



Legislation and Regulation Committee

Greg Lippe, CPA, Chairperson, Public Member
Lavanza Butler, Vice Chairperson, Licensee Member
Amy Gutierrez, Licensee Member
Amjad Khan, Public Member
Valerie Muñoz, Public Member
Albert Wong, PharmD, Licensee Member

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

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

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

III. Legislation for Discussion and Consideration

Attachment 1

The legislature reconvened on January 3, 2018. February 16, 2018, is the last day for bills to be introduced. Because this is the second year of a two-year legislative cycle, legislative deadlines for proposals from last year vary from deadlines for newly introduced measures. A copy of the 2018 tentative legislative calendar is provided in **Attachment 1**.

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

Attachment 2

1. AB 1659 (Low) Healing Arts Boards, Inactive Licenses

Version: As amended January 3, 2018

Status: January 31, 2018 Referred to the Senate

Summary: This measure would prohibit a person with an inactive license from representing that he or she has an active license. This measure would also allow a healing arts board to establish a lower inactive license renewal fee.

Staff Comments: This measure is being brought to the committee to seek input on the policy of the measure. Based on the policy discussion board staff will identify what, if any fiscal impact would occur.

2. AB 1751 (Low) Controlled Substances: CURES Database

Version: As introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

Summary: This measure will allow the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for purposes of interstate sharing of controlled substances reporting information

3. AB 1752 (Low) Controlled Substances: CURES Database

Version: As introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

Summary: This measure expands CURES reporting to also include Schedule V controlled substances as well as other medications of concern identified by the board in regulation. The measure also reduces the time frame for reporting to the CURES system to one working day.

4. AB 1753 (Low) Controlled Substances: CURES

Version: As introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

Summary: This measure would limit the number of authorized security printers approved by the DOJ to three effective January 1, 2020. Further, this measure would require security forms to contain a unique serialized number that must be reported to CURES and would establish reporting requirements to the DOJ on the delivery of security forms to a prescriber.

5. AB 710 (Wood) Cannabidiol

Version: As Amended January 18, 2018

Status: Referred to Senate Business, Professions and Economic Development Committee

Summary: Would allow a product composed of cannabidiol to be prescribed or dispensed in accordance with federal law if the federal government excludes such products from the list of Schedule I items under the federal Controlled Substances Act.

A copy of each measure and bill analysis is provided in **Attachment 2**.

IV. Regulations for Discussion and Consideration

b. **Board Adopted - Approved by the Office of Administrative Law**

1. Regulations to Add Title 16 CCR section 1715.65 Related to the Inventory Reconciliation Report of Controlled Substances

Summary of Regulation: Effective April 1, 2018, this regulation establishes the regulatory requirement to conduct a quarterly inventory and compile an inventory reconciliation report of federal Schedule II Controlled Substances.

2. Regulations to Amend Title 16 CCR section 1760 Related to the Board's Disciplinary Guidelines

Summary of Regulation: Effective April 1, 2018, this regulation reorganizes the Board's Disciplinary Guidelines, incorporates changes that have occurred in law, and clarifies the terms and conditions of probation.

3. Emergency Regulations to Amend Title 16 CCR section 1735.2 Related to Compounding Beyond Use Dates

Summary of Regulation: Effective December 19, 2017, this regulation revises and specifies new requirements for a pharmacist establishing beyond use dates (BUDs) for nonsterile compounded drug preparations. In addition, it clarifies that an existing provision that permits extending the BUD will only apply to sterile compounded drug preparations.

A copy of each adopted regulation text is posted on the board's website and can be obtained using the following link - - http://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml

c. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law - Proposed Regulations to Amend Title 16 CCR section 1749 Related to the Board's Fee Schedule

Attachment 3

The board currently has one regulation undergoing review by the Department or the Office of Administrative Law, the proposed regulations to amend Title 16 CCR section 1749 related to the board's free schedule.

Attachment 3 provides a summary of the regulation changes as well as the general timeline. The board-adopted text is posted on the board's website and can be obtain using the following link - - http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml

d. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review

Attachment 4

The board has several regulations undergoing pre-notice review by the department, including:

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors
2. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
3. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
4. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Trusts

Note: This regulation was returned to board staff for changes after pre-notice review was completed. Board staff will be working on making the requested changes as appropriate and will resubmit the regulation materials.
6. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs
7. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Attachment 4 includes a timeline for each of the proposed regulations as well as the board approved text.

e. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 5

1. Proposed Regulations to Amend Title 16 CCR section 1735.2 Related to the Compounding Self-Assessment Form 17M-39
2. Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

Attachment 5 includes a timeline for each of the proposed regulations as well as the board approved text.

V. Future Committee Meeting Dates

- April 24, 2018
- July 10, 2018
- October 20, 2018

Attachment 2



Bill Number: AB 1659
Current Version: As Amended January 3, 2018
Author: Low
Topic: Healing Arts Boards: Inactive Licenses
Staff Recommendation: None

AFFECTED SECTIONS: Amend BPC sections 701, 702, and 703, Business and Professions Code

STATUS: Referred to Senate

CURRENT LAW:

- Authorizes healing arts board to issue an inactive license.
- BPC 4231 authorizes the board to cancel an active pharmacist license and issue an inactive pharmacist license in its place if a pharmacist fails to provide documentation substantiating the completion of continuing education.

THIS BILL WOULD:

- Prohibit an individual from working as or representing that he or she has an active license when the license is on an inactive status.
- Allow the board to establish a lower fee for renewal of an inactive license.

STAFF COMMENTS:

This measure is being brought to the committee to seek input on the policy of the measure. Based on the policy discussion board staff will identify what, if any, fiscal impact the board would experience.

BILL HISTORY:

01/29/2018	Read third time. Passed. Ordered to the Senate. In Senate. Read first time. To Com. on RLS. for assignment.
01/22/2018	Read second time. Ordered to Consent Calendar.
01/18/2018	From committee: Do pass. To Consent Calendar. (Ayes 17. Noes 0.) (January 18).
01/11/2018	From committee: Do pass and re-refer to Com. on APPR. (Ayes 15. Noes 0.) (January 9). Re-referred to Com. on APPR.
01/04/2018	Re-referred to Com. on NAT. RES. Re-referred to Com. on B. & P. pursuant to Assembly Rule 96.
01/03/2018	From committee chair, with author's amendments: Amend, and re-refer to Com. on NAT. RES. Read second time and amended.
04/24/2017	In committee: Set, first hearing. Hearing canceled at the request of author.
04/05/2017	Re-referred to Com. on NAT. RES.
04/04/2017	From committee chair, with author's amendments: Amend, and re-refer to Com.

	on NAT. RES. Read second time and amended.
04/03/2017	Referred to Com. on NAT. RES.
02/19/2017	From printer. May be heard in committee March 21.
02/17/2017	Read first time. To print.

AMENDED IN ASSEMBLY JANUARY 3, 2018

AMENDED IN ASSEMBLY APRIL 4, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1659

Introduced by Assembly Member Low

February 17, 2017

~~An act to add Sections 43020.2 and 43020.3 to, and to add Chapter 6 (commencing with Section 42370) to Part 3 of Division 30 of, the Public Resources Code, relating to recycling. An act to amend Sections 701, 702, and 703 of the Business and Professions Code, relating to healing arts.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 1659, as amended, Low. ~~Food Service Plastic Packaging Recovery and Recycling Stewardship Act. Healing arts boards: inactive licenses.~~

Existing law establishes healing arts boards in the Department of Consumer Affairs to ensure private businesses and professions deemed to engage in activities which have potential impact upon the public health, safety, and welfare are adequately regulated in order to protect the people of California. Existing law requires each healing arts board to issue inactive licenses to holders of active licenses whose license is not punitively restricted by that board. Existing law prohibits the holder of an inactive license from engaging in any activity for which an active license is required. Existing law requires the renewal fee for an active license to apply to an inactive license.

This bill would prohibit the holder of an inactive license from representing that he or she has an active license. The bill would also

authorize a healing arts board to establish a lower inactive license renewal fee.

~~(1) The California Integrated Waste Management Act of 1989, administered by the Department of Resources Recycling and Recovery, generally regulates the disposal, management, and recycling of solid waste.~~

~~Existing law requires a manufacturer of carpets sold in the state, individually or through a carpet stewardship organization, to submit a carpet stewardship plan to the Department of Resources Recycling and Recovery for approval that would, among other things, increase the amount of postconsumer carpet that is diverted from landfills and recycled into secondary products. Existing law requires the carpet stewardship plan to include a funding mechanism that provides sufficient funding to carry out the plan and requires a manufacturer or carpet stewardship organization to pay the department an annual administrative fee. Existing law requires the department to identify the direct development or regulatory costs incurred by the department prior to the submittal of the carpet stewardship plans, and to establish a fee in an amount adequate to cover these costs, that is paid by a carpet stewardship organization. Existing law imposes administrative civil penalties on a person who violates these provisions.~~

~~This bill, the Food Service Plastic Packaging Recovery and Recycling Stewardship Act, would authorize a city, county, or city and county to establish and implement a residential curbside collection program for the collection and recycling of a particular type of plastic packaging, defined to mean a container or single-use food service packaging product labeled with the same resin code. The bill would require a residential curbside collection program to impose certain requirements on the transportation of plastic packaging collected as a part of the program and on material recovery facilities to which waste that includes that plastic packaging is delivered.~~

~~The bill would require, by June 30, 2018, a manufacturer of plastic packaging sold in this state, individually or through a plastic packaging stewardship organization, to submit to the department one or more plastic packaging stewardship plans, similar to the carpet stewardship plans described above, collectively covering each particular type of plastic packaging distributed, sold, or used in the state by that manufacturer. The bill would require the plan to include a funding mechanism similar to that required in the carpet stewardship law. The bill would require the manufacturer or organization to, among other~~

~~things, establish a plastic packaging stewardship fee that would be imposed on members of the organization and to determine the appropriate projects and programs to be funded by the stewardship fee that would further the efforts to recycle the particular type of plastic packaging. The bill would require each plastic packaging stewardship organization to make reasonable efforts to achieve specified rate of community access to residential curbside collection programs for each type of plastic packaging covered by the organization's plan, with an overall goal of a 75% rate of community access for each type of plastic packaging on or before January 1, 2043.~~

~~Similar to the carpet stewardship organization, a manufacturer or plastic packaging stewardship organization would be required to pay the department an annual administrative fee, as determined by the department. The bill would require the department to identify the direct development or regulatory costs incurred by the department prior to the submittal of plastic packaging stewardship plans and to establish a fee in an amount adequate in aggregate to cover those costs, to be paid by each plastic packaging stewardship organization that submits a plastic packaging stewardship plan. The bill would provide for the imposition of administrative civil penalties upon a person who violates the bill. The bill would establish the Plastic Packaging Stewardship Account in the Integrated Waste Management Fund and would require the fees collected by the department to be deposited in that account, for expenditure by the department, upon appropriation by the Legislature, to cover the department's cost to implement the bill's provisions. The bill would also establish the Plastic Packaging Stewardship Penalty Subaccount in the Integrated Waste Management Fund and would require that the civil penalties collected by the department pursuant to the bill's provisions be deposited in that subaccount, for expenditure by the department, upon appropriation by the Legislature, to cover the department's costs to implement the bill's provisions.~~

~~(2) Existing law requires the department to adopt regulations relating to waste management, including standards for the design, operation, maintenance, and ultimate reuse of solid waste facilities, and for solid waste handling, transfer, composting, transformation, and disposal.~~

~~This bill would authorize a material recovery facility to send residual materials containing plastic packaging to a secondary sorting facility with the capacity of sorting or separating plastic packaging material from the residual material for recycling. The bill would encourage a solid waste landfill that receives solid waste that contains plastic~~

packaging to send the plastic packaging to a material recovery facility, secondary sorting facility, or to a recycling facility that has the capability to sort, separate, or recycle plastic packaging material.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 *SECTION 1. Section 701 of the Business and Professions Code*
2 *is amended to read:*

3 ~~701. Each healing arts board referred to in this division shall~~
4 ~~issue, upon application and payment of the normal renewal fee,~~
5 ~~an inactive license or certificate to a current holder of an active~~
6 ~~license or certificate whose license or certificate is not suspended,~~
7 ~~revoked, or otherwise punitively restricted by that board.~~

8 701. (a) As used in this article, “board” refers to any healing
9 arts board, division, or examining committee which licenses or
10 certifies health professionals.

11 (b) *Each healing arts board referred to in this division shall*
12 *issue, upon application and payment of the normal renewal fee,*
13 *an inactive license or certificate to a current holder of an active*
14 *license or certificate whose license or certificate is not suspended,*
15 *revoked, or otherwise punitively restricted by that board.*

16 *SEC. 2. Section 702 of the Business and Professions Code is*
17 *amended to read:*

18 702. The holder of an inactive healing arts license or certificate
19 issued pursuant to this article shall not ~~engage~~ *do any of the*
20 *following:*

21 (a) *Engage* in any activity for which an active license or
22 certificate is required.

23 (b) *Represent that he or she has an active license.*

24 *SEC. 3. Section 703 of the Business and Professions Code is*
25 *amended to read:*

26 703. (a) An inactive healing arts license or certificate issued
27 pursuant to this article shall be renewed during the same time
28 period at which an active license or certificate is renewed. In order
29 to renew a license or certificate issued pursuant to this article, the
30 holder thereof need not comply with any continuing education
31 requirement for renewal of an active license or certificate.

32 The

1 (b) *The* renewal fee for a license or certificate in an active status
2 shall apply also for renewal of a license or certificate in an inactive
3 ~~status. status, unless a lower fee has been established by the issuing~~
4 ~~board.~~

5 SECTION 1. This act shall be known, and may be cited, as the
6 ~~Food Service Plastic Packaging Recovery and Recycling~~
7 ~~Stewardship Act.~~

8 SEC. 2. Chapter 6 (commencing with Section 42370) is added
9 to Part 3 of Division 30 of the Public Resources Code, to read:

10

11 CHAPTER 6. ~~FOOD SERVICE PLASTIC PACKAGING STEWARDSHIP~~
12 ~~PROGRAM~~

13

14 Article 1. ~~General Provisions~~

15

16 42370. ~~The Legislature finds and declares the following:~~

17 (a) ~~It is the intent of the Legislature, in adopting this chapter,~~
18 ~~to reduce the amount of food service packaging that is littered and~~
19 ~~improperly disposed of, to reduce the amount of food service~~
20 ~~plastic packaging that is disposed of in landfills, to increase~~
21 ~~opportunities for businesses or multifamily complexes to save~~
22 ~~money, to create jobs in California by providing materials for~~
23 ~~recycling manufacturing facilities, to reduce greenhouse gas~~
24 ~~emissions, to keep valuable materials out of landfills, and to create~~
25 ~~a healthy environment for the community and future generations~~
26 ~~by recovering natural resources by increasing the recycling rate~~
27 ~~of food service plastic packaging.~~

28 (b) ~~California is home to a number of food service packaging~~
29 ~~manufacturers that produce a variety of products. These facilities~~
30 ~~employ thousands of Californians and are important components~~
31 ~~of the state's economy.~~

32 (c) ~~All food service packaging, regardless of the material from~~
33 ~~which it is made, has environmental impacts, including, but not~~
34 ~~limited to, raw material acquisition, energy use, greenhouse gas~~
35 ~~emissions and other emissions associated with its manufacture,~~
36 ~~transportation, and disposal, consumption of increasingly scarce~~
37 ~~landfill capacity, and unsightly and environmentally damaging~~
38 ~~consequences of littering and other improper disposal.~~

39 (d) ~~Manufacturers, distributors, and users of food service~~
40 ~~packaging have a shared responsibility to identify, finance, and~~

1 implement food service packaging materials life-cycle management
2 solutions that are both environmentally responsible and
3 economically sustainable. These solutions include, but are not
4 limited to, reduction of food service packaging, reuse of food
5 service packaging materials, enhanced material collection, sorting
6 and recycling programs, antilitter, pollution prevention, and other
7 public education programs, and developing and supporting
8 emerging material recycling and conversion technologies to
9 facilitate greater reuse and recycling of food service packaging
10 materials.

