on B.,P. & C.P. (Ayes 7. Noes 0.) (June 25). Re-referred to Com. on B.,P. & C.P.
06/17/13	Referred to Com. on PUB. S.
05/30/13	In Assembly. Read first time. Held at Desk.
05/30/13	Read third time. Urgency clause adopted. Passed. (Ayes 39. Noes 0. Page 1201.) Ordered to the Assembly.
05/29/13	Read second time. Ordered to third reading.
05/28/13	Ordered to second reading.
05/28/13	Read third time and amended.
05/28/13	Reconsideration granted. (Ayes 39. Noes 0. Page 1115.)
05/28/13	Motion to reconsider made by Senator DeSaulnier.
05/28/13	Read third time. Urgency clause refused adoption. (Ayes 23. Noes 14. Page 1115.)
05/24/13	Read second time and amended. Ordered to third reading.
05/23/13	From committee: Do pass as amended. (Ayes 5. Noes 1. Page 1020.) (May 23).
05/21/13	Set for hearing May 23.
05/20/13	Placed on APPR. suspense file.
05/16/13	Set for hearing May 20.
05/14/13	Read second time and amended. Re-referred to Com. on APPR.
05/13/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 882.) (May

Date	Action
8).	
05/01/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on GOV. & F.
04/24/13	Set for hearing May 8.
04/16/13	From committee: Do pass and re-refer to Com. on GOV. & F. (Ayes 7. Noes 2. Page 564.) (April 15). Re-referred to Com. on GOV. & F.
03/28/13	Set for hearing April 15.
03/11/13	Referred to Coms. on B., P. & E.D. and GOV. & F.
02/25/13	Read first time.
02/24/13	From printer. May be acted upon on or after March 26.
02/22/13	Introduced. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

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

As Amended 6/26/13 - Today's Law As Amended

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 boards, educational researchers, and law enforcement. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support the CURES Prescription Drug Monitoring Program (PDMP). The 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 better 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 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 all prescription drug monitoring programs in California so that they are 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 PDMP so that it is capable of accepting electronic prescriptions, thereby enabling more reliable, complete, and timely prescription monitoring.

SEC. 2. *Section 805.8 is added to the Business and Professions Code, to read:*

805.8. *(a) (1) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, 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 Naturopathic Medicine Committee of the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine shall charge each licensee 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 a fee of up to 1.16 percent of the renewal fee that the licensee was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the licensee renews his or her license and shall be submitted with the licensee's renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(2) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the wholesaler or nonresident wholesaler was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the wholesaler or nonresident wholesaler renews its license and shall be submitted with the wholesaler's or nonresident wholesaler's renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.

(3) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the drug retailer was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the drug retailer renews its license and shall be submitted with the drug retailers' renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating veterinary food-animal drug retailers licensed or certificated by that board.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for operating and maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. 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 Health Care Services and the Department of Justice in developing the materials to be distributed pursuant to this section.

SEC. 4. 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 and Schedule III 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 ~~(e)~~ (e) 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.

(c) This section shall become operative on January 1, 2005.

SEC. 5. 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 ~~from the~~ *in the CURES accounts within the* Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, ~~and the~~ *the Naturopathic Doctor's Fund, the* Osteopathic Medical Board of California Contingent Fund, *the Veterinary Medical Board Contingent Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and 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~~ *prescribe, order, administer, furnish*, or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds for the Department of Justice for the purpose of funding CURES.

~~(b) (c) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department~~ *Department of Justice* may seek and use grant funds to pay the costs incurred ~~from the reporting of controlled substance prescriptions to CURES. Funds~~ *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. Grant funds* shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, ~~or~~ *the* Osteopathic Medical Board of California Contingent ~~Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to~~ *Fund, the Veterinary Medical Board Contingent Fund, the Optometry Fund, or the Board of Podiatric Medicine Fund, for the purpose of funding* CURES.

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

~~(e) (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 ~~persons or~~ 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 may establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, and security of the information within CURES, consistent with this subdivision.*

~~(d) (e)~~ 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 or clinic shall provide~~ *pharmacy, clinic, or other dispenser shall report* the following information to the Department of Justice ~~on a weekly basis~~ *as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, unless monthly reporting is permitted pursuant to subdivision (f) of Section 11190*, and in a format specified by the Department of Justice:

(1) Full name, address, and ~~the~~ 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 and license ~~number;~~ *number, the* federal controlled substance registration ~~number;~~ *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, and federal controlled substance registration number.

- (4) ~~NDC (National Drug Code)~~ *National Drug Code (NDC)* number of the controlled substance dispensed.
- (5) Quantity of the controlled substance dispensed.
- (6) ~~ICD-9 (diagnosis code)~~, *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) (f) This section shall become operative on January 1, 2005. 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 invitees shall be licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, in active practice in California, and a regular user of CURES.~~

(g) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, one or more of the regulatory boards or committees identified in subdivision (a) of Section 805.8 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.

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

(i) The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purpose of funding CURES. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purpose of funding CURES.

SEC. 6. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist ~~may provide a notarized~~ *shall submit an* application developed by the Department of Justice to obtain approval to access information ~~stored on the Internet~~ *online* regarding the controlled substance history of a patient *that is stored on the Internet and* maintained within the Department of Justice, ~~and~~ *and, upon approval,* the department ~~may shall~~ release to that practitioner or ~~pharmacist,~~ *pharmacist* 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).

(A) 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 Drug Enforcement Administration (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.

(B) Any authorized subscriber shall notify the Department of Justice within ~~10~~ *30* days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data

contained in CURES.

(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) ~~It~~ *(1) Until the Department of Justice has issued the notification described in paragraph (3), 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.*

(2) Upon the Department of Justice issuing the notification described in paragraph (3), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall be strongly encouraged to access and consult the electronic history of controlled substances dispensed to an individual under his or her care prior to prescribing or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance.

(3) The Department of Justice shall notify licensed health care practitioners and pharmacists who have submitted the application required pursuant to subdivision (a) when the department determines that CURES is capable of accommodating all users, but not before June 1, 2015. The department shall provide a copy of the notification to the Secretary of State, the Secretary of the Senate, the Chief Clerk of the Assembly, and the Legislative Counsel, and shall post the notification on the department's Internet Web site.

(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. 7. *Section 11165.4 is added to the Health and Safety Code, to read:*

11165.4. *(a) The Department of Justice may seek private funds from insurers, health care service plans, and qualified manufacturers for the purpose of supporting CURES. Insurers, health care service plans, and qualified manufacturers may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (e) of Section 11165. 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.

SEC. 8. *This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts*

constituting the necessity are:

In order to protect the public from the continuing threat of prescription drug abuse at the earliest possible time, it is necessary that this act take effect immediately.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 10, 2013

The Honorable Mark DeSaulnier
Member, California State Senate
State Capitol, Room 5035
Sacramento, CA 95816

RE: SB 809 - Support

Dear Senator DeSaulnier:

The Board of Pharmacy supports SB 809 which would provide for dedicated funding for the Controlled Substances Utilization Review and Evaluation System (CURES) and to ensure point-of-care system access to the Prescription Drug Monitoring Program (PDMP) for pharmacists and prescribers. The Board of Pharmacy has long worked with the Department of Justice to support and ensure the operation of CURES. Moreover, as the regulator of the state's 6,900 pharmacies, we regularly utilize CURES data to identify potential drug diversion and violations of Pharmacy Law.

The board very much appreciates your long-term efforts to secure permanent funding for CURES and to establish a PDMP system that can be accessed by prescribers and pharmacists at the time they provide care to patients.

Please don't hesitate to contact me at (916) 574-7913 or the board's Executive Officer Virginia (Giny) Herold at (916) 574-7911 if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Carolyn Klein".

CAROLYN KLEIN, Manager
Legislation and Regulations



Bill Number:	SB 62
Introduced	1/8/13
Last Amend:	June 27, 2013
Author:	Senator Curren Price, Jr.
Topic:	Coroners: reporting requirements: prescription drug use
Position:	Support (2/13/13)

Current Bill Status: In Assembly Appropriations (As of 7/15/13 no hearing date set)

Affected Sections: Amend Section 802.5 Business and Professions Code (BPC)

SUMMARY

Under existing law, Section 802.5 of the Business and Professions Code, when a coroner receives information that a death may be the result of gross negligence or incompetence, as specified, the coroner shall file a report with the Medical Board of California and other entities. The introduced version of the bill would have added the California State Board of Pharmacy to those entities to which these reports shall be transmitted, and the Board established a position of Support at the February 2013 Board Meeting.

The April 9, 2013, amendment struck from the list of entities that would receive the reports from the coroner's offices. Since that time, staff has requested amendments to authorize the board's specified in subdivision (a) of the bill to share those coroners reports and other information received with the Board of Pharmacy.

EXISTING LAW

Section 802.5 BPC requires that when a coroner receives information that is based on findings where a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence, a report containing specified information shall be filed with specified healing arts boards. The section requires that the initial report be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information. The information reported pursuant to this section is deemed confidential, and provides civil immunity from those required to file such a report.

