



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



DRAFT HOSPITAL PHARMACY SELF-ASSESSMENT

Business and Professions Code section 4102 requires the pharmacist-in-charge of each hospital pharmacy licensed under Chapter 9 of Division 2 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 by July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days of any of the following: (1) a new pharmacy license is issued; (2) there is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy; (3) there is a change in the location of the pharmacy to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply to your pharmacy, then mark the box "N/A". If more space is needed, you may add additional sheets. The self-assessment must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file in the pharmacy and made available to the Board upon request. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Notes:

- If the pharmacy dispenses prescriptions for outpatient use, complete the last section titled Dispenses Employee/Outpatient/Walk-In Customer Prescriptions.
- Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (Form 17M-39).
- Any pharmacy that operates an automated unit dose system (AUDS) and/or an automated patient dispensing system (APDS) must also complete the Automated Drug Delivery System (ADDS) Self-Assessment (Form 17M-112).
- This self-assessment is not an all-inclusive compilation of all pharmacy laws and regulations. The pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy, regardless of whether such laws or regulations are referenced on this self-assessment.

Hospital Name:				
Address:		Telephone:		
License #:		Expiration Date:		
Other License#:		Expiration Date:		
LSC #:				
ADDS License(s)#:		Expiration Date:		
DEA Registration #:		Expiration Date		
Date of DEA Inventory:				
Hours:	Weekdays	Saturday	Sunday	24 Hours
Pharmacist-in-Charge:			License#:	
			Expiration Date:	

Services to be Provided* Check all that apply.	
<input type="checkbox"/>	Exempt Hospital 100 Beds or Less (Drug Room)
<input type="checkbox"/>	General Acute Care
<input type="checkbox"/>	Acute Psychiatric Care
Other Services* Check all that apply.	
<input type="checkbox"/>	Discharge Prescriptions
<input type="checkbox"/>	Emergency Room Prescriptions
<input type="checkbox"/>	Employee Prescriptions
<input type="checkbox"/>	Outpatient Prescriptions/Walk-Ins
<input type="checkbox"/>	Home Health Infusion
<input type="checkbox"/>	Infusion Center
<input type="checkbox"/>	Skilled Nursing Facilities
<input type="checkbox"/>	List Others

*Pharmacies are not legally required to identify the services they provide; however, this can be helpful to both the Board and the licensee in assessing compliance.

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

Attach additional sheets as necessary

(**APH**=Advanced Pharmacist Practitioner **DEA**=Drug Enforcement Administration **INT**=Intern **RPH**=Pharmacist **TCH**=Technician)

Name:		RPH#:		Expiration Date:	
		APH#:		Expiration Date:	
		DEA#:		Expiration Date:	
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		APH#:		Expiration Date:	
		DEA#:		Expiration Date:	
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References:

Abbreviation	Full Reference
BPC	Business and Professions Code
CCR	California Code of Regulations
CC	Civil Code
HSC	Health and Safety Code
21 USC	United States Code
21 CFR	Code of Federal Regulations

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Section 1: Facility Requirements/Operations Standards/Security

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.1	BPC 4116 BPC 4117 BPC 4059.5 16 CCR 1714	The pharmacy is secure to prevent unauthorized access and effective control to prevent theft.				
1.2	16 CCR 1714	The pharmacy is clean, orderly, and free of pests.				
1.3	16 CCR 1714	The pharmacy is equipped with a sink with hot and cold running water for pharmaceutical purposes.				
1.4	BPC 4013	The pharmacy is subscribed to the Board's email notification system .				
1.5	BPC 4113	The pharmacy notifies the Board when a change in PIC occurs.				
1.6	CC 56.10 CC 56.101 16 CCR 1717.1 16 CCR 1717.4 16 CCR 1764	Pharmacy records and prescriptions are maintained in a secure and confidential manner, and any destruction of records containing medical information is done in a manner that preserves the confidentiality of the information contained therein.				
1.7	BPC 4116 BPC 4117 16 CCR 1714 22 CCR 70263	The hospital has established a supply of medications which is accessible without entering the pharmacy or drug storage room during hours when the pharmacist is not available. Access to the supply is limited to designated registered nurses.				
1.8	22 CCR 70263	The pharmacy has a system assuring the availability of prescribed medications 24 hours a day.				