11 (e) Manufacturers of each type of food service packaging
12 material, transporters, solid waste haulers, recyclers, the State of
13 California, local governments, and other stakeholders should work
14 together to develop and implement programs to ensure all food
15 service packaging materials are managed in an environmentally
16 sound and economically sustainable manner.

17 (f) With the enactment of this chapter, the Legislature intends
18 to encourage the development of recycling technologies for food
19 service plastic packaging materials without favoring one type of
20 food service packaging material, whether plastic or otherwise, over
21 another. It is anticipated that the methods and programs that will
22 be developed pursuant to this chapter will serve as models for
23 similar programs addressing other types of food service packaging
24 materials.

25 42370.1.— The purpose of this chapter is to increase the amount
26 of food service plastic packaging waste that is diverted from
27 landfills and recycled into new products or otherwise managed in
28 a manner that is consistent with the state's hierarchy for waste
29 management practices pursuant to Section 40051.

30 42370.2.— (a) For purposes of this chapter, and unless the
31 context otherwise requires, the following definitions shall apply:

32 (1) "Community recycling access rate," for a particular type of
33 plastic packaging, means the number of residents that have access
34 to a residential curbside collection program that accepts that type
35 of plastic packaging for recycling divided by the total number of
36 residents in the State of California.

37 (2) "Department" means the Department of Resources Recycling
38 and Recovery.

39 (3) "Manufacturer" means either of the following:

1 ~~(A) The person or entity in the state that manufactures plastic~~
2 ~~packaging that is sold, offered for sale, or distributed for use in~~
3 ~~the state.~~

4 ~~(B) If there is no person or entity that is a manufacturer of plastic~~
5 ~~packaging for purposes of subparagraph (A), the person or entity~~
6 ~~that imports the plastic packaging into the state for sale,~~
7 ~~distribution, or use in the state.~~

8 ~~(4) “Material recovery facility” means a facility that sorts~~
9 ~~residential solid waste that includes recyclable materials for the~~
10 ~~purpose of separating recyclable materials from materials destined~~
11 ~~for disposal at a landfill.~~

12 ~~(5) “Particular type of plastic packaging” or “type of plastic~~
13 ~~packaging” means all plastic packaging labeled with the same resin~~
14 ~~code pursuant to Section 18015.~~

15 ~~(6) “Plastic packaging” means a container or other single-use~~
16 ~~food service packaging product labeled with a resin code pursuant~~
17 ~~to Section 18015 that is used by a food service provider to carry~~
18 ~~or contain food or beverages that are prepared onsite so that a~~
19 ~~customer may consume the food offsite if the customer wishes to~~
20 ~~do so.~~

21 ~~(7) “Plastic packaging stewardship organization” or~~
22 ~~“organization” means either of the following:~~

23 ~~(A) An organization appointed by one or more manufacturers~~
24 ~~of a particular type of plastic packaging to act as an agent on behalf~~
25 ~~of the manufacturer to design, submit, and administer a plastic~~
26 ~~packaging stewardship plan pursuant to this chapter.~~

27 ~~(B) A plastic packaging manufacturer that complies with this~~
28 ~~chapter as an individual manufacturer.~~

29 ~~(8) “Recycle” means to take a product or material that has been~~
30 ~~used and discarded and divert it from disposal in a landfill for the~~
31 ~~purpose of being transformed, regenerated, or reused in the~~
32 ~~production of a useful product.~~

33 ~~(b) A term not specifically defined in this chapter shall be~~
34 ~~interpreted consistent with its meaning in this division.~~

35
36 ~~Article 2. Food Service Plastic Packaging Stewardship~~
37 ~~Organization~~
38

39 ~~42371. On or before June 30, 2018, a manufacturer of plastic~~
40 ~~packaging distributed, sold, or used in this state shall, individually~~

1 or through a plastic packaging stewardship organization formed
2 pursuant to Section 42371.2, submit to the department one or more
3 plastic packaging stewardship plans, collectively covering each
4 particular type of plastic packaging distributed, sold, or used in
5 this state by that manufacturer, that will do all of the following:

6 (a) Achieve the purposes of this chapter, as described in Section
7 42370.1, and meet the requirements of Section 42372.4.

8 (b) Establish goals that, to the extent feasible based on available
9 technology and information, increase the recycling of plastic
10 packaging, increase the diversion of plastic packaging from
11 landfills, increase the recyclability of plastic packaging, and
12 provide incentives for the market growth of secondary products
13 made from recycled plastic packaging.

14 (c) Describe proposed measures that will be implemented by
15 the organization that reduce the disposal of plastic packaging
16 manufactured by the organization's members in a manner
17 consistent with the state's solid waste management hierarchy,
18 including, but not limited to, source reduction, source separation
19 and processing to segregate and recover recyclable materials, and
20 environmentally sound management of materials that cannot
21 feasibly be recycled.

22 (d) Include a funding mechanism consistent with subdivision
23 (b) of Section 42371.2.

24 (e) Include a process by which the financial activities of the
25 plastic packaging stewardship organization that are related to
26 implementation of the plastic packaging stewardship plan will be
27 subject to an independent audit.

28 42371.2. Manufacturers of one or more than one particular
29 type of plastic packaging may form an organization known as a
30 plastic packaging stewardship organization. A plastic packaging
31 stewardship organization may address a stewardship plan to more
32 than one type of plastic packaging only if all of the manufacturers
33 of that organization manufacture all of the types of plastic
34 packaging to be covered by the plan. A plastic packaging
35 stewardship organization shall do all of the following:

36 (a) Prepare a plastic packaging stewardship plan that meets the
37 requirements of Section 42371.

38 (b) Establish a funding mechanism, consistent with Article 4
39 (commencing with Section 42374), that provides sufficient funding
40 to carry out the plastic packaging stewardship plan, including the

1 administrative, operational, and capital costs of the plan, payment
2 of fees pursuant to Section 42374.6, and incentive payments that
3 will advance the purposes of this chapter.

4 (e) ~~Set the plastic packaging stewardship fee in accordance
5 with Article 4 (commencing with Section 42374).~~

6 (d) ~~Determine the projects and programs to be funded by the
7 plastic packaging stewardship fee collected pursuant to Section
8 42374.4.~~

9
10 Article 3. Food Service Plastic Packaging Recycling Program

11
12 ~~42372. (a) A city, county, or city and county may establish
13 and implement a residential curbside collection program pursuant
14 to this article for the collection and recycling of a particular type
15 of plastic packaging. If a city, county, or city and county establishes
16 and implements a residential curbside collection program, the city,
17 county, or city and county shall notify the department for purposes
18 of tracking community access rates to residential curbside
19 collection programs for each particular type of plastic packaging.~~

20 (b) ~~To help ensure statewide consistency, the department may
21 collaborate with any city, county, or city and county on the
22 establishment and implementation of a residential curbside
23 collection program for a particular type of plastic packaging, and
24 may develop a list that identifies by resin code the particular types
25 of plastic packaging materials accepted for recycling by each
26 program.~~

27 ~~42372.2. (a) A residential curbside collection program
28 established pursuant to this article shall include the following
29 requirements:~~

30 (1) ~~Postconsumer untreated plastic packaging that is collected
31 as part of a residential curbside collection program for a particular
32 type of plastic packaging shall be transported only to a facility
33 where it is feasible to recycle that type of plastic packaging or to
34 a material recovery facility for the purpose of sorting that particular
35 type of plastic packaging before recycling.~~

36 (2) ~~A material recovery facility that receives material from a
37 residential curbside collection program for a particular type of
38 plastic packaging that is unable to separate at least 75 percent of
39 that particular type of plastic packaging from the mixture of solid
40 waste and recyclable materials collected in the residential curbside~~

1 collection program shall send its residual material to a secondary
2 sorting facility if the secondary sorting facility is reasonably
3 available and willing to accept the residual material.

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

5 (1) “Reasonably available” means available at a cost, including
6 the cost of transporting the residual material and any fee charged
7 by the secondary sorting facility receiving the material, that does
8 not exceed the cost of transporting the residual material to a landfill
9 and disposing of the material at that landfill.

10 (2) “Residual material” means any material collected through
11 a residential curbside collection program by, or material delivered
12 through a drop-off program to, a material recovery facility that
13 remains after processing by the material recovery facility.
14 “Processing” means the removal of recyclable material from other
15 material to the extent a material recovery facility is equipped to
16 do so.

17 (3) “Secondary sorting facility” means a facility equipped to
18 sort a particular type of plastic packaging from other recyclable
19 material and solid waste in residual material.

20 (e) The department shall adopt regulations establishing a
21 mechanism by which the department will resolve disputes regarding
22 whether a secondary sorting facility is reasonably available and
23 under what circumstances the department may direct a residential
24 curbside collection program, a recycling facility, or a solid waste
25 facility to transfer residual material containing plastic packaging
26 to a secondary sorting facility in order to further the purposes of
27 this act.

28 42372.4. (a) On and before January 1, 2023, each plastic
29 packaging stewardship organization shall make reasonable efforts
30 to achieve a 15-percent rate of community access to residential
31 curbside collection programs for each type of plastic packaging
32 covered by the organization.

33 (b) On and before January 1, 2028, each plastic packaging
34 stewardship organization shall make reasonable efforts to achieve
35 a 30-percent rate of community access to residential curbside
36 collection programs for each type of plastic packaging covered by
37 the organization.

38 (c) On and before January 1, 2033, each plastic packaging
39 stewardship organization shall make reasonable efforts to achieve
40 a 45-percent rate of community access to residential curbside

1 collection programs for each type of plastic packaging covered by
2 the organization.

3 ~~(d) On and before January 1, 2038, each plastic packaging~~
4 ~~stewardship organization shall make reasonable efforts to achieve~~
5 ~~a 60-percent rate of community access to residential curbside~~
6 ~~collection programs for each type of plastic packaging covered by~~
7 ~~the organization.~~

8 ~~(e) On and before January 1, 2043, each plastic packaging~~
9 ~~stewardship organization shall make reasonable efforts to achieve~~
10 ~~a 75-percent rate of community access to residential curbside~~
11 ~~collection programs for each type of plastic packaging covered by~~
12 ~~the organization.~~

13
14 **Article 4. Plastic Packaging Stewardship Fees and**
15 **Administrative Fees**

16
17 ~~42374. Each plastic packaging stewardship organization shall~~
18 ~~establish a plastic packaging stewardship fee for each particular~~
19 ~~type of plastic packaging covered by the organization, to be paid~~
20 ~~by members of the organization based on the amount of that~~
21 ~~particular type of plastic packaging of each member that is covered.~~
22 ~~The plastic packaging stewardship fee shall be calculated on a per~~
23 ~~pound basis by type of plastic packaging as follows:~~

24 ~~(a) For each type of plastic packaging, if manufactured in the~~
25 ~~state, the organization member shall pay the applicable amount~~
26 ~~for its plastic packaging to be sold or used in the state.~~

27 ~~(b) For each type plastic packaging, if manufactured out of state,~~
28 ~~the organization member shall pay the applicable amount for plastic~~
29 ~~packaging introduced into the state by the organization member.~~

30 ~~42374.2. Each plastic packaging stewardship organization shall~~
31 ~~determine the rules and procedures that are necessary and proper~~
32 ~~to implement the collection of the charge in a fair, efficient, and~~
33 ~~lawful manner.~~

34 ~~42374.4. The plastic packaging stewardship fee for each~~
35 ~~particular type of plastic packaging shall be collected by a plastic~~
36 ~~packaging stewardship organization and deposited in accounts,~~
37 ~~segregated by the type of plastic packaging, that are maintained~~
38 ~~and disbursed by the organization. Moneys collected pursuant to~~
39 ~~this article shall be used by a plastic packaging stewardship~~
40 ~~organization only for purposes of carrying out its duties under this~~

1 chapter and for appropriate projects and programs that would
2 further the efforts to recycle the particular type of plastic packaging
3 for which the moneys were collected, pursuant to the plastic
4 packaging stewardship plan. Those projects or programs may
5 include, but are not limited to, investments in infrastructure that
6 promote the recycling of the particular type of plastic packaging
7 for which the moneys were collected, pursuant to the plastic
8 packaging stewardship plan.

9 42374.6. (a) A plastic packaging stewardship organization
10 submitting a plastic packaging stewardship plan shall pay the
11 department a quarterly administrative fee. The department shall
12 set the fee at an amount that, when paid by every plastic packaging
13 stewardship organization that submits a plastic packaging
14 stewardship plan, is adequate to cover the department's full costs
15 of administering and enforcing this chapter, including any program
16 development costs or regulatory costs incurred by the department
17 prior to plastic packaging stewardship plans being submitted. The
18 department may establish a variable fee based on relevant factors,
19 including, but not limited to, the portion of a particular type of
20 plastic packaging sold in the state by members of the organization
21 compared to the total amount of the same type of plastic packaging
22 sold in the state by all organizations submitting a plastic packaging
23 stewardship plan.

24 (b) The total amount of fees collected annually pursuant to this
25 section shall not exceed the amount necessary to recover costs
26 incurred by the department in connection with the administration
27 and enforcement of the requirements of this chapter.

28 (c) The department shall identify the direct development or
29 regulatory costs it incurs pursuant to this chapter prior to the
30 submittal of a plastic packaging stewardship plan and shall
31 establish a fee in an amount adequate to cover those costs, which
32 shall be paid by a plastic packaging stewardship organization that
33 submits a plastic packaging stewardship plan. The fee established
34 pursuant to this subdivision shall be paid pursuant to the schedule
35 specified in subdivision (d).

36 (d) A plastic packaging stewardship organization subject to this
37 section shall pay a quarterly fee to the department to cover the
38 administrative and enforcement costs of the requirements of this
39 chapter pursuant to subdivision (a) on or before July 1, 2019, and
40 every three months thereafter. The plastic packaging stewardship

1 organization shall pay the applicable portion of the fee pursuant
2 to subdivision (c) on July 1, 2019, and every three months
3 thereafter through July 1, 2043. After the initial year of payment,
4 the total amount of the administrative fees paid for a calendar year
5 shall not exceed 5 percent of the total amount of stewardship fees
6 collected for the preceding calendar year.

7 (e) The department shall deposit the fees collected pursuant to
8 this section into the Plastic Packaging Stewardship Account created
9 pursuant to Section 42377.

10
11 Article 5. Member Reporting

12
13 ~~42375.~~ (a) Each plastic packaging stewardship organization
14 shall submit annual reports on their efforts to recycle plastic
15 packaging to the department. A plastic packaging stewardship
16 organization submitting an annual report on behalf of its members
17 shall identify the individual members of the organization but is
18 not required to distinguish the individual recycling efforts of its
19 members.