THIS BILL WOULD:

As amended, where a coroner receives information based on findings that a death may be the result of prescription drug use, a report containing specified information shall be filed with specified entities. The section specifies information that is to be contained in the report, and

requires that within 90 days of the initial report, copies of the coroner's report, autopsy protocol, and all other relevant information be provided.

FISCAL IMPACT ON THE BOARD:

Depending on the number of reports the board receives, the board may require additional staff resources (four inspectors) to conduct inspections and compliance investigations associated with these reports.

HISTORY

Date	Action
06/27/13	Read second time and amended. Re-referred to Com. on APPR.
06/26/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (June 25).
06/14/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B.,P. & C.P.
06/10/13	Referred to Com. on B.,P. & C.P.
05/29/13	In Assembly. Read first time. Held at Desk.
05/28/13	Read third time. Passed. (Ayes 39. Noes 0. Page 1096.) Ordered to the Assembly.
05/24/13	Read second time. Ordered to third reading.
05/23/13	From committee: Do pass. (Ayes 7. Noes 0. Page 1006.) (May 23).
05/17/13	Set for hearing May 23.
04/29/13	Placed on APPR. suspense file.
04/23/13	Set for hearing April 29.
04/22/13	Read second time and amended. Re-referred to Com. on APPR.
04/18/13	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 10. Noes 0. Page 563.) (April 15).
04/09/13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
03/28/13	Set for hearing April 15.
01/17/13	Referred to Com. on B., P. & E.D.
01/09/13	From printer. May be acted upon on or after February 8.
01/08/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California

LEGISLATIVE INFORMATION

SB-62 Coroners: reporting requirements: prescription drug use. (2013-2014)

As Amended 6/27/13 - Today's Law As Amended

SECTION 1. Section 802.5 of the Business and Professions Code is amended to read:

802.5. (a) When a coroner receives information that is based on findings that were reached by, or documented and approved ~~by a board-certified or board-eligible~~ by, a pathologist indicating that a death may be the result of a physician and surgeon's, podiatrist's, or physician assistant's gross negligence or incompetence, a report shall be filed with the Medical Board of California, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, or the Physician Assistant Board. The initial report shall include the name of the decedent, date and place of death, attending ~~physicians or podiatrists,~~ *physicians, podiatrists, or physician assistants,* and all other relevant information available. The initial report shall be followed, within 90 ~~days,~~ *days or as soon as possible once the coroner's final report of investigation is complete,* by copies of the coroner's report, autopsy protocol, and all other relevant information.

(b) ~~The A~~ report required by ~~this section subdivision (a)~~ shall be confidential. No coroner, physician and surgeon, or medical examiner, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her acting in compliance with this section. No ~~board-certified or board-eligible~~ pathologist, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her providing information under subdivision (a).

(c) When a coroner receives information that is based on findings that were reached by, or documented and approved by, a pathologist indicating that the cause of death is due to a Schedule II, III, or IV drug, a report shall be filed with the Medical Board of California. The initial report shall include, when known, the name of the decedent, date and place of death, attending physicians, podiatrists, or physician assistants, and all other relevant information, including, but not limited to, any information available to identify the prescription drugs, prescribing physicians, and dispensing pharmacy. The initial report shall be followed, within 90 days or as soon as possible once the coroner's final report of investigation is complete, by copies of the coroner's report, autopsy protocol, and all other relevant information.

SEC. 2. *If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.*



Bill Number:	AB 258
Introduced	2/7/13
Amendment Date:	April 23, 2013
Author:	Assembly Member Colonel Rocky J. Chavez
Topic:	State Agencies: Veterans
Position:	(none)

Affected Sections: Add Section 11019.11 to the Government Code (GC)

Status: As of 7/2/13, on the Senate Third Reading File

EXISTING LAW:

Article 1 [of Chapter 1 of Part 1 of Division 3 of Title 2] of the Government Code (Sections 11000.-11019.10) specifies general requirements for state departments and agencies.

THIS BILL WOULD:

Add Section 11019.11 to the Government Code to specify that on or after July 1, 2014, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format:

“Have you ever served in the United States military?”

ACCORDING TO THE AUTHOR:

SB 258 would standardize the way any state government organization would ask an individual as to their veteran status. The author states that individuals who may not identify themselves as a veteran because the way a question is asked may lose out on many Federal benefits to which they are entitled.

STAFF COMMENTS:

The board does not currently query as to a person’s veteran status on individual applications for Pharmacist, Pharmacist Intern, or Pharmacy Technician. This is one of many bills the Department of Consumer Affairs is tracking, and staff continue to monitor this measure.

RELATED LEGISLATION:

AB 1057 would add Section 114.5 to the Business and Professions Code to require every board to inquire on every application for licensure, if the individual applying is serving in, or has previously served in, the military.

FISCAL IMPACT ON THE BOARD:

If enacted, and if AB 1057 is also enacted, the board would need to update its application forms, which would be absorbed with existing staff resources.

HISTORY

7/2/13 – Read second time. Ordered to third reading.

7/1/13 – Passed Senate Appropriations

6/11/13 – Passed out of Senate Com. on Veterans Affairs

4/25/13 – Approved by the Assembly

4/11/13 – Passed from ASM Appropriations

4/4/13 – Passed out of Assembly Comm. on Veterans Affairs



California
LEGISLATIVE INFORMATION

AB-258 State agencies: veterans. (2013-2014)

As Amended 4/23/13 - Today's Law As Amended

SECTION 1. *Section 11019.11 is added to the Government Code, to read:*

11019.11. *(a) Every state agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, shall request that information only in the following format: "Have you ever served in the United States military?"*

(b) This section shall apply only to a written form or written publication that is newly printed on or after July 1, 2014.



Bill Number:	AB 512
Introduced	2/20/13
Amendment Date:	
Author:	Assembly Member Rendon
Topic:	Healing Arts: Licensure Exemption
Position:	Support (4/24/13)

Affected Sections: Amend Section 901 of the Business and Professions Code (BPC)

Status: As of 7/8/13, Passed to the Senate

EXISTING LAW:

Section 901 BPC provides that until 1/1/14, an individual may be exempt from the licensure and regulation requirements for defined health care practitioners, to offer or provide health care services for which he or she is licensed or certified, through a sponsored event, as defined. This section also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other requirements, including the payment of a fee as determined by a board.

THIS BILL:

Currently, until January 1, 2014, an individual can be exempt from licensure and regulation requirements to provide health care services through sponsored events. AB 512 extends these provisions to 2018.

The board established a Support position for AB 512 and stated its support of free and sponsored health care events. The board noted it is in the board's best interest to ensure that matters related to the practice of pharmacy at these events were adequately enforced and monitored.

ACCORDING TO THE AUTHOR:

The author states that the Medical Board of California promulgated regulations in August 2012, but they were not done in time to allow out-of-state practitioners to volunteer at an LA event; The author states that the program needs additional time to demonstrate its success.

STAFF COMMENTS:

The board does not have regulations to specify requirements for pharmacists from other states to serve at sponsored healthcare events, as allowed by Section 901 BPC.

FISCAL IMPACT ON THE BOARD:

None identified

HISTORY

Date	Action
07/08/13	Read third time. Passed. Ordered to the Assembly.
06/25/13	Read second time. Ordered to third reading.
06/24/13	From committee: Do pass. (Ayes 7. Noes 0.) (June 24).
06/10/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (June 10). Re-referred to Com. on APPR.
05/09/13	Referred to Com. on B., P. & E.D.
04/25/13	In Senate. Read first time. To Com. on RLS. for assignment.
04/25/13	Read third time. Passed. Ordered to the Senate. (Ayes 74. Noes 0. Page 1111.)
04/18/13	Read second time. Ordered to third reading.
04/17/13	From committee: Do pass. (Ayes 16. Noes 0.) (April 17).
04/09/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 13. Noes 0.) (April 9). Re-referred to Com. on APPR.
03/04/13	Referred to Com. on B.,P. & C.P.
02/21/13	From printer. May be heard in committee March 23.
02/20/13	Read first time. To print.



California
LEGISLATIVE INFORMATION

AB-512 Healing arts: licensure exemption. (2013-2014)

As Introduced 2/20/13

SECTION 1. Section 901 of the Business and Professions Code is amended to read:

901. (a) For purposes of this section, the following provisions apply:

(1) "Board" means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) "Health care practitioner" means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) "Sponsored event" means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) "Sponsoring entity" means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) "Uninsured or underinsured person" means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she does all of the following:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

- (A) To uninsured or underinsured persons.
 - (B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.
 - (C) In association with a sponsoring entity that complies with subdivision (d).
 - (D) Without charge to the recipient or to a third party on behalf of the recipient.
- (c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with this section or for any act that would be grounds for denial of an application for licensure.
- (d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:
- (1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:
 - (A) The name of the sponsoring entity.
 - (B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.
 - (C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).
 - (D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).
 - (E) Any additional information required by the board.
 - (2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.
- (e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.
- (f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.
- (g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.
- (h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.
- (i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.
- (j) ~~(1) The~~ (1) *The* board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.
- (2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of

termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(l) This section shall remain in effect only until January 1, ~~2014~~, ~~2018~~, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2014~~, ~~2018~~, deletes or extends that date.



