



California State Board of Pharmacy

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

DATE: November 14, 2013

RE: Agenda Item III – Discussion and Possible Action to Initiate a Rulemaking to Amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784, to Update the Self-Assessment Forms for Pharmacies, Hospitals, Wholesalers and Compounding Pharmacies

Attachment 1

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments on or before July 1 of each odd-numbered year to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms also serve as an easy reference guide for a Pharmacist-in-Charge (PIC) or a Designated Representative-in-Charge (DRIC). A self-assessment is required any time there is a change in the PIC or DRIC, when a new permit/license is issued; or (for a wholesaler) when there is a change of address.

Several new laws went into effect in 2013, and many of the changes to the self-assessment forms reflect these new laws:

AB 377 – c. 687, Statutes 2012, Centralized Packaging Pharmacy

SB 41 – c. 738, Statutes 2011, Hypodermic needles and syringes

SB 360 – c. 418, Statutes 2011, Pharmacies: access to CURES reports

SB 431 – c. 646, Statutes 2011, Pharmacies: regulation (mandated reporting to the board of theft, diversion or self-use of dangerous drugs by a licensee)

SB 1301 – c. 709, statutes 2012, Prescription drugs: 90-day supply

SB 1329 – c. 709, Statutes 2012, Prescription Drugs: collection and distribution program

SB 1481 – c. 874, Statutes 2012, Clinical laboratories: community pharmacies

Additional changes were added where references to (existing) statutes provided clarity. For example, where the Community Pharmacy Self-Assessment addressed controlled substances inventory (Section 19 of Form 17M-13), a new item is proposed to provide a reference to existing federal regulation that requires the inventory record indicate if the inventory was taken at the “open of business” or the “close of business.”

Agenda Item III – Proposal to Initiate a Rulemaking to Amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784

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Title 16 CCR § 1715 incorporates two self-assessment forms:

Form 17M-13 – Community Pharmacy Self-Assessment; Hospital Outpatient Self-Assessment
Form 17M-14 – Hospital Self-Assessment

Title 16 CCR § 1735.2 incorporates one self-assessment form:

Form 17M-39 – Compounding Self-Assessment

Note: The proposed changes to Section 1735.2 and to the self-assessment do not reflect the current discussions of the Enforcement/Compounding Committee and the board related to the implementation of recently-enacted legislation (SB 294 and AB 1045) related to compounding and non-resident compounding pharmacies. The majority of the changes to Form 17M-39 reflect new items that reference requirements for a centralized hospital packaging pharmacy (as a result of AB 377, c. 687 statutes 2012).

Title 16 CCR § 1784 incorporates one self-assessment form:

17M-26 – Wholesaler Self-Assessment

Attachment 1 contains proposed regulatory text to amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784. Also attached are proposed amendments to the four self-assessment forms, which are incorporated by reference in these sections (all with proposed revision dates of “11/13”).

Staff is not recommending that a regulation hearing be conducted on this regulatory action, unless one is requested.

Staff Recommendation: *Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR Sections 1715, 1735.2 and 1784 and the Self-Assessment Forms incorporated by reference in those sections, as proposed at this meeting. Authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulations at Sections 1715, 1735.2 and 1784 as described in the notice.*

Attachment 1

BOARD OF PHARMACY

1 **Proposal to Amend Section 1715 in Article 2 of Division 17 of Title 16, California**

2 **Code of Regulations to read:**

3 **§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.**

4 (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
5 4037 of the Business and Professions Code shall complete a self-assessment of the
6 pharmacy's compliance with federal and state pharmacy law. The assessment shall be
7 performed before July 1 of every odd-numbered year. The primary purpose of the self-
8 assessment is to promote compliance through self-examination and education.

9 (b) In addition to the self-assessment required in subdivision (a) of this section, the
10 pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

11 (1) A new pharmacy permit has been issued, or

12 (2) There is a change in the pharmacist-in-charge, and he or she becomes the new
13 pharmacist-in-charge of a pharmacy.

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

15 (c) The components of this assessment shall be on Form 17M-13 (Rev. [11/13 01/11](#))
16 entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-
17 Assessment" and on Form 17M-14 (Rev. [11/13 01/11](#)) entitled "Hospital Pharmacy Self-
18 Assessment" which are hereby incorporated by reference to evaluate compliance with
19 federal and state laws and regulations.

20 (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is
21 performed.

22 Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:
23 Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105,
24 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code.

25

26 **Proposal to Amend Section 1735.2 in Article 4.5 of Division 17 of Title 16, California**

27 **Code of Regulations to read:**

28 **§ 1735.2. Compounding Limitations and Requirements; Self-Assessment.**

29 (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt
30 by a pharmacy of a valid prescription for an individual patient where the prescriber has

31 approved use of a compounded drug product either orally or in writing. Where approval is
32 given orally, that approval shall be noted on the prescription prior to compounding.

33 (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in
34 advance of receipt of a patient-specific prescription where and solely in such quantity as is
35 necessary to ensure continuity of care for an identified population of patients of the
36 pharmacy based on a documented history of prescriptions for that patient population.

37 (c) A “reasonable quantity” as used in Business and Professions Code section 4052(a)(1)
38 means that amount of compounded drug product that:

39 (1) is sufficient for administration or application to patients in the prescriber's office, or for
40 distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by
41 the prescriber; and

42 (2) is reasonable considering the intended use of the compounded medication and the
43 nature of the prescriber's practice; and

44 (3) for any individual prescriber and for all prescribers taken as a whole, is an amount
45 which the pharmacy is capable of compounding in compliance with pharmaceutical
46 standards for integrity, potency, quality and strength of the compounded drug product.

47 (d) A drug product shall not be compounded until the pharmacy has first prepared a
48 written master formula record that includes at least the following elements:

49 (1) Active ingredients to be used.

50 (2) Equipment to be used.

51 (3) Expiration dating requirements.

52 (4) Inactive ingredients to be used.

53 (5) Process and/or procedure used to prepare the drug.

54 (6) Quality reviews required at each step in preparation of the drug.

55 (7) Post-compounding process or procedures required, if any.

56 (e) Where a pharmacy does not routinely compound a particular drug product, the master
57 formula record for that product may be recorded on the prescription document itself.

58 (f) The pharmacist performing or supervising compounding is responsible for the integrity,
59 potency, quality, and labeled strength of a compounded drug product until it is dispensed.

60 (g) All chemicals, bulk drug substances, drug products, and other components used for
61 drug compounding shall be stored and used according to compendial and other applicable
62 requirements to maintain their integrity, potency, quality, and labeled strength.

63 (h) Every compounded drug product shall be given an expiration date representing the
64 date beyond which, in the professional judgment of the pharmacist performing or
65 supervising the compounding, it should not be used. This “beyond use date” of the
66 compounded drug product shall not exceed 180 days from preparation or the shortest
67 expiration date of any component in the compounded drug product, unless a longer date is
68 supported by stability studies of finished drugs or compounded drug products using the
69 same components and packaging. Shorter dating than set forth in this subsection may be
70 used if it is deemed appropriate in the professional judgment of the responsible
71 pharmacist.

72 (i) The pharmacist performing or supervising compounding is responsible for the proper
73 preparation, labeling, storage, and delivery of the compounded drug product.

74 (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-
75 charge shall complete a self-assessment for compounding pharmacies developed by the
76 board. (Incorporated by reference is “Community Pharmacy & Hospital Outpatient
77 Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. [11/13](#) ~~02/12~~.) That form
78 contains a first section applicable to all compounding, and a second section applicable to
79 sterile injectable compounding. The first section must be completed by the pharmacist-in-
80 charge before any compounding is performed in the pharmacy. The second section must be
81 completed by the pharmacist-in-charge before any sterile injectable compounding is
82 performed in the pharmacy. The applicable sections of the self-assessment shall
83 subsequently be completed before July 1 of each odd-numbered year, within 30 days of the
84 start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy
85 license. The primary purpose of the self-assessment is to promote compliance through self-
86 examination and education.