20 (b) A member of a plastic packaging stewardship organization
21 shall be considered in compliance with this section with regards
22 to the types of plastic packaging covered by the organization if
23 the plastic packaging stewardship organization of which it is a
24 member submits a report.

25
26 Article 6. Enforcement

27
28 ~~42376.~~ (a) A civil penalty up to one thousand dollars (\$1,000)
29 per day may be administratively imposed by the department on
30 any person who is in violation of any provision of this chapter, or
31 up to ten thousand dollars (\$10,000) per day if the violation is
32 intentional, knowing, or negligent.

33 (b) In assessing or reviewing the amount of a civil penalty
34 imposed pursuant to subdivision (a) for a violation of this chapter,
35 the department or the court shall consider all of the following:

- 36 (1) The nature and extent of the violation.
37 (2) The number and severity of the violation or violations.
38 (3) The economic effect of the penalty on the violator.

- 1 ~~(4) Whether the violator took good faith measures to comply~~
- 2 ~~with this chapter and the period of time over which these measures~~
- 3 ~~were taken.~~
- 4 ~~(5) The willfulness of the violator’s misconduct.~~
- 5 ~~(6) The deterrent effect that the imposition of the penalty would~~
- 6 ~~have on both the violator and the regulated community.~~
- 7 ~~(7) Any other factor that justice may require.~~

8
9 ~~Article 7. Financial Provisions~~

10
11 ~~42377. (a) The Plastic Packaging Stewardship Account and~~

12 ~~the Plastic Packaging Stewardship Penalty Subaccount are hereby~~

13 ~~established in the Integrated Waste Management Fund.~~

14 ~~(b) All fees collected by the department pursuant to this article~~

15 ~~shall be deposited in the Plastic Packaging Stewardship Account~~

16 ~~and may be expended by the department, upon appropriation by~~

17 ~~the Legislature, to cover the department’s costs to implement this~~

18 ~~chapter.~~

19 ~~(c) All civil penalties collected pursuant to this article shall be~~

20 ~~deposited in the Plastic Packaging Stewardship Penalty Subaccount~~

21 ~~and may be expended by the department, upon appropriation by~~

22 ~~the Legislature, to cover the department’s costs to implement this~~

23 ~~chapter.~~

24
25 ~~Article 8. Antitrust Immunity~~

26
27 ~~42378. (a) Except as provided in subdivision (b), an action~~

28 ~~relating to the establishment, administration, collection, or~~

29 ~~disbursement of the funds associated with implementation of this~~

30 ~~chapter that is taken by the plastic packaging stewardship~~

31 ~~organization or its members is not a violation of the Cartwright~~

32 ~~Act (Chapter 2 (commencing with Section 16700) of Part 2 of~~

- 1 ~~(1) Fixes a price of or for plastic packaging.~~
- 2 ~~(2) Fixes the output or production of plastic packaging.~~
- 3 ~~(3) Restricts the geographic area in which, or customers to~~
- 4 ~~whom, plastic packaging will be sold.~~

5 ~~SEC. 3. Section 43020.2 is added to the Public Resources Code,~~
6 ~~to read:~~

7 ~~43020.2. (a) A solid waste landfill that receives solid waste~~
8 ~~that contains plastic packaging material may landfill the plastic~~
9 ~~packaging material, but is encouraged to send solid waste~~
10 ~~containing plastic packaging material received to a material~~
11 ~~recovery facility, a secondary sorting facility, or a recycling facility~~
12 ~~that has the capability to sort, separate, or recycle plastic packaging~~
13 ~~material.~~

14 ~~(b) For purposes of this section, the definitions of Chapter 6~~
15 ~~(commencing with Section 42370) of Part 3 shall apply.~~

16 ~~SEC. 4. Section 43020.3 is added to the Public Resources Code,~~
17 ~~to read:~~

18 ~~43020.3. (a) A material recovery facility may send residual~~
19 ~~materials containing plastic packaging to a secondary sorting~~
20 ~~facility with the capability of sorting or separating plastic~~
21 ~~packaging material from the residual material for recycling.~~

22 ~~(b) For purposes of this section, the definitions of Chapter 6~~
23 ~~(commencing with Section 42370) of Part 3 shall apply.~~



Bill Number: AB 1751
Current Version: As Introduced January 3, 2018
Author: Low
Topic: Controlled Substances: CURES database
Staff Recommendation: Support

AFFECTED SECTIONS: Amend HSC sections 11165

STATUS: Referred to Assembly Business and Professions Committee

THIS BILL WOULD:

Allow the Department of Justice to enter into an agreement with another entity operating an interstate hub for allowing sharing of prescription drug monitoring information across state lines. Under the provisions of this measure, the interstate data sharing must meet all the patient privacy and data security measures of the CURES system.

STAFF COMMENTS:

The board is the originator of this measure. The board voted to pursue a statutory change to allow interstate data exchange of prescription drug monitoring programs during its November Board Meeting.

The board has a long history of supporting CURES and its use and has supported the concept of sharing prescription drug monitoring information across state lines.

BILL HISTORY:

01/16/2018	Referred to Coms. on B. & P. and PUB. S.
01/04/2018	From printer. May be heard in committee February 3.
01/03/2018	Read first time. To print.

ASSEMBLY BILL

No. 1751

Introduced by Assembly Member Low

January 3, 2018

An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1751, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

This bill would authorize the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines. The bill would require any agreement entered into by the Department of Justice for those purposes to ensure that all access to data within CURES complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11165 of the Health and Safety Code is
2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts
4 to ensure appropriate prescribing, ordering, administering,
5 furnishing, and dispensing of controlled substances, law
6 enforcement and regulatory agencies in their efforts to control the
7 diversion and resultant abuse of Schedule II, Schedule III, and
8 Schedule IV controlled substances, and for statistical analysis,
9 education, and research, the Department of Justice shall, contingent
10 upon the availability of adequate funds in the CURES Fund,
11 maintain the Controlled Substance Utilization Review and
12 Evaluation System (CURES) for the electronic monitoring of, and
13 Internet access to information regarding, the prescribing and
14 dispensing of Schedule II, Schedule III, and Schedule IV controlled
15 substances by all practitioners authorized to prescribe, order,
16 administer, furnish, or dispense these controlled substances.

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

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

25 (2) (A) CURES shall operate under existing provisions of law
26 to safeguard the privacy and confidentiality of patients. Data
27 obtained from CURES shall only be provided to appropriate state,
28 local, and federal public agencies for disciplinary, civil, or criminal
29 purposes and to other agencies or entities, as determined by the
30 Department of Justice, for the purpose of educating practitioners
31 and others in lieu of disciplinary, civil, or criminal actions. Data
32 may be provided to public or private entities, as approved by the
33 Department of Justice, for educational, peer review, statistical, or
34 research purposes, provided that patient information, including
35 any information that may identify the patient, is not compromised.
36 Further, data disclosed to any individual or agency as described
37 in this subdivision shall not be disclosed, sold, or transferred to
38 any third party, unless authorized by, or pursuant to, state and

1 federal privacy and security laws and regulations. The Department
2 of Justice shall establish policies, procedures, and regulations
3 regarding the use, access, evaluation, management, implementation,
4 operation, storage, disclosure, and security of the information
5 within CURES, consistent with this subdivision.

6 (B) Notwithstanding subparagraph (A), a regulatory board whose
7 licensees do not prescribe, order, administer, furnish, or dispense
8 controlled substances shall not be provided data obtained from
9 CURES.

10 (3) In accordance with federal and state privacy laws and
11 regulations, a health care practitioner may provide a patient with
12 a copy of the patient's CURES patient activity report as long as
13 no additional CURES data is provided and keep a copy of the
14 report in the patient's medical record in compliance with
15 subdivision (d) of Section 11165.1.

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

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

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

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

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

39 (5) Quantity of the controlled substance dispensed.

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

3 (7) Number of refills ordered.

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

6 (9) Date of origin of the prescription.

7 (10) Date of dispensing of the prescription.

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

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

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

28 (h) (1) *The Department of Justice may enter into an agreement*
29 *with an entity operating an interstate data share hub for purposes*
30 *of participating in interjurisdictional information sharing between*
31 *prescription drug monitoring programs across state lines.*

32 (2) *Any agreement entered into by the Department of Justice*
33 *for purposes of interstate data sharing shall ensure that all access*
34 *to data within CURES complies with California law and meets the*
35 *same patient privacy and data security standards employed and*
36 *required for direct access of CURES.*



Bill Number: AB 1752

Current Version: As Introduced January 3, 2018

Author: Low

Topic: Controlled Substances: CURES database

Staff Recommendation: Support

AFFECTED SECTIONS: Amend HSC sections 11165 & 11165.1

STATUS: Referred to Assembly Business and Professions Committee

CURRENT LAW:

Current law establishes the Controlled Substance Utilization Review and Evaluation System (CURES) to provide for a means of electronic monitoring of all prescribing and dispensing of schedule II – schedule IV controlled substances per the federal controlled substances schedule. The dispensing of such controlled drugs must be reported within seven work days after the drug has been dispensed.

THIS BILL WOULD:

Expand the requirements of CURES to also include the reporting of schedule V drugs, as well as any other drug identified by the board through regulation. Further, under the provisions of this measure, dispensing would be required to be reported within one working day and date of the sale of the drug would also be reported to the CURES system. The diagnosis code would no longer be required to be reported.

STAFF COMMENTS:

The board is the originator of some of the provisions included in this measure. During the board's November 2017 meeting, the board voted to pursue a statutory proposal that would expand CURES reporting to encompass schedule V drugs and other drugs of concern. Further the board voted to reduce the reporting time to CURES to the next business day.

BILL HISTORY:

01/16/2018	Referred to Coms. on B. & P. and PUB. S.
01/04/2018	From printer. May be heard in committee February 3.
01/03/2018	Read first time. To print.

ASSEMBLY BILL

No. 1752

Introduced by Assembly Member Low

January 3, 2018

An act to amend Sections 11165 and 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1752, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice as soon as reasonably possible, but not more than 7 days after the date a controlled substance is dispensed.

This bill would add Schedule V controlled substances to the CURES database. The bill would additionally authorize the California State Board of Pharmacy, through regulation, to add additional medications to be tracked in the CURES database. The bill would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed. The bill would change what

information is required to be reported by deleting references to classification codes and adding the date of sale of the prescription.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11165 of the Health and Safety Code is
2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts
4 to ensure appropriate prescribing, ordering, administering,
5 furnishing, and dispensing of controlled substances, law
6 enforcement and regulatory agencies in their efforts to control the
7 diversion and resultant abuse of Schedule II, Schedule III,~~and~~
8 ~~Schedule IV~~ IV, and Schedule V controlled substances, and for
9 statistical analysis, education, and research, the Department of
10 Justice shall, contingent upon the availability of adequate funds
11 in the CURES Fund, maintain the Controlled Substance Utilization
12 Review and Evaluation System (CURES) for the electronic
13 monitoring of, and Internet access to information regarding, the
14 prescribing and dispensing of Schedule II, Schedule III,~~and~~
15 ~~Schedule IV~~ IV, and Schedule V controlled substances by all
16 practitioners authorized to prescribe, order, administer, furnish, or
17 dispense these controlled substances. *The California State Board*
18 *of Pharmacy may add through regulation additional medications*
19 *determined to pose a substantial risk of abuse or diversion that*
20 *shall be tracked in CURES.*

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

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

29 (2) (A) CURES shall operate under existing provisions of law
30 to safeguard the privacy and confidentiality of patients. Data
31 obtained from CURES shall only be provided to appropriate state,
32 local, and federal public agencies for disciplinary, civil, or criminal
33 purposes and to other agencies or entities, as determined by the

1 Department of Justice, for the purpose of educating practitioners
2 and others in lieu of disciplinary, civil, or criminal actions. Data
3 may be provided to public or private entities, as approved by the
4 Department of Justice, for educational, peer review, statistical, or
5 research purposes, provided that patient information, including
6 any information that may identify the patient, is not compromised.
7 Further, data disclosed to any individual or agency as described
8 in this subdivision shall not be disclosed, sold, or transferred to
9 any third party, unless authorized by, or pursuant to, state and
10 federal privacy and security laws and regulations. The Department
11 of Justice shall establish policies, procedures, and regulations
12 regarding the use, access, evaluation, management, implementation,
13 operation, storage, disclosure, and security of the information
14 within CURES, consistent with this subdivision.

15 (B) Notwithstanding subparagraph (A), a regulatory board whose
16 licensees do not prescribe, order, administer, furnish, or dispense
17 controlled substances shall not be provided data obtained from
18 CURES.

19 (3) In accordance with federal and state privacy laws and
20 regulations, a health care practitioner may provide a patient with
21 a copy of the patient's CURES patient activity report as long as
22 no additional CURES data is provided and keep a copy of the
23 report in the patient's medical record in compliance with
24 subdivision (d) of Section 11165.1.

25 (d) For each prescription for a Schedule II, Schedule III, ~~or~~
26 ~~Schedule IV~~ *IV, or Schedule V* controlled substance, as defined in
27 the controlled substances schedules in federal law and regulations,
28 specifically Sections 1308.12, 1308.13, ~~and~~ 1308.14, *and 1308.15*,
29 respectively, of Title 21 of the Code of Federal Regulations, *and*
30 *for any additional medications of concern added by the California*
31 *State Board of Pharmacy through regulation*, the dispensing
32 pharmacy, clinic, or other dispenser shall report the following
33 information to the Department of Justice as soon as reasonably
34 possible, but not more than ~~seven days~~ *one working day* after the
35 date a controlled substance is dispensed, in a format specified by
36 the Department of Justice:

37 (1) Full name, address, and, if available, telephone number of
38 the ultimate user or research subject, or contact information as
39 determined by the Secretary of the United States Department of

- 1 Health and Human Services, and the gender, and date of birth of
- 2 the ultimate user.
- 3 (2) The prescriber’s category of licensure, license number,
- 4 national provider identifier (NPI) number, if applicable, the federal
- 5 controlled substance registration number, and the state medical
- 6 license number of any prescriber using the federal controlled
- 7 substance registration number of a government-exempt facility.
- 8 (3) Pharmacy prescription number, license number, NPI number,
- 9 and federal controlled substance registration number.
- 10 (4) National Drug Code (NDC) number of the controlled
- 11 substance dispensed.
- 12 (5) Quantity of the controlled substance dispensed.
- 13 ~~(6) International Statistical Classification of Diseases, 9th~~
- 14 ~~revision (ICD-9) or 10th revision (ICD-10) Code, if available.~~
- 15 ~~(7)~~
- 16 (6) Number of refills ordered.
- 17 ~~(8)~~
- 18 (7) Whether the drug was dispensed as a refill of a prescription
- 19 or as a first-time request.
- 20 ~~(9)~~
- 21 (8) Date of origin of the prescription.
- 22 ~~(10)~~
- 23 (9) Date of dispensing of the prescription.
- 24 (10) *Date of sale of the prescription.*
- 25 (e) The Department of Justice may invite stakeholders to assist,
- 26 advise, and make recommendations on the establishment of rules
- 27 and regulations necessary to ensure the proper administration and
- 28 enforcement of the CURES database. All prescriber and dispenser
- 29 invitees shall be licensed by one of the boards or committees
- 30 identified in subdivision (d) of Section 208 of the Business and
- 31 Professions Code, in active practice in California, and a regular
- 32 user of CURES.
- 33 (f) The Department of Justice shall, prior to upgrading CURES,
- 34 consult with prescribers licensed by one of the boards or
- 35 committees identified in subdivision (d) of Section 208 of the
- 36 Business and Professions Code, one or more of the boards or
- 37 committees identified in subdivision (d) of Section 208 of the
- 38 Business and Professions Code, and any other stakeholder
- 39 identified by the department, for the purpose of identifying

1 desirable capabilities and upgrades to the CURES Prescription
2 Drug Monitoring Program (PDMP).