Bill Number:	AB 1057
Introduced	2/22/13
Amendment Date:	June 3, 2013
Author:	Assembly Member Medina
Topic:	Professions and Vocation: Licenses: Military Service
Position:	None

Affected Sections: Add Section 114.5 to the Business and Professions Code (BPC)

Status: As of 6/25/13 – on the Senate Third Reading File

Position: The board does not have a position on this bill.

EXISTING LAW:

The Business and Professions Code provides for the licensure and regulation of various professions and vocations by DCA board, and provides that a licensee or registrant whose license expired while the licensee or registrant was on military active duty, upon application, may reinstate his or her license without penalty and without examination, if certain requirements are met.

THIS BILL WOULD:

Add Section 114.5 to the Business and Professions Code to require every board on or after January 1, 2015, to inquire on every application for licensure if the applicant is serving in, or has previously served in, the military.

RELATED LEGISLATION:

AB 258 would add Section 11019.11 to the Government Code to specify that on or after July 1, 2014, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format: *“Have you ever served in the United States military?”*

FISCAL IMPACT ON THE BOARD:

This bill may have a fiscal impact on the DCA/board, in that the existing applicant tracking system does not track accommodate the tracking of the information required by this section. Further, and with the department’s migration to a new licensing system (BreZE), the board is unable to modify its existing licensing requirements. Staff will continue to work with DCA on how the department may plan to implement the provisions of the bill for all boards.

To comply with the requirement to inquire as to a person’s military service, the board would be required to update its applications, which would be absorbed with existing staff resources.



California
LEGISLATIVE INFORMATION

AB-1057 Professions and vocations: licenses: military service. (2013-2014)

As Amended 6/3/13 - Today's Law As Amended

SECTION 1. *Section 114.5 is added to the Business and Professions Code, to read:*

114.5. *Commencing January 1, 2015, each board shall inquire in every application for licensure if the individual applying for licensure is serving in, or has previously served in, the military.*



Bill Number:	SB 146
Introduced	1/31/13
Amended:	6/13/13
Author:	Senator Lara
Topic:	Workers' Compensation: medical treatment: billing
Position:	(None)

Current Bill Status: **Urgency Clause Adopted
Ordered to Engrossing and Enrolling (7/3/13)**

Affected Sections: Amend Section 4603.2 of the Labor Code related to Workers' Compensation

EXISTING LAW:

Section 4603.2 of the Labor code provides that any provider of services, as defined, shall submit with a request for payment an itemization of services to include a copy of the prescription.

AS AMENDED, THIS BILL WOULD:

Specify that a copy of a prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement that requires a copy of a prescription for a pharmacy service.

The bill specifies that any request for payment as established by the Division of Workers' Compensation that was denied for not providing a copy of the prescription, may resubmit the bill for payment, until March 31, 2014.

SB 146 also provides that nothing shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

STAFF COMMENTS:

This measure was of interest because, as introduced, SB 146 would have allowed for the billing and payment of pharmacy services without having to provide a copy of the (currently required) prescription; thus, only the electronic record would indicate that such a prescription was filled.

The author states this measure was a result of changes made in the prior session (SB 863) related to the workers' compensation system and that, as enacted, pharmacies and pharmacy billers were not able to comply with requirements of the electronic billing standard – because the system did not allow a copy of a prescription to be attached to an electronic claim.

The amended version does allow specified entities to request a copy of the prescription during a review of records of prescription drugs dispensed by a pharmacy.

FISCAL IMPACT ON THE BOARD:

None identified.

SUPPORT:

CompPharma (sponsor)

OPPOSITION: None known



California
LEGISLATIVE INFORMATION

SB-146 Workers' compensation: medical treatment: billing. (2013-2014)

As Amended 6/13/13 - Today's Law As Amended

SECTION 1. Section 4603.2 of the Labor Code is amended to read:

4603.2. (a) (1) Upon selecting a physician pursuant to Section 4600, the employee or physician shall notify the employer of the name and address, including the name of the medical group, if applicable, of the physician. The physician shall submit a report to the employer within five working days from the date of the initial examination, as required by Section 6409, and shall submit periodic reports at intervals that may be prescribed by rules and regulations adopted by the administrative director.

(2) If the employer objects to the employee's selection of the physician on the grounds that the physician is not within the medical provider network used by the employer, and there is a final determination that the employee was entitled to select the physician pursuant to Section 4600, the employee shall be entitled to continue treatment with that physician at the employer's expense in accordance with this division, notwithstanding Section 4616.2. The employer shall be required to pay from the date of the initial examination if the physician's report was submitted within five working days of the initial examination. If the physician's report was submitted more than five working days after the initial examination, the employer and the employee shall not be required to pay for any services prior to the date the physician's report was submitted.

(3) If the employer objects to the employee's selection of the physician on the grounds that the physician is not within the medical provider network used by the employer, and there is a final determination that the employee was not entitled to select a physician outside of the medical provider network, the employer shall have no liability for treatment provided by or at the direction of that physician or for any consequences of the treatment obtained outside the network.

(b) (1) Any provider of services provided pursuant to Section 4600, including, but not limited to, physicians, hospitals, pharmacies, interpreters, copy services, transportation services, and home health care services, shall submit its request for payment with an itemization of services provided and the charge for each service, a copy of all reports showing the services performed, the prescription or referral from the primary treating physician if the services were performed by a person other than the primary treating physician, and any evidence of authorization for the services that may have been received. Nothing in this section shall prohibit an employer, insurer, or third-party claims administrator from establishing, through written agreement, an alternative manual or electronic request for payment with providers for services provided pursuant to Section 4600.

(A) Notwithstanding the requirements of this paragraph, a copy of the prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement, as provided in this paragraph, that requires a copy of a prescription for a pharmacy service.

(B) Notwithstanding timely billing and payment rules established by the Division of Workers' Compensation, any entity submitting a pharmacy bill for payment, on or after January 1, 2013, and denied payment for not including a copy of the prescription from the treating physician, may resubmit those bills for payment until March 31, 2014.

(C) Nothing in this section shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

(2) Except as provided in subdivision (d) of Section 4603.4, or under contracts authorized under Section 5307.11, payment for medical treatment provided or prescribed by the treating physician selected by the employee or designated by the employer shall be made at reasonable maximum amounts in the official medical fee schedule, pursuant to Section 5307.1, in effect on the date of service. Payments shall be made by

the employer with an explanation of review pursuant to Section 4603.3 within 45 days after receipt of each separate, itemization of medical services provided, together with any required reports and any written authorization for services that may have been received by the physician. If the itemization or a portion thereof is contested, denied, or considered incomplete, the physician shall be notified, in the explanation of review, that the itemization is contested, denied, or considered incomplete, within 30 days after receipt of the itemization by the employer. An explanation of review that states an itemization is incomplete shall also state all additional information required to make a decision. Any properly documented list of services provided and not paid at the rates then in effect under Section 5307.1 within the 45-day period shall be paid at the rates then in effect and increased by 15 percent, together with interest at the same rate as judgments in civil actions retroactive to the date of receipt of the itemization, unless the employer does both of the following:

(A) Pays the provider at the rates in effect within the 45-day period.

(B) Advises, in an explanation of review pursuant to Section 4603.3, the physician, or another provider of the items being contested, the reasons for contesting these items, and the remedies available to the physician or the other provider if he or she disagrees. In the case of an itemization that includes services provided by a hospital, outpatient surgery center, or independent diagnostic facility, advice that a request has been made for an audit of the itemization shall satisfy the requirements of this paragraph.

An employer's liability to a physician or another provider under this section for delayed payments shall not affect its liability to an employee under Section 5814 or any other provision of this division.

(3) Notwithstanding paragraph (1), if the employer is a governmental entity, payment for medical treatment provided or prescribed by the treating physician selected by the employee or designated by the employer shall be made within 60 days after receipt of each separate itemization, together with any required reports and any written authorization for services that may have been received by the physician.

(4) Duplicate submissions of medical services itemizations, for which an explanation of review was previously provided, shall require no further or additional notification or objection by the employer to the medical provider and shall not subject the employer to any additional penalties or interest pursuant to this section for failing to respond to the duplicate submission. This paragraph shall apply only to duplicate submissions and does not apply to any other penalties or interest that may be applicable to the original submission.

(c) Any interest or increase in compensation paid by an insurer pursuant to this section shall be treated in the same manner as an increase in compensation under subdivision (d) of Section 4650 for the purposes of any classification of risks and premium rates, and any system of merit rating approved or issued pursuant to Article 2 (commencing with Section 11730) of Chapter 3 of Part 3 of Division 2 of the Insurance Code.

(d) (1) Whenever an employer or insurer employs an individual or contracts with an entity to conduct a review of an itemization submitted by a physician or medical provider, the employer or insurer shall make available to that individual or entity all documentation submitted together with that itemization by the physician or medical provider. When an individual or entity conducting a *an* itemization review determines that additional information or documentation is necessary to review the itemization, the individual or entity shall contact the claims administrator or insurer to obtain the necessary information or documentation that was submitted by the physician or medical provider pursuant to subdivision (b).