Section 2: Drug Inventory

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4059.5 HSC 11209	The pharmacy receives dangerous drugs and devices consistent with legal requirements.				
2.2	21 USC 360eee-1	The pharmacy complies with applicable provisions of the Drug Supply Chain Security Act.				
2.3	21 USC 331 21 USC 351 21 USC 352 BPC 4059.5 BPC 4115 BPC 4119 BPC 4169 BPC 4342 HSC 111255 HSC 111335 16 CCR 1714 22 CCR 70263 22 CCR 70269	The drug stock is within expiry and maintained to prevent misbranding and adulteration.				
2.4	BPC 4126.5 BPC 4059 BPC 4059.5 BPC 4163 BPC 4169	Dangerous drugs and devices are only obtained from or furnished to persons or entities authorized by pharmacy law.				
2.5	16 CCR 1710	The pharmacy processes orders for central filling of patient cassettes for another hospital or pharmacy within this state and follows all state requirements.				
2.6	BPC 4380 16 CCR 1710 15 USC 13c	Drugs acquired at preferentially low prices permitted under federal law only because of the Nonprofit Institutions Act (15 USC § 13c) are only resold as authorized by BPC 4380.				

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
2.7	BPC 4073 BPC 4074 BPC 4076 BPC 4076.5 BPC 4076.6 BPC 4076.7 16 CCR 1707.5 16 CCR 1717 16 CCR 1744 21 CFR 290.5	Prescriptions are appropriately labeled, and appropriate warning labels are affixed.				
2.8	BPC 4115 BPC 4119.7 22 CCR 70263	Floor stock and drugs maintained on the nursing unit are inspected at least monthly by a pharmacist, intern pharmacist under the direct supervision and control of a pharmacist, or pharmacy technician. Any irregularities are reported as required by law and hospital policy.				
2.9	BPC 4128.4 BPC 4128.5	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.				

Section 3: Pharmacist-in-Charge (PIC)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4113 16 CCR 1709.1	The pharmacy has designated a PIC and vested the PIC with adequate authority to assure the pharmacy's compliance with relevant laws.				
3.2	16 CCR 1709.1	The PIC only serves as PIC of this pharmacy, or if they serve as PIC of another pharmacy, that pharmacy is separated from this pharmacy by a driving distance of no more than 50 miles.				

Section 4: Pharmacy Personnel

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	BPC 4114 BPC 4115 BPC 4115.5 16 CCR1793.7 16 CCR1793.8	The pharmacy complies with applicable staffing requirements.				
4.2	BPC 680 16 CCR 1793.7	Pharmacy personnel are appropriately identified.				
4.3	BPC 4052 BPC 4301	Pharmacists have adequate authority to exercise professional judgement and comply with the law.				
4.4	BPC 4023.5 BPC 4038 BPC 4114 BPC 4115 BPC 4115.5 16 CCR 1726 16 CCR 1793 16 CCR 1793.2 16 CCR 1793.7 16 CCR1793.8	Intern pharmacists, pharmacy technicians and pharmacy technician trainees are performing authorized duties under the supervision of a pharmacist.				
4.5	16 CCR 1717 16 CCR 1712 16 CCR 1793.7 16 CCR1793.8	All prescriptions filled or refilled by nonpharmacist authorized personnel are checked by a pharmacist and documented.				
4.6	BPC 4115.5	Externships in which a pharmacy technician trainee is participating are for a period of no fewer than 120 hours and no more than 140 hours, unless the training involves rotation between a community and hospital pharmacy, in which case the externship does not exceed 340 hours.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.7	16 CCR 1793.7	The pharmacy has a job description for pharmacy technicians.				
4.8	16 CCR 1793.3	Non-licensed personnel are supervised by pharmacists and are permitted to perform the duties specified in CCR section 1793.3(a).				
4.9	BPC 4118.5	A pharmacist, an intern pharmacist or pharmacy technician obtains an accurate medication profile or list of medications for each high-risk patient upon admission and discharge.				
4.10	16 CCR 1793.8	If the hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians, it complies with the requirements set forth in CCR section 1793.8.				