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

6 SEC. 2. Section 11165.1 of the Health and Safety Code is
7 amended to read:

8 11165.1. (a) (1) (A) (i) A health care practitioner authorized
9 to prescribe, order, administer, furnish, or dispense Schedule II,
10 Schedule III,~~or~~ ~~Schedule IV~~, *or Schedule V* controlled
11 substances pursuant to Section 11150 shall, before July 1, 2016,
12 or upon receipt of a federal Drug Enforcement Administration
13 (DEA) registration, whichever occurs later, submit an application
14 developed by the department to obtain approval to electronically
15 access information regarding the controlled substance history of
16 a patient that is maintained by the department. Upon approval, the
17 department shall release to that practitioner the electronic history
18 of controlled substances dispensed to an individual under his or
19 her care based on data contained in the CURES Prescription Drug
20 Monitoring Program (PDMP).

21 (ii) A pharmacist shall, before July 1, 2016, or upon licensure,
22 whichever occurs later, submit an application developed by the
23 department to obtain approval to electronically access information
24 regarding the controlled substance history of a patient that is
25 maintained by the department. Upon approval, the department
26 shall release to that pharmacist the electronic history of controlled
27 substances dispensed to an individual under his or her care based
28 on data contained in the CURES PDMP.

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

32 (i) Materially falsifying an application to access information
33 contained in the CURES database.

34 (ii) Failing to maintain effective controls for access to the patient
35 activity report.

36 (iii) Having his or her federal DEA registration suspended or
37 revoked.

38 (iv) Violating a law governing controlled substances or any
39 other law for which the possession or use of a controlled substance
40 is an element of the crime.

1 (v) Accessing information for a reason other than to diagnose
2 or treat his or her patients, or to document compliance with the
3 law.

4 (C) An authorized subscriber shall notify the department within
5 30 days of any changes to the subscriber account.

6 (D) Commencing no later than October 1, 2018, an approved
7 health care practitioner, pharmacist, and any person acting on
8 behalf of a health care practitioner or pharmacist pursuant to
9 subdivision (b) of Section 209 of the Business and Professions
10 Code may use the department's online portal or a health
11 information technology system that meets the criteria required in
12 subparagraph (E) to access information in the CURES database
13 pursuant to this section. A subscriber who uses a health information
14 technology system that meets the criteria required in subparagraph
15 (E) to access the CURES database may submit automated queries
16 to the CURES database that are triggered by predetermined criteria.

17 (E) Commencing no later than October 1, 2018, an approved
18 health care practitioner or pharmacist may submit queries to the
19 CURES database through a health information technology system
20 if the entity that operates the health information technology system
21 can certify all of the following:

22 (i) The entity will not use or disclose data received from the
23 CURES database for any purpose other than delivering the data
24 to an approved health care practitioner or pharmacist or performing
25 data processing activities that may be necessary to enable the
26 delivery unless authorized by, and pursuant to, state and federal
27 privacy and security laws and regulations.

28 (ii) The health information technology system will authenticate
29 the identity of an authorized health care practitioner or pharmacist
30 initiating queries to the CURES database and, at the time of the
31 query to the CURES database, the health information technology
32 system submits the following data regarding the query to CURES:

33 (I) The date of the query.

34 (II) The time of the query.

35 (III) The first and last name of the patient queried.

36 (IV) The date of birth of the patient queried.

37 (V) The identification of the CURES user for whom the system
38 is making the query.

1 (iii) The health information technology system meets applicable
2 patient privacy and information security requirements of state and
3 federal law.

4 (iv) The entity has entered into a memorandum of understanding
5 with the department that solely addresses the technical
6 specifications of the health information technology system to
7 ensure the security of the data in the CURES database and the
8 secure transfer of data from the CURES database. The technical
9 specifications shall be universal for all health information
10 technology systems that establish a method of system integration
11 to retrieve information from the CURES database. The
12 memorandum of understanding shall not govern, or in any way
13 impact or restrict, the use of data received from the CURES
14 database or impose any additional burdens on covered entities in
15 compliance with the regulations promulgated pursuant to the
16 federal Health Insurance Portability and Accountability Act of
17 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal
18 Regulations.

19 (F) No later than October 1, 2018, the department shall develop
20 a programming interface or other method of system integration to
21 allow health information technology systems that meet the
22 requirements in subparagraph (E) to retrieve information in the
23 CURES database on behalf of an authorized health care practitioner
24 or pharmacist.

25 (G) The department shall not access patient-identifiable
26 information in an entity's health information technology system.

27 (H) An entity that operates a health information technology
28 system that is requesting to establish an integration with the
29 CURES database shall pay a reasonable fee to cover the cost of
30 establishing and maintaining integration with the CURES database.

31 (I) The department may prohibit integration or terminate a health
32 information technology system's ability to retrieve information in
33 the CURES database if the health information technology system
34 fails to meet the requirements of subparagraph (E), or the entity
35 operating the health information technology system does not fulfill
36 its obligation under subparagraph (H).

37 (2) A health care practitioner authorized to prescribe, order,
38 administer, furnish, or dispense Schedule II, Schedule III, ~~or~~
39 ~~Schedule IV~~ *Schedule IV, or Schedule V* controlled substances pursuant to
40 Section 11150 or a pharmacist shall be deemed to have complied

1 with paragraph (1) if the licensed health care practitioner or
2 pharmacist has been approved to access the CURES database
3 through the process developed pursuant to subdivision (a) of
4 Section 209 of the Business and Professions Code.

5 (b) A request for, or release of, a controlled substance history
6 pursuant to this section shall be made in accordance with guidelines
7 developed by the department.

8 (c) In order to prevent the inappropriate, improper, or illegal
9 use of Schedule II, Schedule III, ~~or Schedule IV~~, or *Schedule*
10 *V* controlled substances, the department may initiate the referral
11 of the history of controlled substances dispensed to an individual
12 based on data contained in CURES to licensed health care
13 practitioners, pharmacists, or both, providing care or services to
14 the individual.

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

21 (e) Information concerning a patient's controlled substance
22 history provided to a practitioner or pharmacist pursuant to this
23 section shall include prescriptions for controlled substances listed
24 in Sections 1308.12, 1308.13, ~~and 1308.14~~ 1308.14, and 1308.15
25 of Title 21 of the Code of Federal Regulations.

26 (f) A health care practitioner, pharmacist, and any person acting
27 on behalf of a health care practitioner or pharmacist, when acting
28 with reasonable care and in good faith, is not subject to civil or
29 administrative liability arising from any false, incomplete,
30 inaccurate, or misattributed information submitted to, reported by,
31 or relied upon in the CURES database or for any resulting failure
32 of the CURES database to accurately or timely report that
33 information.

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

36 (1) "Automated basis" means using predefined criteria to trigger
37 an automated query to the CURES database, which can be
38 attributed to a specific health care practitioner or pharmacist.

39 (2) "Department" means the Department of Justice.

1 (3) “Entity” means an organization that operates, or provides
2 or makes available, a health information technology system to a
3 health care practitioner or pharmacist.

4 (4) “Health information technology system” means an
5 information processing application using hardware and software
6 for the storage, retrieval, sharing of or use of patient data for
7 communication, decisionmaking, coordination of care, or the
8 quality, safety, or efficiency of the practice of medicine or delivery
9 of health care services, including, but not limited to, electronic
10 medical record applications, health information exchange systems,
11 or other interoperable clinical or health care information system.

12 (5) “User-initiated basis” means an authorized health care
13 practitioner or pharmacist has taken an action to initiate the query
14 to the CURES database, such as clicking a button, issuing a voice
15 command, or taking some other action that can be attributed to a
16 specific health care practitioner or pharmacist.

O



Bill Number: AB 1753

Current Version: As Introduced January 3, 2018

Author: Low

Topic: Controlled Substances: CURES database

Staff Recommendation: Support

AFFECTED SECTIONS: Amend HSC sections 11161.5, 11162.1, and 11165

STATUS: Referred to Assembly Business and Professions Committee

CURRENT LAW:

Existing law requires controlled substances prescriptions to be written on prescription forms obtained from security printers approved by the Department of Justice (DOJ). Such forms must contain security features designed to prevent counterfeiting. Further, existing law establishes the required elements a dispenser must report to the CURES system.

THIS BILL WOULD:

1. Require the DOJ, beginning January 1, 2020, to limit the number of approved printers to three, consistent with policies that will be developed by DOJ.
2. Require security forms to include a unique serialized number.
3. Require the security printer to submit to the DOJ, via a web-based application, information including:
 - a. Serial numbers.
 - b. Prescribers names and DEA Controlled Substance Registration Certificate number.
 - c. Delivery shipment recipient name.
4. Require inclusion of the prescription serial number into the CURES reporting system.

STAFF COMMENTS:

During its January 2018 Board Meeting, the board discussed the issue of fraudulent security forms and how their use contributed to the opioid epidemic. After discussion, the board voted to pursue a statutory proposal to require e-prescribing while allowing for some exemptions.

This measure includes legislative findings regarding the use of paper prescription pads including a finding that until mandatory e-prescribing is established, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state. The board supports the transition to mandatory e-prescribing and will be pursuing legislation this year. AB 1753 appears to be consistent with the board's goals and provides for a transition period of enhanced accountability until an e-prescribing mandate can be implemented.

BILL HISTORY:

01/16/2018	Referred to Coms. on B. & P. and PUB. S.
01/04/2018	From printer. May be heard in committee February 3.
01/03/2018	Read first time. To print.

ASSEMBLY BILL

No. 1753

Introduced by Assembly Member Low

January 3, 2018

An act to amend Sections 11161.5, 11162.1, and 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1753, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the Department of Justice, as specified. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice.

This bill would, beginning January 1, 2020, require the Department of Justice to limit the number of approved printers to 3, as specified. The bill would require prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a manner prescribed by the Department of Justice, and would require a printer to submit specified information to the Department of Justice for all prescription forms delivered. The bill would require the information

submitted by a dispensing pharmacy, clinic, or other dispenser to the Department of Justice to include the serial number for the corresponding prescription pad, if applicable.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares the following:

2 (a) The prevailing use of paper prescription pads to prescribe
3 controlled substances leads to significant instances of theft and
4 fraud each year, contributing to the prescription drug abuse crisis
5 and fueling criminal enterprises engaged in drug diversion.

6 (b) Prescribing controlled substances by means of electronic
7 transmission prescription, or e-prescribing, has long been
8 considered the most effective way to combat prescription pad theft
9 and fraud.

10 (c) Many states have begun to require that all controlled
11 substances must be prescribed electronically as a means of
12 addressing the public health and public safety crises associated
13 with prescription drug abuse and diversion.

14 (d) Until mandatory e-prescribing is established in California,
15 it is critical that tighter restrictions be placed on the manufacturing
16 and tracking of prescription pads used within the state.

17 SEC. 2. Section 11161.5 of the Health and Safety Code is
18 amended to read:

19 11161.5. (a) Prescription forms for controlled substance
20 prescriptions shall be obtained from security printers approved by
21 the Department of Justice.

22 (b) The department may approve security printer applications
23 after the applicant has provided the following information:

24 (1) Name, address, and telephone number of the applicant.

25 (2) Policies and procedures of the applicant for verifying the
26 identity of the prescriber ordering controlled substance prescription
27 forms.

28 (3) Policies and procedures of the applicant for verifying
29 delivery of controlled substance prescription forms to prescribers.

30 (4) (A) The location, names, and titles of the applicant’s agent
31 for service of process in this state; all principal corporate officers,
32 if any; all managing general partners, if any; and any individual

1 owner, partner, corporate officer, manager, agent, representative,
2 employee, or subcontractor of the applicant who has direct access
3 to, or management or control of, controlled substance prescription
4 forms.

5 (B) A report containing this information shall be made on an
6 annual basis and within 30 days after any change of office,
7 principal corporate officers, managing general partner, or of any
8 person described in subparagraph (A).

9 (5) (A) A signed statement indicating whether the applicant,
10 any principal corporate officer, any managing general partner, or
11 any individual owner, partner, corporate officer, manager, agent,
12 representative, employee, or subcontractor of the applicant who
13 has direct access to, or management or control of, controlled
14 substance prescription forms, has ever been convicted of, or pled
15 no contest to, a violation of any law of a foreign country, the United
16 States, or any state, or of any local ordinance.

17 (B) The department shall provide the applicant and any
18 individual owner, partner, corporate officer, manager, agent,
19 representative, employee, or subcontractor of the applicant who
20 has direct access to, or management or control of, controlled
21 substance prescription forms, with the means and direction to
22 provide fingerprints and related information, in a manner specified
23 by the department, for the purpose of completing state, federal, or
24 foreign criminal background checks.

25 (C) Any applicant described in subdivision (b) shall submit his
26 or her fingerprint images and related information to the department,
27 for the purpose of the department obtaining information as to the
28 existence and nature of a record of state, federal, or foreign level
29 convictions and state, federal, or foreign level arrests for which
30 the department establishes that the applicant was released on bail
31 or on his or her own recognizance pending trial, as described in
32 subdivision (l) of Section 11105 of the Penal Code. Requests for
33 federal level criminal offender record information received by the
34 department pursuant to this section shall be forwarded to the
35 Federal Bureau of Investigation by the department.

36 (D) The department shall assess against each security printer
37 applicant a fee determined by the department to be sufficient to
38 cover all processing, maintenance, and investigative costs generated
39 from or associated with completing state, federal, or foreign
40 background checks and inspections of security printers pursuant

1 to this section with respect to that applicant; the fee shall be paid
2 by the applicant at the time he or she submits the security printer
3 application, fingerprints, and related information to the department.

4 (E) The department shall retain fingerprint impressions and
5 related information for subsequent arrest notification pursuant to
6 Section 11105.2 of the Penal Code for all applicants.

7 (c) The department may, within 60 calendar days of receipt of
8 the application from the applicant, deny the security printer
9 application.

10 (d) The department may deny a security printer application on
11 any of the following grounds:

12 (1) The applicant, any individual owner, partner, corporate
13 officer, manager, agent, representative, employee, or subcontractor
14 for the applicant, who has direct access, management, or control
15 of controlled substance prescription forms, has been convicted of
16 a crime. A conviction within the meaning of this paragraph means
17 a plea or verdict of guilty or a conviction following a plea of nolo
18 contendere. Any action which a board is permitted to take
19 following the establishment of a conviction may be taken when
20 the time for appeal has elapsed, the judgment of conviction has
21 been affirmed on appeal, or when an order granting probation is
22 made suspending the imposition of sentence, irrespective of a
23 subsequent order under the provisions of Section 1203.4 of the
24 Penal Code.

25 (2) The applicant committed any act involving dishonesty, fraud,
26 or deceit with the intent to substantially benefit himself, herself,
27 or another, or substantially injure another.