(2) An individual or entity reviewing an itemization of service submitted by a physician or medical provider shall not alter the procedure codes listed or recommend reduction of the amount of the payment unless the documentation submitted by the physician or medical provider with the itemization of service has been reviewed by that individual or entity. If the reviewer does not recommend payment for services as itemized by the physician or medical provider, the explanation of review shall provide the physician or medical provider with a specific explanation as to why the reviewer altered the procedure code or changed other parts of the itemization and the specific deficiency in the itemization or documentation that caused the reviewer to conclude that the altered procedure code or amount recommended for payment more accurately represents the service performed.

(e) (1) If the provider disputes the amount paid, the provider may request a second review within 90 days of service of the explanation of review or an order of the appeals board resolving the threshold issue as stated in the explanation of review pursuant to paragraph (5) of subdivision (a) of Section 4603.3. The request for a second review shall be submitted to the employer on a form prescribed by the administrative director and shall include all of the following:

(A) The date of the explanation of review and the claim number or other unique identifying number provided

on the explanation of review.

(B) The item and amount in dispute.

(C) The additional payment requested and the reason therefor.

(D) The additional information provided in response to a request in the first explanation of review or any other additional information provided in support of the additional payment requested.

(2) If the only dispute is the amount of payment and the provider does not request a second review within 90 days, the bill shall be deemed satisfied and neither the employer nor the employee shall be liable for any further payment.

(3) Within 14 days of a request for second review, the employer shall respond with a final written determination on each of the items or amounts in dispute. Payment of any balance not in dispute shall be made within 21 days of receipt of the request for second review. This time limit may be extended by mutual written agreement.

(4) If the provider contests the amount paid, after receipt of the second review, the provider shall request an independent bill review as provided for in Section 4603.6.

(f) Except as provided in paragraph (4) of subdivision (e), the appeals board shall have jurisdiction over disputes arising out of this subdivision pursuant to Section 5304.

SEC. 2. *This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:*

In order to avoid jeopardizing injured workers' access to medically necessary medications, it is necessary that this bill take effect immediately.



Bill Number:	SB 445
Introduced	2/21/13
Amendment Date:	
Author:	Senator Current Price, Jr.
Topic:	Controlled Substances Advertising
Position:	(None)

Affected Sections: Amend Section 4121 of the Business and Professions Code (BPC)

Status: In the Assembly. Referred to Assembly Committee on Business, Professions and Consumer Protection

EXISTING LAW:

Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacies.

Notwithstanding Section 651, **Section 4121 BPC** requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances.

Section 4122 BPC requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified.

THIS BILL WOULD:

Amend Section 4121 to specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

ACCORDING TO THE AUTHOR:

In an effort to combat the rising tide of prescription drug abuse and seeking behavior by organized crime and attics, SB 445 seeks to limit drug seeking behavior at pharmacies by prohibiting pharmacies from advertising the sale of controlled substances.

FISCAL IMPACT ON THE BOARD:

None identified.

HISTORY:

Date	Action
05/20/13	Referred to Com. on B.,P. & C.P.
05/06/13	In Assembly. Read first time. Held at Desk.
05/06/13	Read third time. Passed. (Ayes 25. Noes 9. Page 805.) Ordered to the Assembly.
04/30/13	Read second time. Ordered to third reading.
04/29/13	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
04/19/13	Set for hearing April 29.
04/16/13	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 1. Page 564.) (April 15). Re-referred to Com. on APPR.
03/28/13	Set for hearing April 15.
03/11/13	Referred to Com. on B., P. & E.D.
02/22/13	From printer. May be acted upon on or after March 24.
02/21/13	Introduced. Read first time. To Com. on RLS. for assignment. To print.



California
LEGISLATIVE INFORMATION

SB-445 Pharmacies: advertising: controlled substances. (2013-2014)

As Introduced 2/21/13 - Today's Law As Amended

SECTION 1. Section 4121 of the Business and Professions Code is amended to read:

4121. (a) (1) Notwithstanding Section 651, an advertisement of the retail price for a drug that requires a prescription shall be limited to quantities of the drug that are consistent with good medical practice and shall include the strength, dosage form, and the exact dates during which the advertised price will be in effect.

~~(b)~~ (2) This ~~section~~ *subdivision* shall not apply to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(b) Under no circumstances may an advertisement specifically promote the sale or dispensing of any controlled substances.

SEC. 2. *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 2

Title 16. Board of Pharmacy Proposed Language

Proposal To Amend Section 1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1749. Fee Schedule.

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

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520) ~~four hundred dollars (\$400)~~. The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~. The penalty for failure to renew is one hundred fifty dollars (\$150) ~~one hundred and twenty five dollars (\$125)~~.

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~.

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105) ~~fifty dollars (\$50)~~. The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130) ~~fifty dollars (\$50)~~. The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65) ~~twenty-five dollars (\$25)~~.

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260) ~~one hundred eighty-five dollars (\$185)~~.

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115) ~~eighty-five dollars (\$85)~~.

(f) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars (\$150)~~.

(g) The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars (\$150)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50) ~~seventy-five dollars (\$75)~~.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780) ~~six hundred dollars (\$600)~~. The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165) ~~one hundred twenty five dollars (\$125)~~. The penalty for failure to renew is eighty two dollars fifty cents (\$82.50) ~~sixty-two dollars and fifty cents (\$62.50)~~.

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330) ~~two hundred fifty dollars (\$250)~~. If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars (\$110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195) ~~one hundred fifty dollars~~

~~(\$150)~~. The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50) ~~seventy five dollars (\$75)~~.

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780) ~~six hundred dollars (\$600)~~. The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115) ~~seventy five dollars (\$75)~~. The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30) ~~twenty dollars (\$20)~~.

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520) ~~four hundred dollars (\$400)~~. The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) ~~two hundred fifty dollars (\$250)~~. The penalty for failure to renew is one hundred fifty dollars (\$150) ~~one hundred and twenty five dollars (\$125)~~.

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780) ~~six hundred dollars (\$600)~~. The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330) ~~two hundred fifty dollars (\$250)~~. If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars (\$150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195) ~~one hundred ten dollars (\$110)~~. The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50) ~~fifty five dollars (\$55)~~.

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425) ~~four hundred dollars (\$400)~~. The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325) ~~two hundred and fifty dollars (\$250)~~. The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45) ~~thirty dollars (\$30)~~.

(t) The fee for the issuance of a centralized hospital packaging pharmacy shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4128.2, 4196, 4200, 4400, 4401 and 4403, Business and Professions Code.

**Order of Adoption
Board of Pharmacy
California Code of Regulations**

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

~~(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.~~

(b) ~~(e)~~ Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(c) ~~(d)~~ Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

For the 15-Day Modified Text, Section 1762 (b) was stricken.

Added text is noted with double underline: thus, added text

Deleted text is noted with double strike-thru: thus, ~~deleted text~~

Order of Adoption
Board of Pharmacy
California Code of Regulations

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

1 **Title 16. Board of Pharmacy**
2 **Proposed Language**
3

4 **To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to**
5 **read as follows:**

6 **§ 1732.05. Accreditation Agencies for Continuing Education.**

7 (a) The following organizations are approved accreditation agencies:

8 (1) The Accreditation Council for Pharmacy Education.

9 (2) The ~~Pharmacy Foundation of California~~ [California Pharmacists Association](#).

10 (b) Accreditation agencies shall:

11 (1) Evaluate each continuing education provider seeking accreditation in accordance with the
12 provider's ability to comply with the requirements of section 1732.1 of this Division.

13 (2) Maintain a list of the name and address of the person responsible for the provider's continuing
14 education program. The accreditation agency shall require that any change in the responsible person's
15 identity shall be reported to the accreditation agency within 15 days of the effective date of the
16 change.

17 (3) Provide the board with the names, addresses and responsible party of each provider, upon request.

18 (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any
19 of its accredited providers or their coursework.

20 (5) Review at least one course per year offered by each provider accredited by the agency for
21 compliance with the agency's requirements and requirements of the board and, on request, report the
22 findings of such reviews to the board.

23 (6) Take such action as is necessary to assure that the continuing education coursework offered by its
24 providers meets the continuing education requirements of the board.

25 (7) Verify the completion of a specific continuing education course by an individual pharmacist upon
26 request of the board.

27 (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers
28 as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation
29 agency by the board.
30

31 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
32 Business and Professions Code.
33

34 **To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
35 **as follows:**

36 **§ 1732.2. Board Accredited Continuing Education**
37

38 (a) Individuals may petition the board to allow continuing education credit for specific coursework
39 which is not offered by a provider but meets the standards of Section 1732.3.

40 (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance
41 to pharmacy practice and has been approved for continuing education by the Medical Board of
42 California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the
43 Dental Board of California shall, upon satisfactory completion, be considered approved continuing
44 education for pharmacists.

45 (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing
46 the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to
47 section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of
48 continuing education for conducting a review of exam test questions. A subcommittee member shall
49 not receive continuing education hours pursuant to this subdivision if that subcommittee member
50 requests reimbursement from the board for time spent conducting a review of exam test questions.