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

89

90 **Proposal to Amend Section 1784 in Article 10 of Division 17 of Title 16, California**
91 **Code of Regulations to read:**

92 **§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-**
93 **Charge.**

94 (a) The designated representative-in-charge of each wholesaler as defined under section
95 4160 of the Business and Professions Code shall complete a self-assessment of the
96 wholesaler's compliance with federal and state pharmacy law. The assessment shall be
97 performed before July 1 of every odd-numbered year. The primary purpose of the self-
98 assessment is to promote compliance through self-examination and education.

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

102 (1) A new wholesaler permit is issued, or

103 (2) There is a change in the designated representative-in-charge. The new designated
104 representative-in-charge of a wholesaler is responsible for compliance with this
105 subdivision.

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

107 (c) The components of this assessment shall be on Form 17M-26 (Rev. [11/13 01/11](#))
108 entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is
109 hereby incorporated by reference to evaluate compliance with federal and state laws and
110 regulations.

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

113 (e) The wholesaler is jointly responsible with the designated representative-in-charge for
114 compliance with this section.

115 Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections
116 4022.5, 4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and
117 Professions Code.



COMMUNITY PHARMACY SELF-ASSESSMENT HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, a Hospital Outpatient Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment. Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~01/11~~ 11/13).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

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

Hours: Daily _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

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

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

COMMUNITY PHARMACY SELF-ASSESSMENT

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

- | | |
|--|---|
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects . (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.5. The pharmacy sink has hot and cold running water. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.6. The pharmacy has a readily accessible restroom. (CCR 1714) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.8. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d]) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.9. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058) |
| <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | 1.10. Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 24 26 – "Compounding Sterile Injectable Drugs. ") |

Yes No N/A

1.11. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

1.12. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

1.13. The pharmacy reports to the board within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

1.14. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

1.15. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Delivery of Drugs

Yes No N/A

2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

Yes No N/A

2.2. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 2.2.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Drug Stock

Yes No N/A

3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred: (B&PC 4169)

- 3.2.1. At wholesale with an entity licensed with the board as a wholesaler, pharmacy, or manufacturer.
- 3.2.2. That the pharmacy knew or reasonable knew was not adulterated.
- 3.2.3. That the pharmacy knew or reasonable knew was not misbranded.
- 3.2.4. That were not expired or were within the beyond use date.

CORRECTIVE ACTION OR ACTION PLAN: _____

4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 28 and/or Section 29 of this Self-Assessment.)

4. 5. Pharmacist-in-Charge (PIC)

Yes No N/A

~~4.1.~~ 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)

~~Yes No N/A~~

~~4.2.~~ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

~~4.3.~~ 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)

~~4.4.~~ 5.4. Is the PIC in charge of another pharmacy?

~~4.5.~~ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

~~4.6.~~ 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)

~~4.7.~~ 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

5.8. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206.6, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. 6. Duties of a Pharmacist

Yes No N/A

~~5.1.~~ 6.1. The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

~~5.2.~~ 6.2. The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

6.3. Pharmacists are able to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

~~5.3.~~ 6.4. The pharmacist dispenses emergency contraceptive pursuant to statewide protocol found in 16 CCR 1746.

6.5. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (H&SC 1206.6[a])

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

CDPH (CLIA) Registration #: _____ Expiration: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

6. 7. Duties of an Intern Pharmacist

Yes No N/A

~~6.1.~~ 7.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

~~6.2.~~ 7.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

~~6.3.~~ 7.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

7.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. 8. Duties of a Pharmacy Technician

Yes No N/A

~~7.1.~~ 8.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

~~7.2.~~ 8.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

~~7.3.~~ 8.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

~~7.4.~~ 8.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

8.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

8. 9. Duties of Non-Licensed Personnel

Yes No N/A

~~8.1.~~ 9.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

~~8.2.~~ 9.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist’s responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACY PRACTICE

9. 10. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

~~9.1.~~ 10.1. Pharmacists provide oral consultation. (B&PC 4052[a][7], CCR 1707.2)

- ~~9.1.1.~~ 10.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ~~9.1.2.~~ 10.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ~~9.1.3.~~ 10.1.3. upon request; and
- ~~9.1.4.~~ 10.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.

~~9.2.~~ 10.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

~~9.3.~~ 10.3. The pharmacist reviews a patient’s drug therapy and medication record prior to consultation. (CCR 1707.3)

~~9.4.~~ 10.4. Consultation is performed in a manner that protects the patient’s protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

~~9.5.~~ 10.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

~~9.6.~~ 10.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

10. 11. Prescription Requirements

Yes No N/A

~~10.1.~~ [11.1.](#) Prescriptions are complete with all the required information. (B&PC 4040, 4070)

~~10.2.~~ [11.2.](#) Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)

~~10.3.~~ [11.3.](#) If a prescription is orally or electronically transmitted by the prescriber’s agent, the pharmacist makes a reasonable attempt to verify that the prescriber’s agent is authorized to do so, and the agent’s name is recorded. (B&PC 4071)

~~10.4.~~ [11.4.](#) If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

~~10.5.~~ [11.5.](#) The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

~~10.6.~~ [11.6.](#) Facsimile prescriptions are received only from a prescriber’s office. (B&PC 4040[c])

~~10.7.~~ [11.7.](#) Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

~~10.8.~~ [11.8.](#) With the exception of those prescriptions written under H&SC 11159.2 and [H&SC 11167.5](#), all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], [H&SC 11167.5](#))

~~10.9.~~ [11.9.](#) All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

11. 12. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

~~11.1.~~ [12.1.](#) The prescription label contains all the required information. (B&PC 4076)

~~11.2.~~ [12.2.](#) The prescription label is formatted in accordance with CCR_1707.5.

~~11.3.~~ [12.3.](#) If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR_1707.5[a])

- ~~11.4.~~ [12.4.](#) The pharmacy is exempt from the prescription label requirements in CCR 1707.5.
Exemption approved by board from: _____ to _____
- ~~11.5.~~ [12.5.](#) Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)
- ~~11.6.~~ [12.6.](#) The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])
- ~~11.7.~~ [12.7.](#) Generic substitution is communicated to the patient. (B&PC 4073)
- ~~11.7.~~ [12.8.](#) If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)
- ~~11.8.~~ [12.9.](#) The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)
- ~~11.9.~~ [12.10.](#) Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)
- ~~11.10.~~ [12.11.](#) Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)
- ~~11.1.~~ [12.12.](#) The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- ~~11.1.~~ [12.13.](#) ~~This~~ [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 .
- ~~11.11.~~ [12.14.](#) The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)
- ~~11.12.~~ [12.15.](#) Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)
- [12.16.](#) The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

- [12.16.1. Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where \(B&PC 4064.5\[a\]\)](#)
 - [12.16.1.1. The prescriber has not indicated “no change to quantity” or words of similar meaning; \(B&PC 4064.5\[d\]\)](#)
 - [12.16.1.2. The patient has completed an initial 30-day supply; \(B&PC 4064.5\[a\]\[1\]\) \(This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5\[b\]\)](#)
 - [12.16.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; \(B&PC 4064.5\[a\]\[2\]\)](#)
 - [12.16.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; \(B&PC 4064.5\[a\]\[3\]\)](#)
 - [12.16.1.5. The pharmacist is exercising his or her professional judgment. \(B&PC 4064.5\[a\]\[4\]\)](#)
- [12.16.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. \(B&PC 4064.5\[c\]\)](#)