28 (3) The applicant committed any act that would constitute a
29 violation of this division.

30 (4) The applicant knowingly made a false statement of fact
31 required to be revealed in the application to produce controlled
32 substance prescription forms.

33 (5) The department determines that the applicant failed to
34 demonstrate adequate security procedures relating to the production
35 and distribution of controlled substance prescription forms.

36 (6) The department determines that the applicant has submitted
37 an incomplete application.

38 (7) As a condition for its approval as a security printer, an
39 applicant shall authorize the Department of Justice to make any
40 examination of the books and records of the applicant, or to visit

1 and inspect the applicant during business hours, to the extent
2 deemed necessary by the board or department to properly enforce
3 this section.

4 (e) An approved applicant shall submit an exemplar of a
5 controlled substance prescription form, with all security features,
6 to the Department of Justice within 30 days of initial production.

7 (f) The department shall maintain a list of approved security
8 printers and the department shall make this information available
9 to prescribers and other appropriate government agencies, including
10 the Board of Pharmacy.

11 (g) Before printing any controlled substance prescription forms,
12 a security printer shall verify with the appropriate licensing board
13 that the prescriber possesses a license and current prescribing
14 privileges which permits the prescribing of controlled substances
15 with the federal Drug Enforcement Administration (DEA).

16 (h) Controlled substance prescription forms shall be provided
17 directly to the prescriber either in person, by certified mail, or by
18 a means that requires a signature signifying receipt of the package
19 and provision of that signature to the security printer. Controlled
20 substance prescription forms provided in person shall be restricted
21 to established customers. Security printers shall obtain a photo
22 identification from the customer and maintain a log of this
23 information. Controlled substance prescription forms shall be
24 shipped only to the prescriber's address on file and verified with
25 the federal Drug Enforcement Administration or the Medical Board
26 of California.

27 (i) Security printers shall retain ordering and delivery records
28 in a readily retrievable manner for individual prescribers for three
29 years.

30 (j) Security printers shall produce ordering and delivery records
31 upon request by an authorized officer of the law as defined in
32 Section 4017 of the Business and Professions Code.

33 (k) Security printers shall report any theft or loss of controlled
34 substance prescription forms to the Department of Justice via fax
35 or e-mail within 24 hours of the theft or loss.

36 (l) (1) The department shall impose restrictions, sanctions, or
37 penalties, subject to subdivisions (m) and (n), against security
38 printers who are not in compliance with this division pursuant to
39 regulations implemented pursuant to this division and shall revoke
40 its approval of a security printer for a violation of this division or

1 action that would permit a denial pursuant to subdivision (d) of
2 this section.

3 (2) When the department revokes its approval, it shall notify
4 the appropriate licensing boards and remove the security printer
5 from the list of approved security printers.

6 (m) The following violations by security printers shall be
7 punishable pursuant to subdivision (n):

8 (1) Failure to comply with the Security Printer Guidelines
9 established by the Security Printer Program as a condition of
10 approval.

11 (2) Failure to take reasonable precautions to prevent any
12 dishonest act or illegal activity related to the access and control of
13 security prescription forms.

14 (3) Theft or fraudulent use of a prescriber's identity in order to
15 obtain security prescription forms.

16 (n) A security printer approved pursuant to subdivision (b) shall
17 be subject to the following penalties for actions leading to the
18 denial of a security printer application specified in subdivision (d)
19 or for a violation specified in subdivision (m):

20 (1) For a first violation, a fine not to exceed one thousand dollars
21 (\$1,000).

22 (2) For a second or subsequent violation, a fine not to exceed
23 two thousand five hundred dollars (\$2,500) for each violation.

24 (3) For a third or subsequent violation, a filing of an
25 administrative disciplinary action seeking to suspend or revoke
26 security printer approval.

27 (o) *Beginning January 1, 2020, the Department of Justice shall*
28 *limit the number of approved printers to three. The Department*
29 *of Justice shall establish policies governing the selection of the*
30 *three approved vendors based on ability to meet demand and*
31 *prevent fraud and theft of prescription pads and the process of*
32 *revoking approval for currently authorized printers in excess of*
33 *three.*

34 SEC. 3. Section 11162.1 of the Health and Safety Code is
35 amended to read:

36 11162.1. (a) The prescription forms for controlled substances
37 shall be printed with the following features:

38 (1) A latent, repetitive "void" pattern shall be printed across the
39 entire front of the prescription blank; if a prescription is scanned

1 or photocopied, the word “void” shall appear in a pattern across
2 the entire front of the prescription.

3 (2) A watermark shall be printed on the backside of the
4 prescription blank; the watermark shall consist of the words
5 “California Security Prescription.”

6 (3) A chemical void protection that prevents alteration by
7 chemical washing.

8 (4) A feature printed in thermochromic ink.

9 (5) An area of opaque writing so that the writing disappears if
10 the prescription is lightened.

11 (6) A description of the security features included on each
12 prescription form.

13 (7) (A) Six quantity check off boxes shall be printed on the
14 form so that the prescriber may indicate the quantity by checking
15 the applicable box where the following quantities shall appear:

16 1–24

17 25–49

18 50–74

19 75–100

20 101–150

21 151 and over.

22 (B) In conjunction with the quantity boxes, a space shall be
23 provided to designate the units referenced in the quantity boxes
24 when the drug is not in tablet or capsule form.

25 (8) Prescription blanks shall contain a statement printed on the
26 bottom of the prescription blank that the “Prescription is void if
27 the number of drugs prescribed is not noted.”

28 (9) The preprinted name, category of licensure, license number,
29 federal controlled substance registration number, and address of
30 the prescribing practitioner.

31 (10) Check boxes shall be printed on the form so that the
32 prescriber may indicate the number of refills ordered.

33 (11) The date of origin of the prescription.

34 (12) A check box indicating the prescriber’s order not to
35 substitute.

36 (13) An identifying number assigned to the approved security
37 printer by the Department of Justice.

38 (14) (A) A check box by the name of each prescriber when a
39 prescription form lists multiple prescribers.

1 (B) Each prescriber who signs the prescription form shall
2 identify himself or herself as the prescriber by checking the box
3 by his or her name.

4 (15) (A) *A uniquely serialized number, in a manner prescribed*
5 *by the Department of Justice.*

6 (B) *Within the next working day following delivery, a security*
7 *printer shall submit via Web-based application, as specified by*
8 *the Department of Justice, all of the following information for all*
9 *prescription forms delivered:*

10 (i) *Serial numbers of all prescription forms delivered.*

11 (ii) *All prescriber names and Drug Enforcement Administration*
12 *Controlled Substance Registration Certificate numbers displayed*
13 *on the prescription forms.*

14 (iii) *The delivery shipment recipient names.*

15 (b) Each batch of controlled substance prescription forms shall
16 have the lot number printed on the form and each form within that
17 batch shall be numbered sequentially beginning with the numeral
18 one.

19 (c) (1) A prescriber designated by a licensed health care facility,
20 a clinic specified in Section 1200, or a clinic specified in
21 subdivision (a) of Section 1206 that has 25 or more physicians or
22 surgeons may order controlled substance prescription forms for
23 use by prescribers when treating patients in that facility without
24 the information required in paragraph (9) of subdivision (a) or
25 paragraph (3) of this subdivision.

26 (2) Forms ordered pursuant to this subdivision shall have the
27 name, category of licensure, license number, and federal controlled
28 substance registration number of the designated prescriber and the
29 name, address, category of licensure, and license number of the
30 licensed health care facility the clinic specified in Section 1200,
31 or the clinic specified in Section 1206 that has 25 or more
32 physicians or surgeons preprinted on the form. Licensed health
33 care facilities or clinics exempt under Section 1206 are not required
34 to preprint the category of licensure and license number of their
35 facility or clinic.

36 (3) Forms ordered pursuant to this section shall not be valid
37 prescriptions without the name, category of licensure, license
38 number, and federal controlled substance registration number of
39 the prescriber on the form.

1 (4) (A) Except as provided in subparagraph (B), the designated
2 prescriber shall maintain a record of the prescribers to whom the
3 controlled substance prescription forms are issued, that shall
4 include the name, category of licensure, license number, federal
5 controlled substance registration number, and quantity of controlled
6 substance prescription forms issued to each prescriber. The record
7 shall be maintained in the health facility for three years.

8 (B) Forms ordered pursuant to this subdivision that are printed
9 by a computerized prescription generation system shall not be
10 subject to subparagraph (A) or paragraph (7) of subdivision (a).
11 Forms printed pursuant to this subdivision that are printed by a
12 computerized prescription generation system may contain the
13 prescriber's name, category of professional licensure, license
14 number, federal controlled substance registration number, and the
15 date of the prescription.

16 (d) This section shall become operative on January 1, 2012.
17 Prescription forms not in compliance with this division shall not
18 be valid or accepted after July 1, 2012.

19 SEC. 4. Section 11165 of the Health and Safety Code is
20 amended to read:

21 11165. (a) To assist health care practitioners in their efforts
22 to ensure appropriate prescribing, ordering, administering,
23 furnishing, and dispensing of controlled substances, law
24 enforcement and regulatory agencies in their efforts to control the
25 diversion and resultant abuse of Schedule II, Schedule III, and
26 Schedule IV controlled substances, and for statistical analysis,
27 education, and research, the Department of Justice shall, contingent
28 upon the availability of adequate funds in the CURES Fund,
29 maintain the Controlled Substance Utilization Review and
30 Evaluation System (CURES) for the electronic monitoring of, and
31 Internet access to information regarding, the prescribing and
32 dispensing of Schedule II, Schedule III, and Schedule IV controlled
33 substances by all practitioners authorized to prescribe, order,
34 administer, furnish, or dispense these controlled substances.

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

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

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

23 (B) Notwithstanding subparagraph (A), a regulatory board whose
24 licensees do not prescribe, order, administer, furnish, or dispense
25 controlled substances shall not be provided data obtained from
26 CURES.

27 (3) In accordance with federal and state privacy laws and
28 regulations, a health care practitioner may provide a patient with
29 a copy of the patient's CURES patient activity report as long as
30 no additional CURES data is provided and keep a copy of the
31 report in the patient's medical record in compliance with
32 subdivision (d) of Section 11165.1.

33 (d) For each prescription for a Schedule II, Schedule III, or
34 Schedule IV controlled substance, as defined in the controlled
35 substances schedules in federal law and regulations, specifically
36 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21
37 of the Code of Federal Regulations, the dispensing pharmacy,
38 clinic, or other dispenser shall report the following information to
39 the Department of Justice as soon as reasonably possible, but not

1 more than seven days after the date a controlled substance is
2 dispensed, in a format specified by the Department of Justice:

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

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

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

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

17 (5) Quantity of the controlled substance dispensed.

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

20 (7) Number of refills ordered.

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

23 (9) Date of origin of the prescription.

24 (10) Date of dispensing of the prescription.

25 (11) *The serial number for the corresponding prescription pad,*
26 *if applicable.*

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

35 (f) The Department of Justice shall, prior to upgrading CURES,
36 consult with prescribers licensed by one of the boards or
37 committees identified in subdivision (d) of Section 208 of the
38 Business and Professions Code, one or more of the boards or
39 committees identified in subdivision (d) of Section 208 of the
40 Business and Professions Code, and any other stakeholder

- 1 identified by the department, for the purpose of identifying
- 2 desirable capabilities and upgrades to the CURES Prescription
- 3 Drug Monitoring Program (PDMP).
- 4 (g) The Department of Justice may establish a process to educate
- 5 authorized subscribers of the CURES PDMP on how to access and
- 6 use the CURES PDMP.



Bill Number: AB 710

Current Version: As Amended January 18, 2018

Author: Wood

Topic: Cannabidiol

Staff Recommendation: None

AFFECTED SECTIONS: Add BPC section 26002 and Add HSC 11150.2

STATUS: Referred to Senate

CURRENT LAW:

- Establishes the California Uniform Controlled Substances Act that classifies controlled substances into five schedules. Cannabidiol is a compound contained in cannabis and is included as a schedule I controlled substance.
- Federal law also establishes a federal Controlled Substances Act that classifies controlled substances into five schedules. (While similar, variances occur between the federal and state schedule.)

THIS BILL WOULD:

Notwithstanding current state law, allow for the prescribing and dispensing of products composed of cannabidiol if the product is approved by the FDA and placed in a schedule other than schedule I or exempted from the federal Controlled Substances Act.

STAFF COMMENTS:

This measure is like AB 845 that was introduced last year. The board established a neutral position on that measure.

Also, as part of the board’s action during its January 2018 Board Meeting, the board voted to pursue a statutory proposal to reconcile the variances between the state and federal controlled substances schedules. Based on counsel’s review of this measure, it appears that some amendments may need to be offered to address a possible conflict between the two proposals.

BILL HISTORY:

01/18/2018	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.
06/19/2017	In committee: Set, first hearing. Hearing canceled at the request of author.
06/06/2017	In committee: Hearing postponed by committee.
05/24/2017	Referred to Com. on B., P. & E.D.
05/11/2017	Read third time. Passed. Ordered to the Senate. (Ayes 77. Noes 0. Page 1488.) In

	Senate. Read first time. To Com. on RLS. for assignment.
05/04/2017	Read second time. Ordered to Consent Calendar.
05/03/2017	From committee: Do pass. To Consent Calendar. (Ayes 16. Noes 0.) (May 3).
05/01/2017	Re-referred to Com. on APPR.
04/27/2017	From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
04/19/2017	From committee: Do pass and re-refer to Com. on APPR. (Ayes 14. Noes 0.) (April 18). Re-referred to Com. on APPR.
03/28/2017	Re-referred to Com. on B. & P.
03/27/2017	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
03/23/2017	Referred to Com. on B. & P.
02/16/2017	From printer. May be heard in committee March 18.
02/15/2017	Read first time. To print.

AB 710 - (A) Amends the Law

SECTION 1. The Legislature finds and declares that both children and adults with epilepsy are in desperate need of new treatment options and that cannabidiol has shown potential as an effective treatments option. If federal laws prohibiting the prescription of medications composed of cannabidiol are repealed or if an exception from the general prohibition is enacted permitting the prescription of drugs composed of cannabidiol, patients should have rapid access to this treatment option. The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities currently available under state law.

SEC. 2. *Section 26002 is added to the Business and Professions Code, to read:*

26002. This division shall not apply to any product containing cannabidiol that has been approved by the federal Food and Drug Administration that has either been placed on a schedule of the federal Controlled Substances Act other than Schedule I or has been exempted from one or more provisions of that act, and that is intended for prescribed use for the treatment of a medical condition.

SEC. 3. *Section 11150.2 is added to the Health and Safety Code, to read:*

11150.2. (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

(b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.

SEC. 4. 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 California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that patients are able to obtain access to a new treatment modality as soon as federal law makes it available, it is necessary that this act take effect immediately.

Attachment 3

1. Proposed Regulations to Amend Title 16 CCR section 1749 Related to the Board's Fee Schedule

Timeline:

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: November 4, 2016

Rulemaking Initiated: April 14, 2017

Adopted by Board: July 26, 2017

Submitted to DCA: October 10, 2017

Summary of Regulation:

This regulation updates the board's fee schedule to incorporate changes made to pharmacy law in Business and Professions Code section 4400 on July 1, 2017.