51 (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six
52 hours of continuing education per renewal period. The board shall designate on its public agenda
53 which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician
54 requesting continuing education pursuant to this subdivision must sign in and out on an attendance
55 sheet at the board meeting that requires the individual to provide his or her first and last name, license
56 number, time of arrival and time of departure from the meeting.

57 (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be
58 awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician
59 requesting continuing education hours pursuant to this subdivision must sign in and out on an
60 attendance sheet at the committee meeting that requires the individual to provide his or her first and
61 last name, license number, time of arrival and time of departure from the meeting.

62 (f) An individual may be awarded three hours of continuing education for successfully passing the
63 examination administered by the Commission for Certification in Geriatric Pharmacy.
64

65 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232,
66 Business and Professions Code.

67 **To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read**
68 **as follows:**

69 **§ 1732.5. Renewal Requirements for Pharmacist.**

70

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

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

76 1. Emergency/Disaster Response

77 2. Patient Consultation

78 3. Maintaining Control of a Pharmacy's Drug Inventory

79 4. Ethics

80 5. Substance Abuse

81 Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the
82 requirements of this subdivision.

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

85

86 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and
87 4232, Business and Professions Code.



COMMUNITY PHARMACY SELF-ASSESSMENT HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year.** The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, a Hospital Outpatient Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment. Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 07/13).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner Partnership Corporation LLC
 Non-Licensed Owner Other (please specify) _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Daily _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
6. _____ INT # _____ Exp. Date: _____
7. _____ INT # _____ Exp. Date: _____
8. _____ INT # _____ Exp. Date: _____
9. _____ TCH # _____ Exp. Date: _____
10. _____ TCH # _____ Exp. Date: _____
11. _____ TCH # _____ Exp. Date: _____
12. _____ TCH # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY SELF-ASSESSMENT
HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

- | | |
|--|---|
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.5. The pharmacy sink has hot and cold running water. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.6. The pharmacy has a readily accessible restroom. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.8. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d]) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.9. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.10. Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 26 – "Compounding.") |

Yes No N/A

1.11. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

1.12. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

1.13. The pharmacy reports to the board within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

1.14. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

1.15. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Delivery of Drugs

Yes No N/A

2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

Yes No N/A

2.2. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 2.2.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Drug Stock

Yes No N/A

3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred: (B&PC 4169)

- 3.2.1. At wholesale with an entity licensed with the board as a wholesaler, pharmacy, or manufacturer.
- 3.2.2. That the pharmacy knew or reasonable knew was not adulterated.
- 3.2.3. That the pharmacy knew or reasonable knew was not misbranded.
- 3.2.4. That were not expired or were within the beyond use date.

CORRECTIVE ACTION OR ACTION PLAN: _____

4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 28 and/or Section 29 of this Self-Assessment.)

5. Pharmacist-in-Charge (PIC)

Yes No N/A

5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

5.4. Is the PIC in charge of another pharmacy?

5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

5.8. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests? (H&SC 1206.6, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Duties of a Pharmacist

Yes No N/A

6.1. The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

6.2. The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or 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, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

6.3. Pharmacists are able to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

6.4. The pharmacist dispenses emergency contraceptive pursuant to statewide protocol found in 16 CCR 1746.

6.5. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (H&SC 1206.6[a])

6.6. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (H&SC 1206.6)

CDPH (CLIA) Registration #: _____ Expiration: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Duties of an Intern Pharmacist

Yes No N/A

7.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

7.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

7.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

7.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Duties of a Pharmacy Technician

Yes No N/A

8.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

8.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

8.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

8.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

8.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

9. Duties of Non-Licensed Personnel

Yes No N/A

9.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

9.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist’s responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACY PRACTICE

10. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

10.1. Pharmacists provide oral consultation: (B&PC 4052[a][7], CCR 1707.2)

- 10.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- 10.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- 10.1.3. upon request; and
- 10.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.

10.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

10.3. The pharmacist reviews a patient’s drug therapy and medication record prior to consultation. (CCR 1707.3)

10.4. Consultation is performed in a manner that protects the patient’s protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

10.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

10.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Prescription Requirements

Yes No N/A

- 11.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)
- 11.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)
- 11.3. If a prescription is orally or electronically transmitted by the prescriber’s agent, the pharmacist makes a reasonable attempt to verify that the prescriber’s agent is authorized to do so, and the agent’s name is recorded. (B&PC 4071)
- 11.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)
- 11.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])
- 11.6. Facsimile prescriptions are received only from a prescriber’s office. (B&PC 4040[c])
- 11.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])
- 11.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)
- 11.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

- 12.1. The prescription label contains all the required information. (B&PC 4076)
- 12.2. The prescription label is formatted in accordance with CCR_1707.5.
- 12.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR_1707.5[a])

- 12.4. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.
Exemption approved by board from: _____ to _____
- 12.5. Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)
- 12.6. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])
- 12.7. Generic substitution is communicated to the patient. (B&PC 4073)
- 12.8. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)
- 12.9. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)
- 12.10. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)
- 12.11. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)
- 12.12. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- 12.13. The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, or to another pharmacy of common ownership .
- 12.14. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)
- 12.15. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)
- 12.16. The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

- 12.16.1. Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where** (B&PC 4064.5[a])
 - 12.16.1.1. The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])
 - 12.16.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])
 - 12.16.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])
 - 12.16.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; (B&PC 4064.5[a][3])
 - 12.16.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])
- 12.16.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Refill Authorization

Yes No N/A

- 13.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)
- 13.2. Refills are documented. (CCR 1717)
- 13.3. Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)
- 13.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)
- 13.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Quality Assurance and Medication Errors

Yes No N/A

14.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

14.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

14.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

14.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

14.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

14.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- 14.6.1. Date, location, and participants in the quality assurance review;
- 14.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- 14.6.3. Findings and determinations; and
- 14.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

14.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

14.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

15.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

15.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

Yes No N/A

15.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

15.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

15.5. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Prescription Transfer

Yes No N/A

16.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

16.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

16.3. For the **transferring pharmacy**: the prescription hard copy is pulled and “void” is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber’s authorization. (CFR 1306.25, CCR 1717[f])

16.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and “transfer” is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Confidentiality of Prescriptions

Yes No N/A

17.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

17.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

Yes No N/A

17.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

17.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

17.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

17.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

18.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

- 18.2.1. Prescription records (B&PC 4081[a])
- 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- 18.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- 18.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

18.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140, 4149)

- 18.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- 18.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

- 18.3.3. The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145)
- 18.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- 18.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

Yes No N/A

18.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

- 18.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 18.4.2. Furnish or make available mail-back sharps containers.
- 18.4.3. Furnish or make available sharps containers.

18.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

CORRECTIVE ACTION OR ACTION PLAN: _____

19. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

19.1. Is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11[b])

19.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

19.3. Is available for inspection for three years. (CCR 1718)

19.4. Indicates on the inventory record whether the inventory was taken at the “open of business” or at the “close of business.” (CFR 1304.11[a])

19.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

Yes No N/A

19.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

19.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

19.8. U.S. Official Order Form (DEA Form222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)

19.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

19.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

19.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)

19.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

19.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

19.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

19.15. Do pharmacy staff hand initial prescription records or prescription labels, or

19.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

Yes No N/A

19.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

19.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner’s general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

20.1. A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

20.2. An oral prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

- 20.2.1. The licensed facility provides the pharmacy with a copy of the prescriber’s signed order, when available.
- 20.2.2. The prescription is endorsed by the pharmacist with the pharmacy’s name, license, and address.
- 20.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

20.3. An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy’s design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5)

20.4. 19.4. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

20.5. The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as “terminally ill.” (21 CFR 1306.13[b], CCR 1745)

Yes No N/A

20.6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

20.7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

20.8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy’s computer memory. (CCR 1717.4[e])

20.9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

20.10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

20.11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

20.12. Controlled substances written with the “11159.2 exemption” for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

20.13. Electronic prescriptions (e-scripts) for controlled substances that are received by the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

21. Automated Dispensing/Delivery Devices

Yes No N/A

21.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

21.2. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer’s lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342)

Yes No N/A

21.3. For an “automated drug delivery system” located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- 21.3.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])
- 21.3.2. A pharmacist reviews the order and patient’s profile prior to the drug being removed. (H&SC 1261.6[e][2])
- 21.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

21.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- 21.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])
- 21.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

22. Repackaging by the Pharmacy

Yes No N/A

22.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer’s name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

22.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

22.3. Drugs previously dispensed are re-packaged at the patient’s request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

23. Refill Pharmacy

Yes No N/A

23.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

23.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

23.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section 23.