CORRECTIVE ACTION OR ACTION PLAN: _____

12. 13. Refill Authorization

Yes No N/A

- [12.1. 13.1.](#) Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)
- [12.1. 13.2.](#) Refills are documented. (CCR 1717)
- [12.3. 13.3.](#) Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)
- [12.4. 13.4.](#) Refills for Schedule II controlled substances are prohibited. (H&SC 11200)
- [12.5. 13.5.](#) Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

13. 14. Quality Assurance and Medication Errors

Yes No N/A

~~13.1.~~ 14.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

~~13.2.~~ 14.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

~~13.3.~~ 14.3. The pharmacist communicates with the patient or patient’s agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR ~~1711~~[c][2][A], 1711[c][3])

~~13.4.~~ 14.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

~~13.5.~~ 14.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

~~13.6.~~ 14.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ~~13.6.1.~~ 14.6.1. Date, location, and participants in the quality assurance review;
- ~~13.6.2.~~ 14.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ~~13.6.3.~~ 14.6.3. Findings and determinations; and
- ~~13.6.4.~~ 14.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

~~13.7.~~ 14.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

~~13.8.~~ 14.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

~~14.1.~~ 15.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

~~14.2.~~ 15.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

Yes No N/A

~~14.3.~~ 15.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

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

15.5. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~15.~~ 16. Prescription Transfer

Yes No N/A

~~15.1.~~ 16.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

~~15.2.~~ 16.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

~~15.3.~~ 16.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

~~15.4.~~ 16.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~16.~~ 17. Confidentiality of Prescriptions

Yes No N/A

- ~~16.1.~~ [17.1.](#) Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)
- ~~16.2.~~ [17.2.](#) All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)
- Yes No N/A**
- ~~16.3.~~ [17.3.](#) The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])
- ~~16.4.~~ [17.4.](#) If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])
- ~~16.5.~~ [17.5.](#) If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)
- ~~16.6.~~ [17.6.](#) Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~17.~~ [18.](#) Record Keeping Requirements

Yes No N/A

- ~~17.1.~~ [18.1.](#) A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)
- ~~17.2.~~ [18.2.](#) All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):
- ~~17.2.1.~~ [18.2.1.](#) Prescription records (~~CCR~~ [B&PC](#) 4081[a])
 - ~~17.2.2.~~ [18.2.2.](#) Purchase Invoices for all prescription drugs ([B&PC](#) 4081[b])
 - ~~17.2.3.~~ [18.2.3.](#) Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
 - ~~17.2.4.~~ [18.2.4.](#) U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
 - ~~17.2.5.~~ [18.2.5.](#) Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
 - ~~17.2.6.~~ [18.2.6.](#) Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
 - ~~17.2.7.~~ [18.2.7.](#) Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
 - ~~17.2.8.~~ [18.2.8.](#) Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)
- Yes No N/A**
- ~~17.3.~~ [18.3.](#) Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140, 4149)

- ~~17.3.1.~~ 18.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- ~~17.3.2.~~ 18.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- ~~17.3.3.~~ 18.3.3. The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145)
- ~~17.3.4.~~ 18.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- ~~17.3.5.~~ 18.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

Yes No N/A

18.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

- 18.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 18.4.2. Furnish or make available mail-back sharps containers.
- 18.4.3. Furnish or make available sharps containers.

~~17.4.~~ 18.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. ~~19.~~ DEA Controlled Substances Inventory

Inventory:

Yes No N/A

~~18.1.~~ 19.1. Is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11[b])

~~18.2.~~ 19.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

~~18.3.~~ 19.3. Is available for inspection for three years. (CCR 1718)

[19.4. Indicates on the inventory record whether the inventory was taken at the “open of business” or at the “close of business.” \(CFR 1304.11\[a\]\)](#)

~~18.4.~~ [19.5.](#) Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

[Yes No N/A](#)

~~18.5.~~ [19.6.](#) Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red “C.” However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

[Yes No N/A](#)

~~18.6.~~ [19.7.](#) Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

~~18.7.~~ [19.8.](#) U.S. Official Order Form (DEA Form222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)

~~18.8.~~ [19.9.](#) When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

~~18.9.~~ [19.10.](#) When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

~~18.10.~~ [19.11.](#) Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)

~~18.11.~~ [19.12.](#) When dispensed upon an “oral” order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

~~18.12.~~ [19.13.](#) The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

~~18.13.~~ [19.14.](#) Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

~~18.14.~~ [19.15.](#) Do pharmacy staff hand initial prescription records or prescription labels, or

~~18.15.~~ [19.16.](#) Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

Yes No N/A

~~18.16.~~ [19.17.](#) All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

[19.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. \(21 CFR 1306.04\[b\]\)](#)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

~~19.1.~~ [20.1.](#) A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

~~19.2.~~ [20.2.](#) An oral prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription ~~form.~~ form, and: The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

[20.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.](#)

[20.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.](#)

[20.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.](#)

~~19.3.~~ [20.3.](#) An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5)

~~19.4.~~ 20.4. 19.4. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

~~19.5.~~ 20.5. The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

Yes No N/A

~~19.6.~~ 20.6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

~~19.7.~~ 20.7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

~~19.8.~~ 20.8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

~~19.9.~~ 20.9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

~~Yes-No-N/A~~

~~19.10.~~ 20.10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

20.11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

20.12. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

20.13. Electronic prescriptions (e-scripts) for controlled substances that are received by the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

20. 21. Automated Dispensing/Delivery Devices

Yes No N/A

~~20.1.~~ [21.1.](#) Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

~~20.2.~~ [21.2.](#) The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer’s lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342)

Yes No N/A

~~20.3.~~ [21.3.](#) For an “automated drug delivery system” located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- ~~20.3.1.~~ [21.3.1.](#) Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])
- ~~20.3.2.~~ [21.3.2.](#) A pharmacist reviews the order and patient’s profile prior to the drug being removed. (H&SC 1261.6[e][2])
- ~~20.3.3.~~ [21.3.3.](#) Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

~~20.4.~~ [21.4.](#) If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- ~~20.4.1.~~ [21.4.1.](#) Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])
- ~~20.4.2.~~ [21.4.2.](#) Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

21. 22. Repackaging by the Pharmacy

Yes No N/A

~~21.1.~~ [22.1.](#) Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer’s name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

~~21.2.~~ [22.2.](#) A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, [21 CFR Parts 210, 211](#))

~~21.3.~~ 22.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

~~22.~~ 23. Refill Pharmacy

Yes No N/A

~~22.1.~~ 23.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

~~22.2.~~ 23.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

~~22.3.~~ 23.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section 23.

~~22.4.~~ 23.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

~~22.5.~~ 23.5. Refill prescription label meets requirements of B&PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

~~22.6.~~ 23.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

~~22.7.~~ 23.7. Both pharmacies maintain complete and accurate records ~~of~~ of refill. (CCR 1707.4[a][4])

~~22.8.~~ 23.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

~~22.9.~~ 23.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

24. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

24.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

- [24.1.1. Health system pharmacy. \(HSC 125286.20\[j\]\[1\]\[B\]\)](#)
- [24.1.2. Pharmacy affiliated with hemophilia treatment centers. \(HSC 125286.20\[j\]\[1\]\[C\]\)](#)
- [24.1.3. Specialty home care pharmacy. \(HSC 125286.20\[j\]\[1\]\[D\]\)](#)
- [24.1.4. Retail pharmacy. \(HSC 125286.20\[j\]\[1\]\[E\]\)](#)

Yes No N/A

[24.2. The pharmacy meets the following requirements:](#)