Attachment 4

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors

Timeline:

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the Board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

Summary of Regulation:

This regulation establishes the regulatory framework for third-party logistics providers.

2. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Timeline:

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the Board on: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 21, 2017

Summary of Regulation:

This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

3. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Timeline:

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

4. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Timeline:

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Timeline:

Approved by Board: October 27, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

Returned to the Board on: March 28, 2017

Summary of Regulation:

This regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

6. Proposed Regulations to Add Title 16 CCR section 1717.5 Related to Automatic Refill Programs

Timeline:

Approved by Board: May 3, 2017

Submitted to DCA for Pre-Notice Review: November 7, 2017

Summary of Regulation:

This regulation establishes regulatory requirements for automated refill programs.

7. Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Timeline:

Approved by Board: July 25, 2017

Submitted to DCA for Pre-Notice Review: November 20, 2017

Summary of Regulation:

This regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system.

**Third-Party Logistics
Providers and
Dangerous Drug
Distributors
§§ 1780-1783**

Title 16. Board of Pharmacy

Proposed Language

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

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

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

1780. Minimum Standards for ~~Wholesalers~~.

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

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision) official compendium.
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.
- (d) All materials must be examined upon receipt and/or before shipment.
 - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
 - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
 - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
 - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
 - (1) ~~Each W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security,

storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

- (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
 - (3) ~~Each~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
 - (4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

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

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

1781. ~~Exemption Certificate~~ Designated Representative.

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

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

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

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each ~~manufacturers, and~~ wholesalers and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

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

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

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

- (a) A manufacturer, ~~or wholesaler or third-party logistics provider~~ shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or wholesaler, or third-party logistics provider~~ shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler or third-party logistics provider~~ furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler or third-party logistics provider~~ shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler or third-party logistics provider~~ may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler or third-party logistics provider~~ if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler or third-party logistics provider~~ by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler or third-party logistics provider~~ shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
- (e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler or third-party logistics provider~~ to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler or third-party logistics provider~~ shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

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

Pharmacy Technician

**16 CCR § 1793.5,
1793.6, and 1793.65**

Title 16. Board of Pharmacy Proposed Regulation

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

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

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 144, 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 ~~and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202

(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(~~±~~ A) Knowledge and understanding of different pharmacy practice settings.

(2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3 C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

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

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

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

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

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine acceptance into the course of training or appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the following pharmacy technician certification programs until January 1, 2021:

(1) Pharmacy Technician Certification Board, and

(2) National Healthcareer Association's Examination for the Certification of Pharmacy Technicians Program.

(b) Approval of these programs is valid through December 31, 2020.

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

Offsite Storage

16 CCR § 1707

Proposal to Amend 16 CCR § 1707

§ 1707. Waiver Requirements for Off-Site Storage of Records.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Naloxone Fact Sheet

16 CCR § 1746.3

BOARD OF PHARMACY

Proposal to amend § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or substantively similar fact sheet approved by the executive officer. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

**Pharmacy Ownership,
Management, and
Control, Including
Through Trusts
16 CCR § 1709**

**Title 16. Board of Pharmacy
Proposed Text**

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

§1709. Names of Owners and Pharmacist In Charge Disclosure and Notification Requirements

- (a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership (~~individual, partnership or corporation~~) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.
- (b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a transfer of ~~permit~~ license and require application for a change of ownership: any transfer of a of the beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.
- (d) The board may issue, or renew, a license to an entity that is controlled by a revocable or irrevocable trust that meets the requirements of this subsection.
- (1) In addition to the requirements in (a), as part of its application and during its annual renewal, the entity shall also report the name of any other person in any position with management or control of the pharmacy.

- (2) An applicant shall disclose the full name of the trust, and shall provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.
- (3) An applicant shall disclose as part of its application and during its annual renewal the name, address and contact information for each grantor, settlor, trustee, trust protector, as applicable. In addition, the applicant shall disclose the name, address and contact information for each beneficiary named in the trust that is age 18 or greater.
- (4) The licensee, or any person with management or control of the pharmacy, shall notify the board in writing within 30 days of all the following:
- (A) A change in the trustee, protector or any other person with management or control of the pharmacy.
 - (B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.
 - (C) The revocation of the trust.
 - (D) The dissolution of the trust.
 - (E) Any amendment(s) to the trust since the original application.
- (e) An applicant or licensee may be denied, suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4058, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4144, 4149, 4160, 4161, 4196, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

Automatic Refill Programs

16 CCR § 1717.5

**Title 16. Board of Pharmacy
Proposed Text**

Add section 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717.5 Automatic Refill Programs

- a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.
- 1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.
 - 2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.
 - 3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.
 - 4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.
 - 5) The patient or patient's agent shall have the option to withdraw from the program at any time.
 - 6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.
 - 7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.
 - 8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.
 - 9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.
- b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Authority cited: Section 4001.1 and 4005, Business and Professions Code. Reference: Sections 4063 and 4076.6 Business and Professions Code and 1250, Health and Safety Code.

Compounding

**16 CCR §§ 1735.1,
1735.2, 1735.6, 1751.1,
and 1751.4**

Title 16. Board of Pharmacy

Changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Additionally, [Brackets] indicate language that is not being amended.

Amend section 1735.1(c) and (f) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

[.....]

- (c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI.
- (d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.
- (e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.
 - (1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.
 - (2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.
- (f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.2(i) in Article 4.5 of Division 17 of Title 16 California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

[.....]

- (i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.
 - (1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
 - (A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
 - (B) the chemical stability of any one ingredient in the compounded drug preparation;
 - (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
 - (D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
 - (E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
 - (F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
 - (G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:
 - (i) the nature of the drug and its degradation mechanism,
 - (ii) the dosage form and its components,
 - (iii) the potential for microbial proliferation in the preparation,
 - (iv) the container in which it is packaged,
 - (v) the expected storage conditions, and
 - (vi) the intended duration of therapy.
 - Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.
- (2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
 - (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
 - (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
 - (D) The beyond use date assigned for sterility in section 1751.8.
- (3) For sterile compounded drug preparations, ~~E~~ extension of a beyond use date is only allowable when supported by the following:
- (A) Method Suitability Test,
 - (B) Container Closure Integrity Test, and
 - (C) Stability Studies
- (4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
- (5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1735.6(e) in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

[.....]

- (e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:
 - (1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and
 - (2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
 - (3) Each ~~PEG~~ BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may also use a redundant-HEPA filter in series; and
 - (4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.
- (f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

Amend section 1751.1(a)(5) in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

- (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
- (1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
 - (2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
 - (3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
 - (4) Results of viable air and surface sampling.
 - (5) ~~Biannual~~ video of smoke studies in all ISO Class 5 certified spaces.
 - (6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
 - (A) Controlled room temperature.
 - (B) Controlled cold temperature.
 - (C) Controlled freezer temperature.

[.....]

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend section 1751.4(k) in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile Compounding.

[.....]

- (k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of ~~20-24~~ degrees Celsius (~~68-75~~ degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.
- (l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

Attachment 5

1. Proposed Regulations to Amend Title 16 CCR section 1735.2 Related to Compounding Self-Assessment Form 17M-39

Timeline:

Approved by Board: November 8, 2017

Summary of Regulation:

This regulation updates the Self-Assessment form 17M-39 (rev. 12/16) as incorporated by reference in Title 16 CCR section 1735.2.

2. Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14, and 17M-26

Timeline:

Approved by Board: November 8, 2017

Summary of Regulation:

This regulation updates the Self-Assessment forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR sections 1715 and 1784. Additionally, this regulation updates sections 1715 and 1784 with clarifying language as to the completion and certification requirements of the self-assessment forms.

**Compounding
Self-Assessment
§ 1735.2**

Proposal to Amend Section 1735.2(k)

...

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

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name of the pharmacy and the license number of the pharmacy as well as the license numbers for any specialty licenses issued by the board including sterile compounding license number and centralized hospital packaging license number, if applicable.

(B) Address, phone number, fax number, and website address, if applicable, of the pharmacy

(C) Hours of operation of the pharmacy

(D) Name of Accreditation Agency and dates, if applicable

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person’s license number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond “Yea”, “no” or “not applicable” (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that setting.

(4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficient identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in revocation of the pharmacy’s license issued by the board. This certification shall be made under penalty of perjury of the State of California.

(8) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(9) Any identified areas of noncompliance shall be corrected as specified in the certification.

(l) ...

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.



Community Pharmacy & Hospital Outpatient Pharmacy 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 preparations 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 its entirety and may be completed online, printed, readily retrievable 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: _____

Fax: _____

Ownership: Sole Owner Partnership Corporation LLC Trust
 Non-Licensed Owner Other (please specify) _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
 (Please use an additional sheet if necessary)

1. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
2. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
3. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
4. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
5. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
6. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
7. _____	RPH # _____ APH # _____	Exp. Date: _____ Exp. Date: _____
8. _____	INT # _____	Exp. Date: _____
9. _____	INT # _____	Exp. Date: _____
10. _____	INT # _____	Exp. Date: _____
11. _____	TCH # _____	Exp. Date: _____
12. _____	TCH # _____	Exp. Date: _____
13. _____	TCH # _____	Exp. Date: _____
14. _____	TCH # _____	Exp. Date: _____
15. _____	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 8.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

1.1 The pharmacy compounds as defined in CCR 1735(a).

1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

Yes No N/A

2.1 The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

2.2 The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

2.3 The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- 2.3.1 Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- 2.3.2 Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- 2.3.3 Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- 2.3.4 The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**
- 2.3.5 Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**
- 2.3.6 Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

- 2.4.1 Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])
- 2.4.2 Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or
- 2.4.3 Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

Yes No N/A

2.5 The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

- 2.5.1 Active ingredients used.
- 2.5.2 Equipment to be used.
- 2.5.3 Beyond use date (BUD).
- 2.5.4 Inactive ingredients used.
- 2.5.5 Specific and essential compounding steps.
- 2.5.6 Quality reviews required at each step.
- 2.5.7 Post-compounding process or procedures, if required.
- 2.5.8 Instructions for storage and handling.

2.6 The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

2.7 The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

2.8 All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

2.9 Every compounded drug preparation is given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

2.9.1 For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])

- 2.9.1.1 The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
- 2.9.1.2 The chemical stability of any one ingredient in the compounded drug preparation;
- 2.9.1.3 The chemical stability of the combination of all ingredients in the compounded drug preparation,
- 2.9.1.4 180 days for non-aqueous formulations,
- 2.9.1.5 14 days for water-containing oral formulations, and
- 2.9.1.6 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

2.9.2 For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])

- 2.9.2.1 The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,
- 2.9.2.2 The chemical stability of any one ingredient in the sterile compounded drug preparation,
- 2.9.2.3 The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- 2.9.2.4 The beyond use date assigned for sterility in CCR 1751.8.

2.9.3 Extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])

- 2.9.3.1 Method Suitability Test,
- 2.9.3.2 Container Closure Integrity Test, and
- 2.9.3.3 Stability Studies.

2.9.4 The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

2.9.5 Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

2.10 Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

2.11 Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

2.11.1 Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

2.11.2 Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

3.1 The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

3.1.1 The master formula document.

3.1.2 A compounding log consisting of a single document containing all of the following:

3.1.2.1 The name and strength of the compounded drug preparation.

3.1.2.2 The date the drug preparation was compounded.

3.1.2.3 The identity of the pharmacy personnel who compounded the drug preparation.

3.1.2.4 The identity of the pharmacist reviewing the final drug preparation.

3.1.2.5 The quantity of each component used in compounding the drug preparation.

3.1.2.6 The manufacturer or supplier, expiration date and lot number of each component.

3.1.2.7 The pharmacy assigned reference or lot number for the compounded drug preparation.

3.1.2.8 The beyond use date or beyond use date and time of the final compounded drug preparation.

3.1.2.9 The final quantity or amount of drug preparation compounded.

3.1.2.10 Documentation of quality reviews and required post-compounding process and procedures.

3.2 The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

3.3 Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

3.4 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 Preparation (CCR 1735.4)

Yes No N/A

- 4.1 Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])
 - 4.1.1 Name of the compounding pharmacy and dispensing pharmacy (if different);
 - 4.1.2 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
 - 4.1.3 Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
 - 4.1.4 The beyond use date for the drug preparation;
 - 4.1.5 The date compounded; and
 - 4.1.6 The lot number or pharmacy reference number.
- 4.2 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])
- 4.3 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])
- 4.4 Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) 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 beyond use date. (CCR 1735.4[d])
- 4.5 All hazardous agents bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

- 5.1 The pharmacy maintains written policies and procedure for compounding which establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])
- 5.2 The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])
- 5.3 The policies and procedures include at least the following: (CCR 1735.5[c][1-11])
 - 5.3.1 Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
 - 5.3.2 A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
 - 5.3.3 Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

- 5.3.4 Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- 5.3.5 Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
- 5.3.6 Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
- 5.3.7 Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- 5.3.8 Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- 5.3.9 Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- 5.3.10 Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- 5.3.11 Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

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 compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- 6.2 All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- 6.3 All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
 - 6.3.1 Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.
- 6.4 When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])
- 6.5 Hazardous drug compounding is completed in an externally vented physically separate room with the following requirements: (CCR 1735.6[e])
 - 6.5.1 Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when preparations are assigned a BUD of 12 hrs or less or when nonsterile products are compounded; and
 - 6.5.2 Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
 - 6.5.3 Each PEC in the room is externally vented; and
 - 6.5.4 All surfaces within the room are smooth, seamless, impervious, and non-shedding.

Yes No N/A

6.6 This pharmacy has applied and was granted a waiver by the board for the following physical construction or alteration to a facility or physical environment. (CCR 1735.6[f])

6.6.1 Waiver approved the Board. Please see attached.

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

7.1 The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

7.2 The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

7.3 Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (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 preparation. (CCR 1735.8[a])

8.2 The pharmacy's quality assurance plan includes the written procedures and standards for at least 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 analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- 8.2.3 Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- 8.2.4 Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- 8.2.5 Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

9. Duties of a Pharmacy Issuing a Compounded Drug Recall (B&PC 4126.9)

Yes No N/A

- 9.1 When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (B&PC 4126.9[a][1-2])
 - 9.1.1 Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
 - 9.1.2 The recalled drug was dispensed, or is intended for use, in this state.
- 9.2 A recall notice issued pursuant to subdivision (a) is made as follows: (B&PC 4126.9[b][1-3])
 - 9.2.1 If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.
 - 9.2.2 If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.
 - 9.2.3 If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.
- 9.3 If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (B&PC 4126.9[c])

COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (B&PC 4127)

Yes No

If yes, complete Sections 10 through 25.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

10. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

- 10.1 Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (B&PC 4123)
 - 10.1.1 The contractual arrangement is reported to the board within 30 days of commencing that compounding.