23.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

23.5. Refill prescription label meets requirements of B&PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

23.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

23.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

23.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

23.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

24. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

24.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

24.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

24.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

24.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

24.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

Yes No N/A

24.2. The pharmacy meets the following requirements:

- 24.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])
- 24.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])
- 24.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])
- 24.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])
- 24.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])
- 24.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])
- 24.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])
- 24.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])
- 24.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])
- 24.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])
- 24.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])
- 24.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

25. Policies and Procedures

Yes No N/A

25.1. There are written policies and procedures in place for:

- 25.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052.1[a][3])
- 25.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a][c])
- 25.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b][c])
- 25.1.4. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])
- 25.1.5. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])
- 25.1.6. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])
- 25.1.7. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B&PC 4059.5[f][1])
- 25.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- 25.1.9. Reporting requirements to protect the public; (B&PC 4104)
- 25.1.10. Preventing the dispensing of a prescription drug that is contrary to the law;- (B&PC 733)
- 25.1.11. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)
- 25.1.12. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

Yes No N/A

25.2. Does your pharmacy employ the use of a common electronic file?

- 25.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

COMPOUNDING

26. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 Rev. 07/13. (CCR 1735.2[j])

27. NUCLEAR PHARMACY

Yes No N/A

27.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

27.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

27.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. 05/13.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

28. PHARMACIES THAT DONATE DRUGS TO A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

28.1. The pharmacy donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150202.5, 150204)

- 28.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- 28.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

Yes No N/A

28.2. No controlled substances shall be donated. (H&SC 150204[c][1])

28.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- 28.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 28.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])
- 28.3.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])
- 28.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 28.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

29. PHARMACIES THAT OPERATE A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

29.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

- 29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150201[a][1])
 - Is county owned (H&SC 150201[a][1]) or
 - Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[a][1], 150200)
- 29.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

29.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

29.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

Yes No N/A

29.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

29.5. The pharmacy complies with the county's established written procedures. (H&SC 105024[b])

Drugs and Maintenance of Drug Stock

29.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

29.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

29.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

29.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 15204[c])

- 29.9.1. Are received from authorized sources. (H&SC 150202, 150203)
- 29.9.2. No controlled substances are received. (H&SC 150204[c][1])
- 29.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])
- 29.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])
- 29.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 29.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])
- 29.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

29.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

Transferring Donated Drugs From One Participating Entity to Another

Yes No N/A

29.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

29.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

29.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

29.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

29.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

29.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

29.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration
(www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:

Law-Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program

(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)

Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES

4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
<http://www.ag.ca.gov/bne>

CURES Patient Activity Report Request Forms:

<http://www.ag.ca.gov/bne/trips.php>

PRESCRIBER BOARDS:

Medical Board of California

2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
<http://www.mbc.ca.gov>

Dental Board of California

2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing

1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-3350
Fax: (916) 574-7697
<http://www.rn.ca.gov/>

Board of Optometry

2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California

1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: (916) 928-8392
<http://www.ombc.ca.gov>

Physician Assistant Committee

2500 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine

2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

FEDERAL AGENCIES:**Food and Drug Administration
– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering System (CSOS): <http://www.deaecom.gov/>**DEA - Fresno**

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

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www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year.** The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. 05/13) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 07/13).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner Partnership Corporation LLC
Non-Licensed Owner Other (please specify) _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Daily _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

- 1. _____ RPH # _____ Exp. Date: _____
- 2. _____ RPH # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
- 6. _____ RPH # _____ Exp. Date: _____
- 7. _____ RPH # _____ Exp. Date: _____
- 8. _____ RPH # _____ Exp. Date: _____
- 9. _____ INT # _____ Exp. Date: _____
- 10. _____ INT # _____ Exp. Date: _____
- 11. _____ INT # _____ Exp. Date: _____
- 12. _____ TCH # _____ Exp. Date: _____
- 13. _____ TCH # _____ Exp. Date: _____
- 14. _____ TCH # _____ Exp. Date: _____
- 15. _____ TCH # _____ Exp. Date: _____
- 16. _____ TCH # _____ Exp. Date: _____
- 17. _____ TCH # _____ Exp. Date: _____
- 18. _____ TCH # _____ Exp. Date: _____

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If “NO,” enter an explanation on “CORRECTIVE ACTION or ACTION PLAN” lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

- 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)
- 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])
- 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])
- 1.4. The pharmacy reports to the board within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])
- 1.5. The pharmacy maintains “night stock” medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
- 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
- 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)
- 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

1.12. Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 24 – “Compounding Sterile Injectable Drugs”)

1.13. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Nursing Stations

Yes No N/A

2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

2.2. The pharmacist completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Delivery of Drugs

Yes No N/A

3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

Yes No N/A

3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

- 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

4. Drug Stock

Yes No N/A

4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. PHARMACIES THAT DONATE DRUGS TO A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150202, 150202.5, 150204)

- 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- 5.1.2. The hospital pharmacy’s primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, board and care, or mail order. (H&SC 150202.5)

5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])
- 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])
- 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

6. Pharmacist-in-Charge (PIC)

Yes No N/A

6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 709, 1709.1)

6.2. The PIC has adequate authority to assure the pharmacy’s compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])

6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

Yes No N/A

6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Duties of a Pharmacist

Yes No N/A

7.1. Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)

7.2. Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2. (B&PC 4027, 4051, 4052, 4052.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Duties of an Intern Pharmacist

Yes No N/A

8.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, CCR 1726)

Yes No N/A

- 8.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])
- 8.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist may not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])
- 8.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

9. Duties of a Pharmacy Technician

Yes No N/A

- 9.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)
- 9.2. The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])
- 9.3. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)
- 9.4. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
- 9.5. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)
- 9.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)
- 9.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])
- 9.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)
- 9.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
 - 9.8.2. Compounded or repackaged products are previously checked by a pharmacist.
 - 9.8.3. The overall operations are the responsibility of the pharmacist-in-charge.

- 9.8.4. The pharmacy technician check technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- 9.8.5. There is an ongoing evaluation of the program that uses specially trained pharmacy technicians to check the work of other pharmacy technicians.

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Duties of Non-Licensed Personnel

Yes No N/A

- 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)
- 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACY PRACTICE

11. Pharmaceutical Service Requirements

Yes No N/A

- 11.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:
 - 11.1.1. Basic information concerning investigational drugs and adverse drug reactions;
 - 11.1.2. Repackaging and compounding records;
 - 11.1.3. Physician orders;
 - 11.1.4. Wards, nursing stations and night stock medications;
 - 11.1.5. Drugs brought into the facility by patients for storage or use;
 - 11.1.6. Bedside medications;
 - 11.1.7. Emergency drug supply;
 - 11.1.8. Pass medications;
 - 11.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\Outdated drugs;
 - 11.1.10. Routine distribution of inpatient medications;
 - 11.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
 - 11.1.12. Handling of medication when pharmacist not on duty; and
 - 11.1.13. Use of electronic image and data order transmissions.

Yes No N/A

11.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

11.2.1. Destruction of controlled substances; and

11.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Medication/Chart Order

Yes No N/A

12.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

12.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

12.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Labeling and Distribution

Yes No N/A

13.1. Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076, CCR 1751.2)

13.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

13.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Duration of Drug Therapy

Yes No N/A

- The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[jj])

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

- 15.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)
- 15.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)
- 15.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)
- 15.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Quality Assurance and Medication Errors

Yes No N/A

- 16.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)
- 16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- 16.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])
- 16.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

Yes No N/A

- 16.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- 16.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);
- 16.6.1. Date, location, and participants in the quality assurance review;
 - 16.6.2. Pertinent data and other information related to the medication error(s) reviewed;
 - 16.6.3. Findings and determinations;
 - 16.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- 16.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])
- 16.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Record Keeping Requirements

Yes No N/A

- 17.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)
- 17.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:
- 17.2.1. Prescription records (B&PC 4081[a])
 - 17.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
 - 17.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
 - 17.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)
 - 17.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
 - 17.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
 - 17.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
 - 17.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
 - 17.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1])
- 17.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503, B&PC 4160)

Yes No N/A

- 17.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
- 17.5. A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11)
- 17.6. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
- 17.7. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
- 17.8. DEA Forms 222 are properly executed. (21 CFR 1305.09)
- 17.9. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)
- 17.10. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)
- 17.11. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)
- 17.12. Do pharmacy staff hand initial prescription records and prescription labels, OR
- 17.13. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. After-Hours Supply of Medication

Yes No N/A

- The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Drug Supplies for Use in Medical Emergencies

Yes No N/A

- 19.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])
- 19.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])
- 19.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])
- 19.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the written policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

- Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

21. Emergency Room Dispensing

Yes No N/A

- 21.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B&PC 4068[a])
 - 21.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
 - 21.1.2. The dangerous drug is acquired by the hospital pharmacy;
 - 21.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
 - 21.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

- 21.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- 21.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

- 21.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])
- 21.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])
- 21.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- 21.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)
- 21.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)
- 21.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

22. Discharge Medication/Consultation Services

Yes No N/A

- 22.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)
- 22.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)
- 22.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)
- 22.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])
- 22.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: _____ to _____

Yes No N/A

- 22.6. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- 22.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- 22.8. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)
- 22.9. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)
- 22.10. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
- 22.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)
- 22.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

23. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

- 23.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])
If the answer is "yes," name of hospital: _____
- 23.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])
If the answer is "yes," name of supplying pharmacy:
If the answer to this and the previous question is "no" or "not applicable" go to Section 23.
- 23.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])
- 23.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])
- 23.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])
- 23.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3])
- 23.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

24. Centralized Hospital Packaging Pharmacy

Yes No N/A

- 24.1. The pharmacy packages unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)
- Hospitals to which central packaged unit dose medications are provided:*
- 24.1.1. _____ Distance (miles): _____
- 24.1.2. _____ Distance (miles): _____
- 24.1.3. _____ Distance (miles): _____
- 24.1.4. _____ Distance (miles): _____
- 24.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)
- 24.3. All unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient's bedside. The barcode information contains: (B&PC 4128.4)
- 24.3.1. The date the medication was prepared.
 - 24.3.2. The components used in the drug product.
 - 24.3.3. The lot number or control number.
 - 24.3.4. The expiration date.
 - 24.3.5. The National Drug Code Directory number.
 - 24.3.6. The name of the centralized hospital packaging pharmacy.
- 24.4. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. (B&PC 4128.5)
- 24.5. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

25. Policies and Procedures

Yes No N/A

- 25.1. There are written policies and procedures in place for:
- 25.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.
 - 25.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])

- 25.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])
- 25.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])
- 25.1.5. Reporting to the board within 30 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
- 25.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])
- 25.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- 25.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- 25.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

26. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 Rev. 07/13. (CCR 1735.2[j])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24

Business and Professions Code (B&PC), Chapter 9, Division 2

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219

Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

<http://www.pharmacy.ca.gov>

Pharmacy Law may be obtained by contacting:

LawTech Publishing Co.