- [24.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. \(HSC 125286.25\[a\]\)](#)
- [24.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. \(HSC 125286.25\[b\]\)](#)
- [24.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. \(HSC 125286.25\[c\]\)](#)
- [24.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. \(HSC 125286.25\[d\]\)](#)
- [24.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. \(HSC 125286.25\[e\]\)](#)
- [24.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. \(HSC 125286.25\[f\]\)](#)
- [24.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. \(HSC 125286.25\[g\]\)](#)
- [24.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. \(HSC 125286.25\[h\]\)](#)
- [24.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. \(HSC 125286.25\[i\]\)](#)
- [24.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. \(HSC 125286.25\[j\]\)](#)
- [24.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. \(HSC 125286.25\[k\]\)](#)

- [24.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. \(HSC 125286.25\[l\]\)](#)

23. 25. Policies and Procedures

Yes No N/A

~~23.1.~~ [25.1.](#) There are written policies and procedures in place for:

- ~~23.1.1.~~ [25.1.1.](#) The pharmacist’s administration of immunizations by injection pursuant to a prescriber’s order; (B&PC 4052.1[a][3])
- ~~23.1.2.~~ [25.1.2.](#) Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it ~~effects~~ [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])
- ~~23.1.3.~~ [25.1.3.](#) Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, [including the reporting to the board within 14 days of receipt or development](#); (B&PC 4104[b][c])
- ~~23.1.4.~~ [25.1.4.](#) Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])
- ~~23.1.5.~~ [25.1.5.](#) Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist’s responsibilities for checking all work performed by ancillary staff, and pharmacist’s responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])
- ~~23.1.6.~~ [25.1.6.](#) Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])
- ~~23.1.7.~~ [25.1.7.](#) The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B&PC 4059.5[f][1])
- ~~23.1.8.~~ [25.1.8.](#) Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- ~~23.1.9.~~ [25.1.9.](#) Reporting requirements to protect the public; (B&PC 4104)
- ~~23.1.10.~~ [25.1.10.](#) Preventing the dispensing of a prescription drug that is contrary to the law; (B&PC 733)
- ~~23.1.11.~~ [25.1.11.](#) Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient’s medical condition; and (B&PC 733)
- ~~23.1.12.~~ [25.1.12.](#) Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient’s language, including the

selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

Yes No N/A

~~23.2.~~ 25.2. Does your pharmacy employ the use of a common electronic file?

- ~~23.2.1.~~ 25.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

COMPOUNDING

~~24.~~ 26. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 Rev. ~~01/11~~ 05/13. (CCR 1735.2[jj])

~~25.~~ 27. NUCLEAR PHARMACY

Yes No N/A

~~25.1.~~ 27.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

~~25.2.~~ 27.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

~~25.3.~~ 27.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. ~~01/11~~ 05/13.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

28. PHARMACIES THAT DONATE DRUGS TO A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

28.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204)

- 28.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150202.5)

28.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

Yes No N/A

28.2. No controlled substances shall be donated. (H&SC 150204[c][1])

28.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

28.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

28.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

28.3.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

28.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

28.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

29. PHARMACIES THAT OPERATE A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

29.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150201[a][1])

Is county owned (H&SC 150201[a][1]) or

Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[a][1], 150200)

29.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

29.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

29.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

Yes No N/A

29.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

29.5. The pharmacy complies with the county's established written procedures. (H&SC 105024[b])

Drugs and Maintenance of Drug Stock

29.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

29.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

29.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

29.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 15204[c])

29.9.1. Are received from authorized sources. (H&SC 150202, 150203)

29.9.2. No controlled substances are received. (H&SC 150204[c][1])

29.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

29.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

29.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

29.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

29.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

29.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

Transferring Donated Drugs From One Participating Entity to Another

Yes No N/A

29.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

29.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

29.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

29.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

29.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

Dispensing to Eligible Patients

29.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

29.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____



The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24
Business and Professions Code (B&PC), Chapter 9, Division 2
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration
(www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:

Law-Tech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program

(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)

Prescription Collection
8030 S. Willow Street, Bldg 3 Unit 3
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES

4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
<http://www.ag.ca.gov/bne>

CURES Patient Activity Report Request Forms:

<http://www.ag.ca.gov/bne/trips.php>

PRESCRIBER BOARDS:

Medical Board of California

2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
<http://www.mbc.ca.gov>

Dental Board of California

2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing

1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-3350
Fax: (916) 574-7697
<http://www.rn.ca.gov/>

Board of Optometry

2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California

1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: (916) 928-8392
<http://www.ombc.ca.gov>

Physician Assistant Committee

2500 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine

2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

FEDERAL AGENCIES:**Food and Drug Administration
– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering System (CSOS): <http://www.deaecom.gov/>**DEA - Fresno**

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~01/14~~ 11/13) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~01/14~~ 11/13).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

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

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

Hours: Daily _____ Sat _____ Sun _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

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

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If “NO,” enter an explanation on “CORRECTIVE ACTION or ACTION PLAN” lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

- 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)
- 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])
- 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])
- 1.4. The pharmacy reports to the board within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])
- 1.5. The pharmacy maintains “night stock” medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
- 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
- 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)
- 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

1.12. Does the pharmacy compound sterile injectable drugs?
(If yes, complete section 24 – “Compounding Sterile Injectable Drugs”)

1.13. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Nursing Stations

Yes No N/A

2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

2.2. The pharmacist completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Delivery of Drugs

Yes No N/A

3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

Yes No N/A

3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

- 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

4. Drug Stock

Yes No N/A

4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. PHARMACIES THAT DONATE DRUGS TO A COUNTY-APPROVED DRUG REPOSITORY AND DISTRIBUTION PROGRAM

Yes No N/A

- 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, 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, 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])

5. 6. Pharmacist-in-Charge (PIC)

Yes No N/A

- ~~5.1.~~ 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)
- ~~5.2.~~ 6.2. The PIC has adequate authority to assure the pharmacy’s compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])
- ~~5.3.~~ 6.3. Is the PIC in charge of another pharmacy?
- If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])
- If yes, name of other pharmacy _____

Yes No N/A

~~5.4.~~ 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)

~~5.5.~~ 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: _____

~~6.~~ 7. **Duties of a Pharmacist**

Yes No N/A

~~6.1.~~ 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)

~~6.2.~~ 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. (B&PC 4027, 4051, 4052, 4052.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~7.~~ 8. **Duties of an Intern Pharmacist**

Yes No N/A

~~7.1.~~ 8.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, CCR 1726)

Yes No N/A

- ~~7.2.~~ [8.2.](#) All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])
- [8.3.](#) [During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. \(CCR 1714.1\[d\]\)](#)
- ~~7.3.~~ [8.4.](#) The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~8.~~ [9.](#) Duties of a Pharmacy Technician

Yes No N/A

- ~~8.4.~~ [9.1.](#) Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)
- ~~8.2.~~ [9.2.](#) The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])
- ~~8.3.~~ [9.3.](#) Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)
- ~~8.4.~~ [9.4.](#) A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
- ~~8.5.~~ [9.5.](#) The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)
- ~~8.6.~~ [9.6.](#) The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)
- [9.7.](#) [During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. \(B&PC 4115\[g\], CCR 1714.1\[c\]\)](#)
- ~~8.7.~~ [9.8.](#) The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)
 - ~~8.7.1.~~ [9.8.1.](#) Pharmacists are deployed to the inpatient care setting to provide clinical services.
 - ~~8.7.2.~~ [9.8.2.](#) Compounded or repackaged products are previously checked by a pharmacist.
 - ~~8.7.3.~~ [9.8.3.](#) The overall operations are the responsibility of the pharmacist-in-charge.

- ~~8.7.4.~~ 9.8.4. The pharmacy technician check technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ~~8.7.5.~~ 9.8.5. There is an ongoing evaluation of the program that uses specially trained pharmacy technicians to check the work of other pharmacy technicians.