11. Compounding Sterile from Nonsterile Ingredients; Requirements

Yes No N/A

- 11.1 The pharmacy compounds sterile preparations from one or more nonsterile ingredients in one of the following environments: (B&PC 4127.7)
 - 11.1.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. (B&PC 4127.7[a])
 - 11.1.2 An ISO Class 5 cleanroom. (B&PC 4127.7[b])
 - 11.1.3 A barrier isolator that provides an ISO Class 5 environment for compounding. (B&PC 4127.7[c])

12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

- 12.1 The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

- 12.2 The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])
 - 12.2.1 The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
 - 12.2.2 The pharmacy is ventilated in a manner in accordance with Section 505.7 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
 - 12.2.3 The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
 - 12.2.3.1 Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.
 - 12.2.3.1.1 Certification records must be retained in the pharmacy.
 - 12.2.3.2 Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.
 - 12.2.3.3 A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.
 - 12.2.3.4 There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.7 and 505.7.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

- 13.1 The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)
 - 13.1.1 In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])
 - 13.1.2 Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])
 - 13.1.3 The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])

- 13.1.4 A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])
- 13.1.5 The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])
 - 13.1.5.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
 - 13.1.5.2 An ISO Class 5 cleanroom.
 - 13.1.5.3 A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

- 13.2 The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.7)
 - 13.2.1 Be ventilated in a manner not interfering with laminar air flow.

- 13.3 Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.7.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

- 14.1 In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])
 - 14.1.1 Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
 - 14.1.2 Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
 - 14.1.3 Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
 - 14.1.4 Results of viable air and surface sampling.
 - 14.1.5 Video of smoke studies in all ISO certified spaces.
 - 14.1.6 Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
 - 14.1.6.1 Controlled room temperature.
 - 14.1.6.2 Controlled cold temperature.
 - 14.1.6.3 Controlled freezer temperature.
 - 14.1.7 Certification(s) of the sterile compounding environment(s).
 - 14.1.8 Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.
 - 14.1.9 Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).

- 14.1.10 Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.
- 14.1.11 Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

14.2 The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

14.3 The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy labels each compounded sterile drug preparations with at least the following information: (CCR 1751.2[a-c])

- 15.1.1 The telephone number of the pharmacy.
- 15.1.2 Instructions for storage, handling, and administration.
- 15.1.3 All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action. CCR 1751.3[a])

16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- 16.2.1 Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- 16.2.2 Airflow considerations and pressure differential monitoring.
- 16.2.3 An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- 16.2.4 Cleaning and maintenance of ISO environments and segregated compounding areas.
- 16.2.5 Compounded sterile drug preparation stability and beyond use dating.
- 16.2.6 Compounding, filling, and labeling of sterile drug preparations.

- 16.2.7 Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- 16.2.8 Depyrogenation of glassware (if applicable).
- 16.2.9 Facility management including certification and maintenance of controlled environments and related equipment.
- 16.2.10 For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- 16.2.11 Hand hygiene and garbing.
- 16.2.12 Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- 16.2.13 Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- 16.2.14 Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- 16.2.15 Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- 16.2.16 Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.17 Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.18 Proper use of equipment and supplies.
- 16.2.19 Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- 16.2.20 Record keeping requirements.
- 16.2.21 Temperature monitoring in compounding and controlled storage areas.
- 16.2.22 The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- 16.2.23 Use of automated compounding devices (if applicable).
- 16.2.24 Visual inspection and other final quality checks of sterile drug preparations.

Yes No N/A

16.3 For lot compounding, the pharmacy maintains written policies and procedures which include at least the following: (CCR 1751.3[b][1-3])

- 16.3.1 Use of master formula documents and compounding logs.
- 16.3.2 Appropriate documentation.
- 16.3.3 Appropriate sterility and potency testing.

16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.3[c][1-2])

- 16.4.1 Process validation for chosen sterilization methods.
- 16.4.2 End-product evaluation, quantitative, and qualitative testing.

16.5 All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

- 17.1 No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. (CCR 1751.4[a])
- 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired. (CCR 1751.4[b])
- 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])
- 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly. (CCR 1751.4[d][1-4])
- 17.4.1 All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- 17.4.2 Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- 17.4.3 Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- 17.4.4 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.
- 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e][1-4])
- 17.5.1 At the beginning of each shift;
- 17.5.2 At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- 17.5.3 After each spill; and
- 17.5.4 When surface contamination is known or suspected.
- 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality. (CCR 1751.4[f])
- 17.6.1 Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.
- 17.6.2 Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).
- 17.6.2.1 Certification records are retained for at least 3 years.
- 17.6.3 Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])
- 17.6.3.1 Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- 17.6.3.2 Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
- 17.6.3.3 Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

17.6.4 Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

Yes No N/A

- 17.7 Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.7.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. (CCR 1751.4[g])
- 17.7.1 Additionally, each PEC used to compound hazardous agents shall be externally vented.
- 17.7.2 The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).
- 17.7.3 Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])
- 17.7.4 During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

17.8 If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

17.9 Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

17.10 Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is performed under dynamic conditions which simulate actual production. Viable surface sampling is performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management. (CCR 1751.4[j])

17.11 The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

- 18.1 When compounding sterile drug preparations the following standards are met: (CCR 1751.5[a][1-6])
 - 18.1.1 Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.
 - 18.1.2 Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.
 - 18.1.3 Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place which documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.
 - 18.1.4 Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.
 - 18.1.5 Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.
 - 18.1.6 Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.
- 18.2 When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

- 19.1 Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])
- 19.2 The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])
- 19.3 Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment. (CCR 1751.6[c])
- 19.4 The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations. (CCR 1751.6[d])

Yes No N/A

- 19.5 The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])
- 19.5.1 The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure 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 must address at least the following: (CCR 1751.6[e][1][A-J])
 - 19.5.1.1 Aseptic technique.
 - 19.5.1.2 Pharmaceutical calculations and terminology.
 - 19.5.1.3 Sterile preparation compounding documentation.
 - 19.5.1.4 Quality assurance procedures.
 - 19.5.1.5 Aseptic preparation procedures.
 - 19.5.1.6 Proper hand hygiene, gowning and gloving technique.
 - 19.5.1.7 General conduct in the controlled area (aseptic area practices).
 - 19.5.1.8 Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
 - 19.5.1.9 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
 - 19.5.1.10 Container, equipment, and closure system selection.
 - 19.5.2 Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

- 20.1 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 the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])
- 20.1.1 The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])
 - 20.1.1.1 Procedures for cleaning and sanitization of the sterile preparation area.
 - 20.1.1.2 Actions to be taken in the event of a drug recall.
 - 20.1.1.3 Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

- 20.2.1 The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])
- 20.2.2 Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])
- 20.2.3 The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])
 - 20.2.3.1 The quality assurance program yields an unacceptable result.

20.2.3.2 There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

20.2.4 The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

- 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])
- 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])
- 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), 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. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])
- 20.5.1 The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B])
- 20.5.1.1 Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.
- 20.5.1.2 Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

21. **Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)**

Yes No N/A

- 21.1 Every sterile compounded drug preparation is given and labeled with a beyond use date in compliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations: (CCR 1751.8)
- 21.2 The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])
- 21.2.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; **and**

- 21.2.2 The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; **and**
- 21.2.3 Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

Yes No N/A

- 21.3 The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])
 - 21.3.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
 - 21.3.2 The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
 - 21.3.3 The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

- 21.4 The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])
 - 21.4.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

- 21.5 The beyond use date states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])
 - 21.5.1 The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and
 - 21.5.2 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer’s original containers; and
 - 21.5.3 The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

- 21.6 Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is be labeled “for immediate use only” and administration shall begin no later than one hour following the start of the compounding process. (CCR 1751.8[e])
 - 21.6.1 Unless the “immediate use” preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

- 21.6.2 If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.
- 21.6.3 "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.
- 21.6.4 Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

Yes No N/A

- 21.7 The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

- 22.1 Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

- 22.2 Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])
 - 22.2.1 When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.
 - 22.2.2 When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
 - 22.2.3 If the puncture time is not noted on the container, the container is immediately discarded.

- 22.3 Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded. (CCR 1751.9[c])

23. Sterile Compounding Reference Materials (CCR 1751.10)

Yes No N/A

- 23.1 The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

24. Sterile Compounding License Renewal (B&PC 4127.1, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (B&PC 4127.1, 4127.2)

Yes No N/A

- 24.1 The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.
- 24.2 The board reviews a current copy of the pharmacy’s policies and procedures for sterile compounding.
- 24.3 The board is provided with copies of all inspection reports conducted of the pharmacy’s premises in the prior 12 months documenting the pharmacy’s operation.
- 24.4 The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy’s operation.
- 24.5 The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.
- 24.6 A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (B&PC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

25. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (B&PC 4127.9)

Yes No N/A

- 25.1 The pharmacy contacts 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 (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (B&PC 4127.9[a] B&PC 4127.1 and 4127.2)
- 25.2 A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (B&PC 4127.9[b][1])
- 25.3 A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (B&PC 4127.9[b][2])
- 25.4 A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (B&PC 4127.9[b][3])

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 _____
(Pharmacist-in-Charge)

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 _____

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Self-Assessment Forms

§ 1715 and 1784

17M – 13

17M – 14

17M – 26

**Title 16. Board of Pharmacy
Proposed Regulation**

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall 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 primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall 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, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) A pharmacist-in-charge of a community pharmacy shall use the components of this assessment shall be on Form 17M-13 (Rev. 10/14 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment". Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment and on Form 17M-14 (Rev. 10/14 16) entitled "Hospital Pharmacy Self-Assessment." Both forms are hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations.~~

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

(B) Address, phone number, and website address, if applicable, of the pharmacy

(C) DEA registration number, expiration date and date of most recent DEA inventory

(D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code.

Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager.

The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.~~ Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA;
inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date,
if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of
each Board-licensed staff person currently employed by the licensee in the facility at the
time the self-assessment is completed, the person's license type and number, and the
expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes",
"no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the
self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible
manager shall provide a corrective action or action plan to come into compliance with the
law.

(5) The designated representative-in-charge or responsible manager shall initial each page
of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under
penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he
or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the
timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of
Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page
of the self-assessment that he or she has read and reviewed the completed self-assessment
and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.



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 its entirety and may be completed online, printed, readily available and retained in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ 10/16).

Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~02/12~~ 10/16).

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 Trust
 Non-Licensed Owner Other (please specify)

Permit License #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit License# _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Weekdays _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):

Please use an additional sheet if necessary. APP APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
APP APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ 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: _____

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

- 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

- 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)

- 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

- 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)

- 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)

- 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)

- 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. A pharmacy may also provide this information in a video in lieu of the poster. Additional “Notice to Consumers” in languages other than English may also be posted. (B&PC 4122, CCR ~~1707.2~~ 1707.6)

- 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])~~ “Point to Your Language” poster is posted in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6(c))

- ~~1.8~~ 1.9. 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])

- ~~1.9~~ 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)

~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – “Compounding.”)

Yes No N/A

~~1.11~~ 1.12. 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~~ 1.13. 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~~ 1.14. The pharmacy reports to the board within 14 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~~ 1.15. 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~~ 1.16. 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 premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(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])

2.3 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d])

2.4 Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section[d][iii])

2.5 The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of the DQSA Section 582[d][iii])

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 with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- 3.2.3. Are not expired.

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 29 [donate drugs] or Section 30 [operate program] 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. (B&PC 4113(c), 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~~ 5.7. 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, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Duties of a Pharmacist

Yes No N/A

6.1. The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)

Only a pharmacist:

- transmits a valid prescription to another pharmacist (B&PC 4052)
- administers drugs and biological products ordered by the prescriber; (B&PC 4052)
- provides consultation, training and education to patients about drug therapy disease management and disease prevention; (B&PC 4052)
- provides professional information and participates in multidiscipline review of patient progress; (B&PC 4052)
- furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; (B&PC 4052 (a)(10), B&PC 4052(a)(11), 4052.01, B&PC 4052.3, B&PC 4052.8, 4052.9)
- responds to end of life option drugs (Health and Safety Code section 443.59 (b)(2))
- orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052 (a)(12)

6.2. 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))

Only a 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))

6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency 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; initiating and 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)

6.4. Pharmacists are ~~able to provide~~ access to 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)

6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (B&PC 1206.6)

Yes No N/A

6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #: _____ Expiration: _____

6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052(b))

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Duties of an Advance Practice Pharmacist

Yes No N/A

~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

~~7.2~~ 7.1. The advance practice pharmacist has received an advance practice pharmacist ~~recognition license~~ by from the board and may do the following: (B&PC 4016.5, 4210)

- ~~7.2.1~~ 7.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ~~7.2.2~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ~~7.2.2~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ~~7.2.2~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ~~7.2.2~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

8. Duties of an Intern Pharmacist

Yes No N/A

8.1. 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)

Yes No N/A

8.2. 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)

8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209, CCR 1726)

8.4. 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: _____

9. Duties of a Pharmacy Technician

Yes No N/A

- 9.1. Registered pharmacy technicians are performing only perform 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)
- 9.2. 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])
- 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or ~~her self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
- 9.4. 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])
- 9.5. 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: _____

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. (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. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

- 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7]~~, B&P 4052[a][8], CCR 1707.2):
- 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
 - 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
 - 11.1.3. upon request; and
 - 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.
 - 11.1.5. unless a patient declines the consultation directly to the pharmacist.
- 11.2. 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)
- 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)
- 11.4. 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])
- 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- 11.6. 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: _____

12. Prescription Requirements

Yes No N/A

- 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)
- 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)
- 12.3. 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)
- 12.4. 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)

- 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])
- 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])
- 12.7. 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])
- 12.8. 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)
- 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])
- 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1311.100, 1306.11)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

- 13.1. The prescription label contains all the required information. (B&PC 4076)
- 13.2. The prescription label is formatted in accordance with CCR 1707.5.
- ~~13.3. 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])~~

Yes No N/A

- ~~13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~
- ~~13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~
- ~~13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~
- ~~13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~

~~13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

Exemption approved by board from: _____ to _____

13.6. ~~The~~ Expiration dates of a ~~drugs'~~ drug's effectiveness ~~are~~ is consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

13.7. 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[b][2])

13.8. Generic substitution is communicated to the patient. (B&PC 4073)

13.9. 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 or as otherwise allowed. (B&PC 4115, CCR 1793.7, CCR 1712)

13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

13.11. 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. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

13.14. Medication guides are provided on required medications. (21 CFR 208.1)

~~13.14~~15. 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 received drugs, or to another pharmacy of common ownership.

~~13.15~~16. 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)

Yes No N/A

~~13.16~~17. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

13.18. 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)

~~13.17~~ 19. The pharmacy dispenses not more than a 90-day supply of a dangerous drug with the following exceptions medications (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

- Controlled substances

- Psychotropic medications
 - Self-administered hormonal contraception
- 13.1720.1 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])
- 13.1720.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])
 - 13.1720.1.2. 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])
 - 13.1720.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])
 - 13.1720.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])
 - 13.1720.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])
- 13.1720.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])
- 13.1821. The pharmacist includes 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 may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Refill Authorization

Yes No N/A

- 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)
- 14.2. Refills are documented. (CCR 1717)
- 14.3. 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)
- 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

Yes No N/A

14.5. 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: _____

15. Quality Assurance and Medication Errors

Yes No N/A

- 15.1. 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)
- 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- 15.3. 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])
- 15.4. 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])
- 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])
 - 15.6.1. Date, location, and participants in the quality assurance review;
 - 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
 - 15.6.3. Findings and determinations; and
 - 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- 15.7. 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])
- 15.8. 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: _____

16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

16.1. 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])

16.2. 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)

16.3. 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], HSC 11153)

~~16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])~~

16.5 ~~4~~. 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.)