1060 Calle Cordillera, Suite 105

San Clements CA 92673

(800) 498-0911 Ext. 5

<http://www.lawtechpublishing.com>

Pharmacist Recovery Program

(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)

Prescription Collection

8030 S. Willow Street, Bldg 3 Unit 3

Manchester, NH 03103

Phone: (888) 492-7341

Fax: (877) 508-6704

CURES

P.O. Box 160447

Sacramento, CA 95816-1089

Phone: (916) 319-9062

Fax: (916) 319-9448

<http://www.ag.ca.gov/bne>

CURES Patient Activity Report Request Forms:

<http://www.ag.ca.gov/bne/trips.php>

PRESCRIBER BOARDS:

Medical Board of California

2005 Evergreen St., Suite 1200

Sacramento, CA 95815

Phone: (800) 633-2322

Phone: (916) 263-2382

Fax: (916) 263-2944

<http://www.mbc.ca.gov>

Dental Board of California

2005 Evergreen St., Suite 1550

Sacramento, CA 95815

Phone: (877) 729-7789

Phone: (916) 263-2300

Fax: (916) 263-2140

<http://www.dbc.ca.gov>

Board of Registered Nursing

1625 N. Market Blvd., Suite N217

Sacramento, CA 95834

Phone: (916) 322-3350

Fax: (916) 574-7697

<http://www.rn.ca.gov>

Board of Optometry

2420 Del Paso Road, Suite 255

Sacramento, CA 95834

Phone: (916) 575-7170

Fax: (916) 575-7292

<http://www.optometry.ca.gov>

Osteopathic Medical Board of California

1300 National Drive, Suite #150

Sacramento, CA 95834

Phone: (916) 928-8390

Fax: (916) 928-8392

<http://www.ombc.ca.gov>

Physician Assistant Committee

2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine

2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

FEDERAL AGENCIES:**Food and Drug Administration****– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website: <http://www.dea diversion.usdoj.gov>

Online Registration – New Applicants:

http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.dea diversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.dea diversion.usdoj.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering System (CSOS): <http://www.deaecom.gov/>**DEA - Fresno**

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631



WHOLESALE DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

- sole owner partnership corporation LLC
- non- licensed owner Other (please specify) _____

CA Wholesaler Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____

DEA Registration # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Daily _____ Sat _____ Sun _____ 24 Hours

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License # _____ Expiration Date _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

- 1. _____ DR#/RPH# _____ Exp. Date _____
- 2. _____ DR#/RPH# _____ Exp. Date _____
- 3. _____ DR#/RPH# _____ Exp. Date _____
- 4. _____ DR#/RPH# _____ Exp. Date _____
- 5. _____ DR#/RPH# _____ Exp. Date _____
- 6. _____ DR#/RPH# _____ Exp. Date _____
- 7. _____ DR#/RPH# _____ Exp. Date _____
- 8. _____ DR#/RPH# _____ Exp. Date _____
- 9. _____ DR#/RPH# _____ Exp. Date _____
- 10. _____ DR#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If “NO,” enter an explanation on the “CORRECTIVE ACTION OR ACTION PLAN” lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

2.1.1. Are clean and orderly
 2.1.2. Are well ventilated
 2.1.3. Are free from rodents and insects
 2.1.4. Are adequately lit
 2.1.5. Have plumbing in good repair
 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area?
(CCR 1780[a])

2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

Yes No N/A

2.5. Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

2.6. The wholesale premises is equipped with the following specific security features:
 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).
 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).
 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

Yes No N/A

2.7. Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.9. The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.2. Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d])

3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

Yes No N/A

- 3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

- 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)
- 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])

6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

7. Drug Stock

Yes No N/A

7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)

7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

7.4. Do all drug containers you store on your premises have a manufacturer’s expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

Yes No N/A

- 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs’ safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

- 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169)

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

- 8.5.1. the pharmacy originally purchased the drugs from you?
- 8.5.2. your business is a “reverse distributor”?
- 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

8.6. Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

Yes No N/A

- 8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?
- 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?
- 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?
- 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

- 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?
- 8.8.2. comply with the pharmacy law of the receiving state within the United States?
- 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?
- 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?
- 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

Yes No N/A

- 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.

Yes No N/A

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

Yes No N/A

8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

Yes No N/A

9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

- 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 9.3.2. Has never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

10. Outgoing Shipments of Drugs

Yes No N/A

10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

10.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

10.3. List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

11. Delivery of Drugs

Yes No N/A

11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer’s licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

Yes No N/A

11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059[d])

11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

12. Controlled Substances

Yes No N/A

12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

12.3. Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

12.6. Does the biennial inventory record document the inventory was taken at the “close of business” or “opening of Business.” (CFR 1304.11)

12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

- 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
- 12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
- 12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
- 12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
- 12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

- 12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])
- 12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])
- 12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

Yes No N/A

- 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])
- 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)
- 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.13[b])
- 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])
- 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)
- 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))
- 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1305.09[d], 1305.17[a] [b], and H&SC 11252, 11253, 1304.03)
- 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)
- 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

Yes No N/A

- 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

13. Policies and Procedures

13.1. Does this business maintain and adhere to policies and procedures for:
(CCR 1780[f])

Yes No N/A

- 13.1.1. Receipt of drugs?
- 13.1.2. Security of drugs?
- 13.1.3. Storage of drugs? (including maintaining records to document proper storage)
- 13.1.4. Inventory of drugs? (including correcting inaccuracies in inventories)
- 13.1.5. Distributing drugs?
- 13.1.6. Identifying, recording and reporting theft or losses?
- 13.1.7. Correcting errors and inaccuracies in inventories?
- Physically quarantining and separating:
- 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
- 13.1.9. drugs that have been partially used?
- 13.1.10. drugs where the outer or secondary seals on the container have been broken?
- 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?
- 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

14. Training

Yes No N/A

- Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN _____

15. Dialysis Drugs

Yes No N/A

- 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.
- 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])
- 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])
- 15.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)
- 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

16. Record Keeping Requirements

Yes No N/A

- 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])
- 16.2. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.
- 16.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])
- 16.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)
- 16.5. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])
- 16.6. Are required records stored off-site only if a board issued written waiver has been granted?

16.7. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

- 16.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])
- 16.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])
- 16.10. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])
- 16.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

- 16.12. Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):
-
-

- 16.13. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

- 16.14. Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

- 16.15. If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

17. Reporting Requirements to the Board

Yes No N/A

- 17.1. A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c]).
- 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B&PC 4305.5[a])
- 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
- 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

- 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])
- 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])
- 17.8. Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:
1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
 2. identify purchases of any dangerous drugs at preferential or contract prices
 3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])
- 17.9. I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])
- 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
- 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

18. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a])

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy’s license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:
LawTech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
Phone: (800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
<http://www.mbc.ca.gov>

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
<http://www.rn.ca.gov/>

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: (916) 928-8392
<http://www.ombc.ca.gov>

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

Federal Agencies:

Food and Drug Administration

– Industry Compliance

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/pp106Login.jsp>

Controlled Substance Ordering System

(CSOS): <http://www.deacom.gov/>

DEA Registration Support (all of CA):

(800) 882-9539

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043



COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug products to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year.** The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner Partnership Corporation LLC
 Non-Licensed Owner Other (please specify) _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

- 2. _____ RPH # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
- 6. _____ RPH # _____ Exp. Date: _____
- 7. _____ INT # _____ Exp. Date: _____
- 8. _____ INT # _____ Exp. Date: _____
- 9. _____ INT # _____ Exp. Date: _____
- 10. _____ TCH # _____ Exp. Date: _____
- 11. _____ TCH # _____ Exp. Date: _____
- 12. _____ TCH # _____ Exp. Date: _____
- 13. _____ TCH # _____ Exp. Date: _____
- 14. _____ TCH # _____ Exp. Date: _____
- 15. _____ TCH # _____ Exp. Date: _____
- 16. _____ TCH # _____ Exp. Date: _____

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 9.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