CORRECTIVE ACTION OR ACTION PLAN: _____

9. 10. Duties of Non-Licensed Personnel

Yes No N/A

- ~~9.1.~~ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)
- ~~9.2.~~ 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

10. 11. Pharmaceutical Service Requirements

Yes No N/A

- ~~10.4.~~ 11.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:
 - ~~10.4.1.~~ 11.1.1. Basic information concerning investigational drugs and adverse drug reactions;
 - ~~10.4.2.~~ 11.1.2. Repackaging and compounding records;
 - ~~10.4.3.~~ 11.1.3. Physician orders;
 - ~~10.4.4.~~ 11.1.4. Wards, nursing stations and night stock medications;
 - ~~10.4.5.~~ 11.1.5. Drugs brought into the facility by patients for storage or use;
 - ~~10.4.6.~~ 11.1.6. Bedside medications;
 - ~~10.4.7.~~ 11.1.7. Emergency drug supply;
 - ~~10.4.8.~~ 11.1.8. Pass medications;
 - ~~10.4.9.~~ 11.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\Outdated drugs;
 - ~~10.4.10.~~ 11.1.10. Routine distribution of inpatient medications;
 - ~~10.4.11.~~ 11.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
 - ~~10.4.12.~~ 11.1.12. Handling of medication when pharmacist not on duty; and
 - ~~10.4.13.~~ 11.1.13. Use of electronic image and data order transmissions.

Yes No N/A

~~40.2.~~ 11.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ~~40.2.1.~~ 11.2.1. Destruction of controlled substances; and
- ~~40.2.2.~~ 11.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

41. 12. Medication/Chart Order

Yes No N/A

~~41.4.~~ 12.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

~~41.2.~~ 12.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

~~41.3.~~ 12.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

42. 13. Labeling and Distribution

Yes No N/A

~~42.4.~~ 13.1. Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076, CCR 1751.2)

~~42.2.~~ 13.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

~~42.3.~~ 13.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to 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: _____

13. 14. Duration of Drug Therapy

Yes No N/A

The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[jj])

CORRECTIVE ACTION OR ACTION PLAN: _____

14. 15. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

14.1. 15.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

14.2. 15.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

14.3. 15.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

14.4. 15.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

15. 16. Quality Assurance and Medication Errors

Yes No N/A

15.1. 16.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

15.2. 16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

15.3. 16.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

15.4. 16.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

Yes No N/A

- ~~45.5.~~ [16.5.](#) Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- ~~45.6.~~ [16.6.](#) The record for quality assurance review for a medication error contains: (CCR 1711[e]);
- ~~45.6.1.~~ [16.6.1.](#) Date, location, and participants in the quality assurance review;
 - ~~45.6.2.~~ [16.6.2.](#) Pertinent data and other information related to the medication error(s) reviewed;
 - ~~45.6.3.~~ [16.6.3.](#) Findings and determinations;
 - ~~45.6.4.~~ [16.6.4.](#) Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- ~~45.7.~~ [16.7.](#) The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])
- ~~45.8.~~ [16.8.](#) Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

16. [17.](#) Record Keeping Requirements

Yes No N/A

- ~~46.1.~~ [17.1.](#) A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)
- ~~46.2.~~ [17.2.](#) All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:
- ~~46.2.1.~~ [17.2.1.](#) Prescription records (B&PC 4081[a])
 - ~~46.2.2.~~ [17.2.2.](#) Purchase Invoices for all prescription drugs (B&PC 4081[b])
 - ~~46.2.3.~~ [17.2.3.](#) Biennial controlled substances inventory (21 CFR 1304.11)
 - ~~46.2.4.~~ [17.2.4.](#) U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)
 - ~~46.2.5.~~ [17.2.5.](#) Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
 - ~~46.2.6.~~ [17.2.6.](#) Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
 - ~~46.2.7.~~ [17.2.7.](#) Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
 - ~~46.2.8.~~ [17.2.8.](#) Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
 - [17.2.9. Centrally stored unused medications donated to a drug repository and distribution program. \(H&SC 150200, 150202\[a\]\[1\]\)](#)
- ~~46.3.~~ [17.3.](#) Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503, B&PC 4160)

Yes No N/A

- ~~46.4.~~ [17.4.](#) If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
- ~~46.5.~~ [17.5.](#) A controlled substances inventory is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11)
- ~~46.6.~~ [17.6.](#) Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
- ~~46.7.~~ [17.7.](#) Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
- ~~46.8.~~ [17.8.](#) DEA Forms 222 are properly executed. (21 CFR 1305.09)
- ~~46.9.~~ [17.9.](#) When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)
- ~~46.10.~~ [17.10.](#) Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)
- ~~46.11.~~ [17.11.](#) Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)
- ~~46.12.~~ [17.12.](#) Do pharmacy staff hand initial prescription records and prescription labels, OR
- ~~46.13.~~ [17.13.](#) Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~47.~~ [18.](#) After-Hours Supply of Medication

Yes No N/A

- The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

18- 19. Drug Supplies for Use in Medical Emergencies

Yes No N/A

- 18-1. 19.1.** A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])
- 18-2. 19.2.** Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])
- 18-3. 19.3.** The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])
- 18-4. 19.4.** The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the written policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

19- 20. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

- Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

20- 21. Emergency Room Dispensing

Yes No N/A

- 20-1. 21.1.** A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply (B&PC 4068[a]):
 - 20-1.1. 21.1.1.** The hospital pharmacy is closed and there is no pharmacist available in the hospital;
 - 20-1.2. 21.1.2.** The dangerous drug is acquired by the hospital pharmacy;
 - 20-1.3. 21.1.3.** The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
 - 20-1.4. 21.1.4.** The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

- ~~20.4.5.~~ 21.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ~~20.4.6.~~ 21.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

- ~~20.2.~~ 21.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])
- ~~20.3.~~ 21.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])
- ~~20.4.~~ 21.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- ~~20.5.~~ 21.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)
- ~~20.6.~~ 21.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)
- ~~20.7.~~ 21.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~21.~~ 22. Discharge Medication/Consultation Services

Yes No N/A

- ~~21.1.~~ 22.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)
- ~~21.2.~~ 22.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)
- ~~21.3.~~ 22.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)
- ~~21.4.~~ 22.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])
- ~~21.5.~~ 22.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: _____ to _____

Yes No N/A

- ~~21.6.~~ [22.6.](#) Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- ~~21.7.~~ [22.7.](#) The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- ~~21.8.~~ [22.8.](#) Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)
- ~~21.9.~~ [22.9.](#) If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)
- ~~21.10.~~ [22.10.](#) Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)
- ~~21.11.~~ [22.11.](#) Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)
- ~~21.12.~~ [22.12.](#) Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: _____

22. ~~23.~~ Central Fill—Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

- ~~22.1.~~ [23.1.](#) Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])
If the answer is "yes," name of hospital: _____
- ~~22.2.~~ [23.2.](#) Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])
If the answer is "yes," name of supplying pharmacy: _____
If the answer to this and the previous question is "no" or "not applicable" go to Section 23.
- ~~22.3.~~ [23.3.](#) Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])
- ~~22.4.~~ [23.4.](#) Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])
- ~~22.5.~~ [23.5.](#) Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])
- ~~22.6.~~ [23.6.](#) Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3])
- ~~22.7.~~ [23.7.](#) Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

24. Centralized Hospital Packaging Pharmacy

Yes No N/A

24.1. The pharmacy packages unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

24.1.1. _____ Distance (miles): _____

24.1.2. _____ Distance (miles): _____

24.1.3. _____ Distance (miles): _____

24.1.4. _____ Distance (miles): _____

24.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

24.3. All unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient's bedside. The barcode information contains: (B&PC 4128.4)

24.3.1. The date the medication was prepared.

24.3.2. The components used in the drug product.

24.3.3. The lot number or control number.

24.3.4. The expiration date.

24.3.5. The National Drug Code Directory number.

24.3.6. The name of the centralized hospital packaging pharmacy.

24.4. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. (B&PC 4128.5)

24.5. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~23.~~ 25. Policies and Procedures

Yes No N/A

~~23.1.~~ 25.1. There are written policies and procedures in place for:

~~23.1.1.~~ 25.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.