~~16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Prescription Transfer

Yes No N/A

17.1. Only pharmacists may transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

17.2. 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

17.3. 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])

Yes No N/A

17.4. 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: _____

18. Confidentiality of Prescriptions

Yes No N/A

18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

18.4. 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])

18.5. 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)

18.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

19. Record Keeping Requirements

Yes No N/A

19.1. A ~~All~~ completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and maintained for three years. (CCR 1715)

19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

- 19.2.1. Prescription records (B&PC 4081[a])
- 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

- 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4145.5)

- 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- 19.3.3. The sale of 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 4145.5)
- 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- 19.3.5. 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)

19.4. 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])

- 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 19.4.2. Furnish or make available mail-back sharps containers.
- 19.4.3. Furnish or make available sharps containers.

19.5. 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)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

19.6. The pharmacy ~~dispenses~~ furnish epinephrine auto-injector to an authorized entity ~~a prehospital emergency medical care person or lay rescuer~~ for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3, 4119.4)

PIC
Initials

- 19.6.1. A ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1], 4119.4)
- 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1], 4119.4)
- 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2], 4119.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

20. DEA Controlled Substances Inventory

- | Yes | No | N/A | Inventory: |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[b]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.3. <u>All completed inventories are</u> is available for inspection for three years. (CCR 1718) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.6. 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]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.7. 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) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) 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) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20.9. 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)

Yes No N/A

20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form 222, 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)

20.11. 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)

20.12. 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])

20.13. 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.

20.14. 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)

20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

20.16. 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])

20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

20.18. 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: _____

21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

21.1. A faxed prescription for a Schedule II controlled substance is dispensed only after the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

21.2. An oral or electronically transmitted 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)

- 21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- 21.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- 21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- 21.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)

21.3. 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])

21.4. 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)

21.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written when requested by the patient or practitioner. (21 USC 829[f])

21.56. 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)

21.67. 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)

- 21.78. 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])
- 21.89. 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])
- Yes No N/A
 21.910. 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])
- 21.1011. 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)
- 21.1112. 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)
- 21.1213. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

22. Automated Dispensing/Delivery Devices

- Yes No N/A
 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)
- 22.2. The pharmacy has registered with the board all automated drug delivery systems that it operates in any location within 30 days of installation, removal, and at the time of renewal. (B&PC 4105.5(b))
- 22.3. The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (B&PC 4105.5(c))
- 22.4. The pharmacy reports drugs losses as required by law. (B&PC 4105.5(c))
- 22.25. 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, 21 CFR Part 201.17, H&SC 111355)

22.34. 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:

- 22.3.1. 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])
- 22.3.2. A pharmacist reviews the order and patient’s profile prior to the drug being removed. (H&SC 1261.6[e][2])
- 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

22.4. 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:

- 22.4.1. 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])
- 22.4.2. 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: _____

23. Repackaging by the Pharmacy

Yes No N/A

23.1. 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)

23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

23.3. Drugs previously dispensed are re-packaged at the patient’s request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

24. Refill Pharmacy

Yes No N/A

24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

24.2. 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)

24.3. 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.

24.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

24.5. 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])

24.6. 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])

Yes No N/A

24.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

24.9. 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: _____

Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

25.2. The pharmacy meets the following requirements:

25.2.1. 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])

- 25.2.2. 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])
- 25.2.3. 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])
- 25.2.4. 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])
- 25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])
- 25.2.6. 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])
- 25.2.7. 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])
- 25.2.8. 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])
- 25.2.9. 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])
- 25.2.10. 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])
- 25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])
- 25.2.12. 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])

26. Policies and Procedures

Yes No N/A

26.1. There are written policies and procedures in place for:

- ~~26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~
- 26.1.2. 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])
- 26.1.3. 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])
- 26.1.4. 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])
- 26.1.5. 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])
- 26.1.6. 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])
- 26.1.7. 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])
- 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- 26.1.9. Reporting requirements to protect the public; (B&PC 4104)
- ~~26.1.10. Preventing the dispensing of a prescription drug that is contrary to the law; A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B&PC 733)~~
- 26.1.11. 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)
- 26.1.12. 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

26.2. Does your pharmacy employ the use of a common electronic file?

- 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

- 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)
- 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)
- 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)
- 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)
- 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)
- 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])
- 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)
- 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a], CCR 1746.3)

- 26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.
- 26.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

26.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.9, CCR 1746.2)

26.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

27. Compounding

Yes No N/A

27.1. 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. ~~02/12~~ 10/16) (CCR 1735.2{jj})

28. Nuclear Pharmacy

Yes No N/A

28.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

28.2. 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)

28.3. 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. ~~02/12~~ 10/16.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

29. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

29.1.2. 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)

29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

29.4.1. 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])

29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

29.4.3. 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])

29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

29.4.5. 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])

30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])

30.1.1.1 Is county owned (H&SC 150201[b][1]) or

30.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)

30.1.2. 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])

Yes No N/A

30.2. 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: _____

30.3. 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])

30.4. 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: _____

30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

Drugs and Maintenance of Drug Stock

30.6. 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])

30.7. 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])

30.8. 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])

30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

- 30.9.1. Are received from authorized sources. (H&SC 150202, 150203)
- 30.9.2. No controlled substances are received. (H&SC 150204[c][1])
- 30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])
- 30.9.4. 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])
- 30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])
- 30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])
- 30.9.7. 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])

Yes No N/A

30.10. 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

30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

30.12. 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:

30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

30.14. 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])

30.15. 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

30.16. 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])

30.17. 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 State Board of Pharmacy

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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 its 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. 10/14 10/16) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12 10/16.)

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: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging Permit #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Weekdays _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):
APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
APP APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
6. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
7. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
8. _____ RPH # _____ Exp. Date: _____
APP APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____
9. _____ INT # _____ Exp. Date: _____
10. _____ INT # _____ Exp. Date: _____
11. _____ INT # _____ Exp. Date: _____
12. _____ INT # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____
16. _____ 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 14 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 drugs?
(If yes, complete section 27 — "Compounding") (If yes, complete Compounding Self-Assessment Form 17M-39 10/16)

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, intern, or pharmacy technician 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. (B&PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

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])
- 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])
- 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (Title II of the DQSA Section 582[d][i])
- 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (Title II of the DQSA Section 582[d][ii])
- 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (Title II of DQSA Section 582[d][iii])

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])

Yes No N/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)
- 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Pharmacies That Donate Drugs to a Voluntary 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, and meets the following requirements: (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, 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 1709.1[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 _____

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. ~~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) Only a pharmacist: (BPC 4052, BPC 4052.2, CCR 1717(c), CCR 1793.1)~~

- ~~The pharmacist r~~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.

~~7.2 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. 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: (B&PC 4027, 4051, 4052, 4052.2)~~

- 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;
- Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (I) successfully completed

clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2)

7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Duties of an Advanced Practice Pharmacist

Yes No N/A

~~8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

8.2.8.1 The advance practice pharmacist has received an advance practice pharmacist ~~recognition license~~ by from the board and may do the following: (B&PC 4016.5, 4210)

- ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ~~8.2.1~~ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ~~8.2.1~~ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ~~8.2.1~~ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ~~8.2.1~~ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

9. Duties of an Intern Pharmacist

Yes No N/A

9.1. 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, 4119.6, 4119.7, CCR 1726)

- 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)
- 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])

Yes No N/A

- 9.2. 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])
- 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])
- 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned when applicable. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Duties of a Pharmacy Technician

Yes No N/A

- 10.1. 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)
- ~~10.2.~~ 10.2. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)
- ~~10.2~~ 10.3. ~~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])
- ~~10.2~~ 10.4. 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)
- ~~10.2~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her ~~self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
- ~~10.2~~ 10.6. 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)
- ~~10.6.~~ The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

10.7. 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])

Yes No N/A

10.8. 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)

- 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

10.9. Pharmacy technician duties include the following:

- 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Duties of Non-Licensed Personnel

Yes No N/A

11.1. 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)

11.2. 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

12. Pharmaceutical Service Requirements

Yes No N/A

12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- 12.1.2. Repackaging and compounding records;
- 12.1.3. Physician orders;
- 12.1.4. Wards, nursing stations and night stock medications;
- 12.1.5. Drugs brought into the facility by patients for storage or use;
- 12.1.6. Bedside medications;
- 12.1.7. Emergency drug supply;
- 12.1.8. Pass medications;
- 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- 12.1.10. Routine distribution of inpatient medications;
- 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- 12.1.12. Handling of medication when pharmacist not on duty; and
- 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- 12.2.1. Destruction of controlled substances; and
- 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Medication/Chart Order

Yes No N/A

13.1. 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)

13.2. 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])

Yes No N/A

13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Labeling and Distribution

Yes No N/A

14.1. Unit dose medication and ~~parenteral admixtures~~ compounded preparations 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 1735.4, CCR 1751.2)

14.2. 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]).

14.3. 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 receive 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: _____

15. Duration of Drug Therapy

Yes No N/A

15.1. 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: _____

16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

16.2. 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.)

16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

16.4. 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)

16.5. 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)

Date Waiver Approved _____

Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Quality Assurance and Medication Errors

Yes No N/A

- 17.1. 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)
- 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- 17.3. 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])

Yes No N/A

- 17.4. 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])
- 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);
- 17.6.1. Date, location, and participants in the quality assurance review;
 - 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
 - 17.6.3. Findings and determinations;
 - 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- 17.7. 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])
- 17.8. 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: _____

18. Record Keeping Requirements

Yes No N/A

- 18.1. A ~~All~~ completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and is 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:
- 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)
- 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 and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
- 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1]), 150204(k), B&PC 4105(c).

Yes No N/A

- 18.3. 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)
- 18.4. 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)
- 18.5. A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11)
- 18.6 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)
- ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
- ~~18.6~~ 18.8. 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)
- ~~18.6~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)
- ~~18.6~~ 18.10. 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 1305.13)
- ~~18.6~~ 18.11. 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)
- ~~18.6~~ 18.12. 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)

- ~~18.6~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR
- ~~18.6~~ 18.14. 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: _____

19. After-Hours Supply of Medication

Yes No N/A

- 19.1. 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: _____

20. Drug Supplies for Use in Medical Emergencies

Yes No N/A

- 20.1. 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])
- 20.2. 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])
- 20.3. 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])
- 20.4. 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: _____

21. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

21.1. 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: _____

22. Emergency Room Dispensing

Yes No N/A

22.1. 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])

- 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- 22.1.2. The dangerous drug is acquired by the hospital pharmacy;
- 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- 22.1.4. 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;
- 22.1.5. 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
- 22.1.6. 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;

22.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

- 22.4. 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)
- 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)
- 22.6. 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)
- 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)
- 22.8. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- 22.9. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

23. Discharge Medication/Consultation Services

Yes No N/A

- 23.1. 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)
- 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)
- 23.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)
- ~~23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])~~
- ~~23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.
 _____ Exemption approved by board from: _____ to _____~~
- 23.6. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- 23.7. 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)

- 23.86. 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)
- 23.97. 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)
- 23.108. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
- 23.119. 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)
- 23.1210. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)
- 23.1311. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- 23.1412. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

24. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

- 24.1. 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: _____
- 24.2. 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 23-25.
- 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])
- 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

- 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])
- 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3])
- 24.7. 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])

25. Centralized Hospital Packaging Pharmacy

Yes No N/A

- 25.1. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located 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:
 - 25.1.1. _____ Distance (miles): _____
 - 25.1.2. _____ Distance (miles): _____
 - 25.1.3. _____ Distance (miles): _____
 - 25.1.4. _____ Distance (miles): _____
 - 25.1.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
 - 25.1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to Section 4128.4.
 - 25.1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.
- 25.2. 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)
- 25.3. ~~All~~ Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded ~~and readable~~ to be machine readable at the inpatient's bedside using barcode medication administrative software. The barcode information contains the required information: (B&PC 4128.4)
 - ~~25.3.1. The date the medication was prepared.~~ The barcode medication administration software shall permit health care practitioners to ensure, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration.
 - ~~25.3.2. The components used in the drug product.~~ The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the patient.
 - ~~25.3.3. The lot number or control number.~~

- ~~25.3.4. The expiration date.~~
- ~~25.3.5. The National Drug Code Directory number.~~
- ~~25.3.6. The name of the centralized hospital packaging pharmacy.~~

Yes No N/A

25.4. ~~The Any 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 displays a human-readable label that contains the following: (B&PC 4128.5)~~

- 25.4.1 The date the medication was prepared.
- 25.4.2 The beyond-use date
- 25.4.3 The establishd name of the drug.
- 25.4.4 The quantity of each active ingredient.
- 25.4.6 The lot number or control number assigned by the centralized hospital packaging pharmacy.
- 25.4.5 Special storage or handling requirements.
- 25.4.7 The name of the centralized hospital packaging pharmacy.

25.5 The pharmacist is able to retrieve all of the following information using the lot number or control number: (B&PC 4128.5)

- 25.5.1 The components used in the drug product.
- 25.5.2 The expiration date of each of the drug's components.
- 25.5.3 The National Drug Code Directory number.

25.56. 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: _____

26. Policies and Procedures

Yes No N/A

26.1. There are written policies and procedures in place for:

- 26.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.
- 26.1.2. 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])
- 26.1.3. 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])
- 26.1.4. 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])
- 26.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
- 26.1.6. 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])
- 26.1.7. 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])
- 26.1.8. 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])
- 26.1.9. 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: _____

27. 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. ~~02/12~~ 10/16). (CCR 1735.2[ff])

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)



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 _____

Ownership: Please mark one

sole owner partnership corporation LLC

non-licensed owner Other (please specify) _____

CA Wholesaler Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____
(Use additional sheets if needed.)

DEA Registration # _____ Expiration Date _____

VAWD Accreditation # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Weekdays _____ Sat _____ Sun _____ 24 Hours

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License # _____ Expiration Date _____

Website Address (optional): _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

- 1. _____ DREXE#/RPH# _____ Exp. Date
- 2. _____ DREXE#/RPH# _____ Exp. Date
- 3. _____ DREXE#/RPH# _____ Exp. Date
- 4. _____ DREXE#/RPH# _____ Exp. Date
- 5. _____ DR#EXE/RPH# _____ Exp. Date
- 6. _____ DREXE#/RPH# _____ Exp. Date
- 7. _____ DREXE#/RPH# _____ Exp. Date
- 8. _____ DREXE#/RPH# _____ Exp. Date
- 9. _____ DREXE#/RPH# _____ Exp. Date
- 10. _____ DREXE#/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, third-party logistics provider, 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 email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.9. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~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 12 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 at least 18 years of age and is 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], 4053.1(b))

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)
- 5.3. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

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 ~~11~~ 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], CFR 1307.21)

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])

Yes No N/A

8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

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).~~

Yes No N/A

8.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (Title II of the DQSA Section 582[c])

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)

Yes No N/A

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)

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. Have 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 4059.5[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, IV and V 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 that 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

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 from? 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 1305.13[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 1305.17[c], 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 1305.17[d])

Yes No N/A

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])

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 the following: (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 drug-(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

- 14.1 Are 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~~ 16.
- 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])

16.2.1. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (Title II of the DQSA Section 582[c])

16.3.2. 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.~~

16.4.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

16.5.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

16.6.5. 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])

16.7.6. Are required records stored off-site only if a board issued written waiver has been granted?

16.8.7. 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 _____

16.9.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

16.10.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

~~16.11.10. 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])~~

~~16.12.11. 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.~~13.12~~. 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]):
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- 16.~~14.13~~. 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.~~15.14~~. 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.~~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

18.1. 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]) Use additional sheets if necessary.

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/app106Login.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: (619) 616-4100

DEA—Oakland

1301 Clay Street, Suite 460N
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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
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Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043