1.1. The pharmacy compounds prescriptions as defined in CCR 1735.

1.2. The compounding pharmacist understands the definitions of equipment, integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

2.1. The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined. (CCR 1735.2[b])

2.2. The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

2.2.1. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

2.2.2. Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

2.2.3. Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

2.3. The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements: (CCR 1735.2[d][1-6])

2.3.1. Active ingredients used.

2.3.2. Equipment to be used.

2.3.3. Expiration dating requirements.

2.3.4. Inactive ingredients used.

2.3.5. Process and/or procedure used to prepare the drug.

2.3.6. Quality reviews required at each step in the preparation of the drug.

2.3.7. Post-compounding process or procedures if required.

Yes No N/A

- 2.4. The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])
- 2.5. All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])
- 2.6. Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The “beyond use date” of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

- 3.1. A record for each compounded drug product includes the following: (CCR 1735.3[a][1-10])
- 3.1.1. The master formula record.
 - 3.1.2. The date the drug product was compounded.
 - 3.1.3. The identity of the pharmacy personnel who compounded the drug product.
 - 3.1.4. The identity of the pharmacist reviewing the final drug product.
 - 3.1.5. The quantity of each component used in compounding the drug product.
 - 3.1.6. The manufacturer or supplier, expiration date and lot number of each component.
Exempt from this requirement are sterile drug products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - 3.1.7. The pharmacy assigned reference or lot number for the compounded drug product.
 - 3.1.8. The expiration date of the final compounded drug product.
 - 3.1.9. The quantity or amount of drug product compounded.
- 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])
- 3.3. Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])

Yes No N/A

3.4. The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])

3.5. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

4.1. The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])

4.2. The prescription label contains all the information required in B&PC 4076 and is formatted in accordance with CCR 1707.5. (CCR 1735.4[a])

4.3. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])

4.4. The pharmacy is exempt from the prescription label requirements in CCR 1707.5. (B&PC 4076.5[d])

Exemption approved by the board from: _____ to: _____

4.5. The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])

4.6. Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date. (CCR 1735.4[c])

4.7. Compounded drug products received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient’s bedside. (B&PC 4128.4, 4128.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

5.1. The pharmacy maintains a written policy and procedure manual for compounding that establishes the following: (CCR 1735.5 [a])

5.1.1. Procurement procedures.

5.1.2. Methodologies for the formulation and compounding of drugs.

5.1.3. Facilities and equipment cleaning, maintenance and operations.

5.1.4. Other standard operating procedures related to compounding.

- 5.2. The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])

Yes No N/A

- 5.3. The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])
- 5.4. The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2])
- 5.5. The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[c][3])
- 5.6. The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[c][4])
- 5.7. The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[c][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

- 6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- 6.2. All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- 6.3. All equipment used to compound drug products is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
- 6.4. Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

- 7.1. The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

7.2. The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

Yes No N/A

7.3. Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

7.4. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

8.1. The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

8.2. The pharmacy's quality assurance plan includes the written procedures and standards for the following:

8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

8.2.2. Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[c])

8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

8.2.4. Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

9. Centralized Hospital Packaging Pharmacy (B&PC 4128 et seq.)

Yes No N/A

9.1. The pharmacy compounds unit dose medications only for inpatients of one or more hospitals under common ownership within a 75-mile radius. (B&PC 4128[a])

Hospitals to which central packaged unit dose medications are provided:

9.1.1. _____ Distance (miles): _____

9.1.2. _____ Distance (miles): _____

9.1.3. _____ Distance (miles): _____

9.1.4. _____ Distance (miles): _____

Yes No N/A

9.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

9.3. Compounded unit dose drugs for administration to inpatients are barcoded. (B&PC 4128[a][1], 4128.4)

9.4. Barcoded unit dose compounded drugs are readable at an inpatient's bedside and include the following: (B&PC 4128.4)

- 9.4.1. The date the medication was prepared.
- 9.4.2. The components used.
- 9.4.3. The lot number or control number.
- 9.4.4. The expiration date.
- 9.4.5. The National Drug Code Directory number.
- 9.4.6. The name of the centralized hospital packaging pharmacy.

9.5. Labels for compounded unit dose drugs prepared by the centralized hospital packaging pharmacy contain the following: (B&PC 4128.5)

- 9.5.1. The expiration date.
- 9.5.2. The established name of the drug.
- 9.5.3. The quantity of the active ingredient.
- 9.5.4. Special storage or handling requirements.

COMPOUNDING STERILE INJECTABLE DRUGS

Does the pharmacy compound sterile injectable drugs? Yes No

If yes, complete Sections 10 through 20.

10. FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS: Permit or Accreditation

Yes No N/A

The pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

11. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

- 11.1. The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.
- 11.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.

12. Sterile Injectable Compounding: Compounding Area (CCR 1751)

Yes No N/A

- 12.1. If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:
- 12.1.1. An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])
- 12.1.2. An ISO class 5 cleanroom (B&PC 4127.7[b])
- 12.1.3. A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])
- 12.2. The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)
- 12.2.1. The laminar airflow hoods and clean room are certified annually; (CCR 1751)
- 12.2.2. Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)
- 12.2.3. A sink with hot and cold running water; (CCR 1751)
- 12.2.4. A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

- 13.1. Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])
- 13.2. Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])
- 13.2.1. The training and competency evaluation of employees in sterile product procedures;
- 13.2.3. Refrigerator and freezer temperatures;

- 13.2.3. Certification of the sterile compounding environment;
- 13.2.4. Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);
- 13.2.5. Inspection for expired or recalled pharmaceutical products or raw ingredients; and
- 13.2.6. Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

13.3. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

- 14.1. In addition to the labeling information required under Business and Professions Code section 4076 and CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])
- 14.1.1. Telephone number of the pharmacy, unless dispensed for a hospital in-patient;
 - 14.1.2. Name and concentrations of ingredients contained in the product;
 - 14.1.3. Instructions for storage and handling; and
 - 14.1.4. A special label that states "Chemotherapy—Dispose of Properly" or "Cytotoxic – Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

- 15.1. The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and, in addition to the elements required by section 1735.5, includes: (CCR 1751.2[a][1-7])
- 15.1.1. Compounding, filling, and labeling of sterile injectable compounds;
 - 15.1.2. Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;
 - 15.1.3. Equipment and supplies;
 - 15.1.4. Training of staff in preparation of sterile injectable products;
 - 15.1.5. Training of patient and/or caregiver in the administration of compounded sterile injectable products;

- 15.1.6. Procedures for the handling and disposal of cytotoxic agents;
- 15.1.7. Quality assurance program; and
- 15.1.8. Record keeping requirements.

Yes No N/A

15.2. Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])

15.3. Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])

15.4. If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])

- 15.4.1. Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and
- 15.4.2. All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])

15.5. Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])

- 15.5.1. Competency evaluation;
- 15.5.2. Storage and handling of products and supplies;
- 15.5.3. Storage and delivery of final products;
- 15.5.4. Process validation;
- 15.5.5. Personnel access and movement of materials into and near the controlled area;
- 15.5.6. Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations);
- 15.5.7. A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;
- 15.5.8. Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;
- 15.5.9. For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;
- 15.5.10. Sterilization; and
- 15.5.11. End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

- 16.1. The compounding environment meets criteria specified in the pharmacy’s written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])
- 16.2. Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])
- 16.3. All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])
- 16.4. Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])
- 16.5. The preparation of parenteral cytotoxic agents is done in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations and includes: (CCR 1751.4[e])
 - 16.5.1. A laminar airflow hood, which is certified annually.
 - 16.5.2. Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

- 17.1. When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.5[a])
- 17.2. When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])
 - 17.2.1. Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])
 - 17.2.2. Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])
 - 17.2.3. No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])
 - 17.2.4. Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and
 - 17.2.5. Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

Yes No N/A

- 18.1. Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])
- 18.2. The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.6[b])
- 18.3. Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])
- 18.4. The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])
- 18.5. When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])
- 18.6. The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])
 - 18.6.1. Aseptic technique;
 - 18.6.2. Pharmaceutical calculations and terminology;
 - 18.6.3. Sterile product compounding documentation;
 - 18.6.4. Quality assurance procedures;
 - 18.6.5. Aseptic preparation procedures;
 - 18.6.6. Proper gowning and gloving technique;
 - 18.6.7. General conduct in the controlled area;
 - 18.6.8. Cleaning, sanitizing, and maintaining equipment used in the controlled area;
 - 18.6.9. Sterilization techniques; and
 - 18.6.10. Container, equipment, and closure system selection.
- 18.7. Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])
 - 18.7.1. Checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])
 - 18.7.2. Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])
 - 18.7.3. Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

- 19.1. There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])
- 19.2. The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])
- 18.2.1. Cleaning and sanitization of the parenteral medication preparation area;
 - 18.2.2. The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;
 - 18.2.3. Actions to be taken in the event of a drug recall; and
 - 18.2.4. Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).
- 19.3. Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])
- 19.3.1. The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])
 - 19.3.2. The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])
 - 19.3.3. The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])
 - 19.3.4. Completed medium samples are incubated. (CCR 1751.7[b])
 - 19.3.5. If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])
 - 19.3.6. Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])
- Yes No N/A
- 19.4. Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

(Pharmacist-in-Charge)