~~23.1.2.~~ 25.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])

- ~~23.1.3.~~ 25.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])
- ~~23.1.4.~~ 25.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])
- ~~23.1.5.~~ 25.1.5. Reporting to the board within 30 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
- ~~23.1.6.~~ 25.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])
- ~~23.1.7.~~ 25.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- ~~23.1.8.~~ 25.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- ~~23.1.9.~~ 25.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

~~24.~~ 26. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 Rev. ~~01/11~~ 11/13. (CCR 1735.2[j])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

D
R
A

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24

Business and Professions Code (B&PC), Chapter 9, Division 2

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219

Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

<http://www.pharmacy.ca.gov>

Pharmacy Law may be obtained by contacting:

LawTech Publishing Co.

1060 Calle Cordillera, Suite 105

San Clements CA 92673

(800) 498-0911 Ext. 5

<http://www.lawtechpublishing.com>

Pharmacist Recovery Program

(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)

Prescription Collection

8030 S. Willow Street, Bldg 3 Unit 3

Manchester, NH 03103

Phone: (888) 492-7341

Fax: (877) 508-6704

CURES

P.O. Box 160447

Sacramento, CA 95816-1089

Phone: (916) 319-9062

Fax: (916) 319-9448

<http://www.ag.ca.gov/bne>

CURES Patient Activity Report Request Forms:

<http://www.ag.ca.gov/bne/trips.php>

PRESCRIBER BOARDS:

Medical Board of California

2005 Evergreen St., Suite 1200

Sacramento, CA 95815

Phone: (800) 633-2322

Phone: (916) 263-2382

Fax: (916) 263-2944

<http://www.mbc.ca.gov>

Dental Board of California

2005 Evergreen St., Suite 1550

Sacramento, CA 95815

Phone: (877) 729-7789

Phone: (916) 263-2300

Fax: (916) 263-2140

<http://www.dbc.ca.gov>

Board of Registered Nursing

1625 N. Market Blvd., Suite N217

Sacramento, CA 95834

Phone: (916) 322-3350

Fax: (916) 574-7697

<http://www.rn.ca.gov>

Board of Optometry

2420 Del Paso Road, Suite 255

Sacramento, CA 95834

Phone: (916) 575-7170

Fax: (916) 575-7292

<http://www.optometry.ca.gov>

Osteopathic Medical Board of California

1300 National Drive, Suite #150

Sacramento, CA 95834

Phone: (916) 928-8390

Fax: (916) 928-8392

<http://www.ombc.ca.gov>

Physician Assistant Committee

2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine

2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

FEDERAL AGENCIES:**Food and Drug Administration****– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website: <http://www.dea diversion.usdoj.gov>

Online Registration – New Applicants:

http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.dea diversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

<https://www.dea diversion.usdoj.gov/webforms/app106Login.jsp>

Online DEA 222 Controlled Substance Ordering System (CSOS): <http://www.deacom.gov/>**DEA - Fresno**

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631



WHOLESALE DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18 21.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022.
(http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____

Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

- sole owner partnership corporation LLC
- non- licensed owner Other (please specify) _____

CA Wholesaler Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____

DEA Registration # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Daily _____ Sat _____ Sun _____ 24 Hours

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC License # / RPH License # _____ Expiration Date _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist):

- 1. _____ DR#/RPH# _____ Exp. Date _____
- 2. _____ DR#/RPH# _____ Exp. Date _____
- 3. _____ DR#/RPH# _____ Exp. Date _____
- 4. _____ DR#/RPH# _____ Exp. Date _____
- 5. _____ DR#/RPH# _____ Exp. Date _____
- 6. _____ DR#/RPH# _____ Exp. Date _____
- 7. _____ DR#/RPH# _____ Exp. Date _____
- 8. _____ DR#/RPH# _____ Exp. Date _____
- 9. _____ DR#/RPH# _____ Exp. Date _____
- 10. _____ DR#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If “NO,” enter an explanation on the “CORRECTIVE ACTION OR ACTION PLAN” lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

- 1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**
- 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. ~~(CCR~~ (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~~
(CCR 1780[c][2]).

Explain how your security system complies with these requirements.

Yes No N/A

2.7. Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.9. The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.2. Is the designated representative-in-charge responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d])

3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

Yes No N/A

- 3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

- 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

~~Yes No N/A~~

- 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ [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 ~~H~~ [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 [H 12](#) of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

- 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169)

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

- 8.5. Does your business only receive drugs from a pharmacy if:
 - 8.5.1. the pharmacy originally purchased the drugs from you?
 - 8.5.2. your business is a “reverse distributor”?
 - 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

8.6. Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

Yes No N/A

- 8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?
- 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?
- 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?
- 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

- 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?
- 8.8.2. comply with the pharmacy law of the receiving state within the United States?
- 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?
- 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?
- 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

Yes No N/A

- 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.

Yes No N/A

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

~~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)

~~Yes No N/A~~

8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~H~~ 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

Yes No N/A

9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

- 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 9.3.2. Has never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

9. 10. Outgoing Shipments of Drugs

Yes No N/A

~~9.1.~~ 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])

~~9.2.~~ 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])

~~9.3.~~ 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 ~~H~~ 12 of this document.

10. 11. Delivery of Drugs

Yes No N/A

~~10.1.~~ 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

- ~~10.2.~~ [11.2.](#) Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059[d])
- ~~10.3.~~ [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])
- ~~10.4.~~ [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 _____

~~11.~~ [12.](#) **Controlled Substances**

Yes No N/A

- ~~11.1.~~ [12.1.](#) Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)
- ~~11.2.~~ [12.2.](#) Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])
- ~~11.3.~~ [12.3.](#) Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
- ~~Yes No N/A~~
- ~~11.4.~~ [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])
- ~~11.5.~~ [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)

- ~~11.6.~~ [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)

~~11.7.~~ 12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

~~11.8.~~ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

~~11.9.~~ 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)

~~11.10.~~ 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])

~~11.11.~~ 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])

~~11.12.~~ 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])

~~11.13.~~ 12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

~~11.14.~~ 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~~ (CFR 1301.74[f])

~~11.15.~~ 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])

~~11.16.~~ 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

- ~~11.17.~~ [12.17.](#) When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])
- ~~11.18.~~ [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)
- ~~11.19.~~ [12.19.](#) When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.13[b])
- ~~11.20.~~ [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~~ [\(CFR 1305.13\[e\]\)](#))
- ~~11.21.~~ [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](#))
- ~~11.22.~~ [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))
- ~~11.23.~~ [12.23.](#) Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1305.09[d], 1305.17[a] [b], and ~~H&S~~ [H&SC](#) 11252, 11253, 1304.03)
- ~~11.24.~~ [12.24.](#) Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- ~~11.25.~~ [12.25.](#) Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- ~~11.26.~~ [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])
- ~~11.27.~~ [12.27.](#) Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)

Yes No N/A

~~11.28.~~ [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])

~~11.29.~~ [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 _____

~~12.~~ [13.](#) Policies and Procedures

~~12.1.~~ [13.1.](#) Does this business maintain and adhere to policies and procedures for: (CCR 1780[f])

Yes No N/A

~~12.1.1.~~ [13.1.1.](#) Receipt of drugs?

~~12.1.2.~~ [13.1.2.](#) Security of drugs?

~~12.1.3.~~ [13.1.3.](#) Storage of drugs? (including maintaining records to document proper storage)

~~12.1.4.~~ [13.1.4.](#) Inventory of drugs? (including correcting inaccuracies in inventories)

~~12.1.5.~~ [13.1.5.](#) Distributing drugs?

~~12.1.6.~~ [13.1.6.](#) Identifying, recording and reporting theft or losses?

~~12.1.7.~~ [13.1.7.](#) Correcting ~~errors?~~ [errors and inaccuracies in inventories?](#)

Physically quarantining and separating:

~~12.1.8.~~ [13.1.8.](#) returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?

~~12.1.9.~~ [13.1.9.](#) drugs that have been partially used?

~~12.1.10.~~ [13.1.10.](#) drugs where the outer or secondary seals on the container have been broken?

~~12.1.11.~~ [13.1.11.](#) drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

~~12.1.12.~~ [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 _____

13. 14. Training

Yes No N/A

- Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN _____

14. 15. Dialysis Drugs

Yes No N/A

- 14.1. 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.
- 14.2. 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])
- 14.3. 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])
- 14.4. 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)
- 14.5. 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 _____

15. 16. Record Keeping Requirements

Yes No N/A

- ~~15.1.~~ 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])

- ~~15.2.~~ 16.2. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.

- ~~15.3.~~ 16.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

- ~~15.4.~~ 16.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

- ~~15.5.~~ 16.5. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

- ~~15.6.~~ 16.6. Are required records stored off-site only if a board issued written waiver has been granted?

~~15.7.~~ 16.7. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

~~Yes No N/A~~

- ~~15.8.~~ 16.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

- ~~15.9.~~ 16.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

- ~~15.10.~~ 16.10. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

- ~~15.11.~~ 16.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

- ~~15.12.~~ [16.12.](#) Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):
-
-

~~Yes No N/A~~

- ~~15.13.~~ [16.13.](#) Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)
- ~~15.14.~~ [16.14.](#) Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])
- ~~15.15.~~ [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 ~~H~~ [12](#) of this document.

~~16.~~ [17.](#) Reporting Requirements to the Board

Yes No N/A

- ~~16.1.~~ [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]).
- ~~16.2.~~ [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])
- ~~16.3.~~ [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)
- ~~16.4.~~ [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

- ~~16.5.~~ 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)
- ~~16.6.~~ 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])
- ~~16.7.~~ 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])
- ~~16.8.~~ 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])
- ~~16.9.~~ 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])
- ~~16.10.~~ 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)
- ~~16.11.~~ 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 _____

17. 18. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a])

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

California Board of Pharmacy

1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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/>

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

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/>

Pharmacist Recovery Program

Phone: (800) 522-9198 (24 hours a day)

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>

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>

Physician Assistant Committee

2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.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 Podiatric Medicine

2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

Federal Agencies:

Food and Drug Administration

– Industry Compliance

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/pp106Login.jsp>

Controlled Substance Ordering System

(CSOS): <http://www.deacom.gov/>

DEA Registration Support (all of CA):

(800) 882-9539

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043



COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug products to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year.** The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding Permit # _____ Expiration: _____

or Accredited by: _____ From: _____ To: _____

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

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

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

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

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

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 8.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

1.1. The pharmacy compounds prescriptions as defined in CCR 1735.

1.2. The compounding pharmacist understands the definitions of equipment, integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

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

2.2. The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

2.2.1. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

2.2.2. Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

2.2.3. Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

2.3. The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements: (CCR 1735.2[d][1-6])

2.3.1. Active ingredients used.

2.3.2. Equipment to be used.

2.3.3. Expiration dating requirements.

2.3.4. Inactive ingredients used.

2.3.5. Process and/or procedure used to prepare the drug.

2.3.6. Quality reviews required at each step in the preparation of the drug.

2.3.7. Post-compounding process or procedures if required.

Yes No N/A

- 2.4. The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])
- 2.5. All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])
- 2.6. Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The "beyond use date" of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

- 3.1. A record for each compounded drug product includes the following: (CCR 1735.3[a][1-10])
- 3.1.1. The master formula record.
 - 3.1.2. The date the drug product was compounded.
 - 3.1.3. The identity of the pharmacy personnel who compounded the drug product.
 - 3.1.4. The identity of the pharmacist reviewing the final drug product.
 - 3.1.5. The quantity of each component used in compounding the drug product.
 - 3.1.6. The manufacturer or supplier, expiration date and lot number of each component.
Exempt from this requirement are sterile drug products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispatched CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - 3.1.7. The pharmacy assigned reference or lot number for the compounded drug product.
 - 3.1.8. The expiration date of the final compounded drug product.
 - 3.1.9. The quantity or amount of drug product compounded.
- 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])
- 3.3. Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])

Yes No N/A

3.4. The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])

3.5. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

4.1. The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])

4.2. The prescription label contains all the information required in B&PC 4076 and is formatted in accordance with CCR 1707.5. (CCR 1735.4[a])

4.3. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])

4.4. The pharmacy is exempt from the prescription label requirements in CCR 1707.5. (B&PC 4076.5[d])

Exemption approved by the board from: _____ to: _____

4.5. The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])

4.6. Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date. (CCR 1735.4[c])

4.7. Compounded drug products received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

5.1. The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]):

5.1.1. Procurement procedures.

5.1.2. Methodologies for the formulation and compounding of drugs.

5.1.3. Facilities and equipment cleaning, maintenance and operations.

5.1.4. Other standard operating procedures related to compounding.

Yes No N/A

- 5.2. The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])

Yes No N/A

- 5.3. The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])
- 5.4. The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2])
- 5.5. The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[c][3])
- 5.6. The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[c][4])
- 5.7. The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[c][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

- 6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- 6.2. All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- 6.3. All equipment used to compound drug products is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
- 6.4. Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

- 7.1. The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

7.2. The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

Yes No N/A

7.3. Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

7.4. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

8.1. The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

8.2. The pharmacy's quality assurance plan includes the written procedures and standards for the following:

8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

8.2.2. Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[c])

8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

8.2.4. Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

(Continued on Next Page)

9. Centralized Hospital Packaging Pharmacy (B&PC 4128 et seq.)

Yes No N/A

9.1. The pharmacy compounds unit dose medications only for inpatients of one or more hospitals under common ownership within a 75-mile radius. (B&PC 4128[a])

Hospitals to which central packaged unit dose medications are provided:

9.1.1. _____ Distance (miles): _____

9.1.2. _____ Distance (miles): _____

9.1.3. _____ Distance (miles): _____

9.1.4. _____ Distance (miles): _____

Yes No N/A

- 9.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)
- 9.3. Compounded unit dose drugs for administration to inpatients are barcoded. (B&PC 4128[a][1], 4128.4)
- 9.4. Barcoded unit dose compounded drugs are readable at an inpatient's bedside and include the following: (B&PC 4128.4)
- 9.4.1. The date the medication was prepared.
 - 9.4.2. The components used.
 - 9.4.3. The lot number or control number.
 - 9.4.4. The expiration date.
 - 9.4.5. The National Drug Code Directory number.
 - 9.4.6. The name of the centralized hospital packaging pharmacy.
- 9.5. Labels for compounded unit dose drugs prepared by the centralized hospital packaging pharmacy contain the following: (B&PC 4128.5)
- 9.5.1. The expiration date.
 - 9.5.2. The established name of the drug.
 - 9.5.3. The quantity of the active ingredient.
 - 9.5.4. Special storage or handling requirements.

COMPOUNDING STERILE INJECTABLE DRUGS

Does the pharmacy compound sterile injectable drugs? Yes No

If yes, complete Sections **9** 10 through **19** 20.

9, 10. FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS: Permit or Accreditation

Yes No N/A

- The pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

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

Yes No N/A

~~40.4.~~ 11.1. The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

- ~~40.4.1.~~ 11.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.

41. 12. Sterile Injectable Compounding: Compounding Area (CCR 1751)

Yes No N/A

~~44.4.~~ 12.1. If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

- ~~44.4.1.~~ 12.1.1. An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])
- ~~44.4.2.~~ 12.1.2. An ISO class 5 cleanroom (B&PC 4127.7[b])
- ~~44.4.3.~~ 12.1.3. A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

~~44.2.~~ 12.2. The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)

- ~~44.2.1.~~ 12.2.1. The laminar airflow hoods and clean room are certified annually; (CCR 1751)
- ~~44.2.2.~~ 12.2.2. Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)
- ~~44.2.3.~~ 12.2.3. A sink with hot and cold running water; (CCR 1751)
- ~~44.2.4.~~ 12.2.4. A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

42. 13. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

~~42.4.~~ 13.1. Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

~~42.2.~~ 13.2. Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

- ~~42.2.1.~~ 13.2.1. The training and competency evaluation of employees in sterile product procedures;

- ~~42.2.2.~~ [13.2.2.](#) Refrigerator and freezer temperatures;
- ~~42.2.3.~~ [13.2.3.](#) Certification of the sterile compounding environment;
- ~~42.2.4.~~ [13.2.4.](#) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);
- ~~42.2.5.~~ [13.2.5.](#) Inspection for expired or recalled pharmaceutical products or raw ingredients; and
- ~~42.2.6.~~ [13.2.6.](#) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

~~42.3.~~ [13.3.](#) The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

~~13.~~ [14.](#) Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

- ~~43.1.~~ [14.1.](#) In addition to the labeling information required under Business and Professions Code section 4076 and CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])
- ~~43.1.1.~~ [14.1.1.](#) Telephone number of the pharmacy, unless dispensed for a hospital in-patient;
 - ~~43.1.2.~~ [14.1.2.](#) Name and concentrations of ingredients contained in the product;
 - ~~43.1.3.~~ [14.1.3.](#) Instructions for storage and handling; and
 - ~~43.1.4.~~ [14.1.4.](#) A special label that states "Chemotherapy—Dispose of Properly" or "Cytotoxic – Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

~~14.~~ [15.](#) Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

- ~~44.1.~~ [15.1.](#) The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and, in addition to the elements required by section 1735.5, includes: (CCR 1751.2[a][1-7])
- ~~44.1.1.~~ [15.1.1.](#) Compounding, filling, and labeling of sterile injectable compounds;
 - ~~44.1.2.~~ [15.1.2.](#) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;
 - ~~44.1.3.~~ [15.1.3.](#) Equipment and supplies;
 - ~~44.1.4.~~ [15.1.4.](#) Training of staff in preparation of sterile injectable products;

- ~~14.4.5.~~ [15.1.5.](#) Training of patient and/or caregiver in the administration of compounded sterile injectable products;
- ~~14.4.6.~~ [15.1.6.](#) Procedures for the handling and disposal of cytotoxic agents;
- ~~14.4.7.~~ [15.1.7.](#) Quality assurance program; and
- ~~14.4.8.~~ [15.1.8.](#) Record keeping requirements.

Yes No N/A

- ~~14.2.~~ [15.2.](#) Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])
- ~~14.3.~~ [15.3.](#) Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])
- ~~14.4.~~ [15.4.](#) If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])
 - ~~14.4.1.~~ [15.4.1.](#) Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and
 - ~~14.4.2.~~ [15.4.2.](#) All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])
- ~~14.5.~~ [15.5.](#) Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])
 - ~~14.5.1.~~ [15.5.1.](#) Competency evaluation;
 - ~~14.5.2.~~ [15.5.2.](#) Storage and handling of products and supplies;
 - ~~14.5.3.~~ [15.5.3.](#) Storage and delivery of final products;
 - ~~14.5.4.~~ [15.5.4.](#) Process validation;
 - ~~14.5.5.~~ [15.5.5.](#) Personnel access and movement of materials into and near the controlled area;
 - ~~14.5.6.~~ [15.5.6.](#) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations);
 - ~~14.5.7.~~ [15.5.7.](#) A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;
 - ~~14.5.8.~~ [15.5.8.](#) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;
 - ~~14.5.9.~~ [15.5.9.](#) For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;
 - ~~14.5.10.~~ [15.5.10.](#) Sterilization; and
 - ~~14.5.11.~~ [15.5.11.](#) End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

15. 16. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

- ~~15.4.~~ 16.1. The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])
- ~~15.2.~~ 16.2. Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])
- ~~15.3.~~ 16.3. All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])
- ~~15.4.~~ 16.4. Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])
- ~~15.5.~~ 16.5. The preparation of parenteral cytotoxic agents is done in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations and includes: (CCR 1751.4[e])
 - ~~15.5.1.~~ 16.5.1. A laminar airflow hood, which is certified annually.
 - ~~15.5.2.~~ 16.5.2. Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

16. 17. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

- ~~16.1.~~ 17.1. When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.5[a])
- ~~16.2.~~ 17.2. When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])
 - ~~16.2.1.~~ 17.2.1. Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])
 - ~~16.2.2.~~ 17.2.2. Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])
 - ~~16.2.3.~~ 17.2.3. No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])
 - ~~16.2.4.~~ 17.2.4. Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and
 - ~~16.2.5.~~ 17.2.5. Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

47. 18. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

Yes No N/A

- ~~47.4.~~ 18.1. Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])
- ~~47.2.~~ 18.2. The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.6[b])
- ~~47.3.~~ 18.3. Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])
- ~~47.4.~~ 18.4. The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])
- ~~47.5.~~ 18.5. When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])
- ~~47.6.~~ 18.6. The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])
 - ~~47.6.1.~~ 18.6.1. Aseptic technique;
 - ~~47.6.2.~~ 18.6.2. Pharmaceutical calculations and terminology;
 - ~~47.6.3.~~ 18.6.3. Sterile product compounding documentation;
 - ~~47.6.4.~~ 18.6.4. Quality assurance procedures;
 - ~~47.6.5.~~ 18.6.5. Aseptic preparation procedures;
 - ~~47.6.6.~~ 18.6.6. Proper gowning and gloving technique;
 - ~~47.6.7.~~ 18.6.7. General conduct in the controlled area;
 - ~~47.6.8.~~ 18.6.8. Cleaning, sanitizing, and maintaining equipment used in the controlled area;
 - ~~47.6.9.~~ 18.6.9. Sterilization techniques; and
 - ~~47.6.10.~~ 18.6.10. Container, equipment, and closure system selection.

Yes-No-N/A

- ~~47.7.~~ 18.7. Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])
 - ~~47.7.1.~~ 18.7.1. ~~checks~~ Checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])
 - ~~47.7.2.~~ 18.7.2. Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])
 - ~~47.7.3.~~ 18.7.3. Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

18-19. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

- 18-1. 19.1.** There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])
- 18-2. 19.2.** The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])
- 18.2.1. Cleaning and sanitization of the parenteral medication preparation area;
 - 18.2.2. The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;
 - 18.2.3. Actions to be taken in the event of a drug recall; and
 - 18.2.4. Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).
- 18-3. 19.3.** Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])
- 18-3.1. 19.3.1.** The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])
 - 18-3.2. 19.3.2.** The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])
 - 18-3.3. 19.3.3.** The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])
 - 18-3.4. 19.3.4.** Completed medium samples are incubated. (CCR 1751.7[b])
 - 18-3.5. 19.3.5.** If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])
 - 18-3.6. 19.3.6.** Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])
- Yes No N/A**
- 18-4. 19.4.** Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

19-20. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

(Continued on next page.)

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

(Pharmacist-in-Charge)