Section 5: Chart Order/Prescriptions

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 688 BPC 4019 BPC 4040 16 CCR 1717.4	The pharmacy receives the original, an electronic transmission, or a copy of the medication chart order.				
5.2	BPC 688 BPC 4019 BPC 4040 22 CCR 70263	The chart or medical record of the patient contains all the information required by BPC 4040 and orders are signed as required by law.				
5.3	16 CCR 1707.1	The pharmacy maintains medication profiles on all patients as required by CCR1707.1.				
5.4	16 CCR 1707.3	A pharmacist reviews a patient's drug therapy and medication record before each prescription drug is delivered.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.5	BPC 4078 HSC 11010 HSC 11164 HSC 11212 22 CCR 70263	Investigational drugs are properly labeled, stored, and distributed pursuant to the written order of the investigator.				
5.6	16 CCR 1761	Prior to dispensing a prescription, where necessary, a pharmacist contacts the prescriber to obtain information needed to validate the prescription.				
5.7	BPC 4040 BPC 4070 BPC 4071 16 CCR 1712 16 CCR 1717	Orally or electronically transmitted prescriptions transmitted by the prescriber or prescriber's agent are only received by a pharmacist or pharmacy intern and document the required information.				

Section 6: Quality Assurance/Medication Error Reporting Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	BPC 4125 16 CCR 1711	The pharmacy has a quality assurance program that meets the requirements of the law and regulation.				
6.2	16 CCR 1711	A record of the quality assurance review related to the use of an unlicensed ADDs is reported to the Board at the time of annual renewal of the facility license.				

Section 7: Record Keeping Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.1	BPC 4081 BPC 4105 BPC 4052.04 BPC 4059.5 BPC 4113.1 BPC 4333 16 CCR 1717.1 16 CCR 1717.5 HSC 11159 CC 56.10 CC 56.101	Pharmacy records are maintained, able to be readily retrieved, and retained as required by law.				
7.2	BPC 4081 BPC 4105	The pharmacy has digitized its records consistent with legal provisions.				
7.3	BPC 4105 16 CCR 1707	The pharmacy has received an approved waiver to store records off-site and maintains records on the licensed premise as required by law.				

Section 8: Policies and Procedures

The pharmacy has policies and procedures covering the following matters:

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.1	BPC 4104	Action to be taken 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.				
8.2	BPC 4104	Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.3	16 CCR 1717.1 CC 56.10 CC 56.101	Written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.				
8.4	BPC 4059.5	Written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility when the pharmacy is closed and no pharmacist is on duty.				
8.5	BPC 733	Protocols that ensure that patients have timely access to prescribed drugs and devices despite a pharmacist's refusal to dispense on ethical, moral or religious grounds.				
8.6	16 CCR 1715.65	Written policies and procedures for performing inventory activities and preparing inventory reconciliation reports.				
8.7	BPC 4081 16 CCR 1793.7	Policies and procedures related to pharmacy personnel and pharmacy operations. (If the pharmacy employs or uses pharmacy technicians, this shall include written policies and procedures adequate to ensure compliance with the provisions of Article 11 (Ancillary Personnel) of Division 17 of Title 16 of the California Code of Regulations.)				
8.8	16 CCR 1711	Written policies and procedures regarding the pharmacy's quality assurance program.				
8.9	BPC 4118.5	If intern pharmacists or pharmacy technicians perform the task of obtaining an accurate medication profile or list for high-risk patients, the hospital has established policies and procedures for training and proctoring intern pharmacists and pharmacy technicians by the hospital pharmacy department.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.10	16 CCR 1793.8	If the pharmacy has a technician checking technician program as described in CCR 1793.8, the facility's policies and procedures (1) specify the parameters for the direct supervision of the program by a pharmacist, and (2) prescribe the specialized and advanced training of the technician who performs the checking function.				
8.11	BPC 4074 16 CCR 1707.2	A written policy to ensure that each patient shall receive information about discharge medications that meets the requirements of BPC 4074.				
8.12	BPC 4119.7	The furnishing of dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets, and protocols.				
8.13	BPC 4115 BPC 4119.6 BPC 4119.7 22 CCR 70263	Written policies and procedures regarding the use, restocking, sealing, and inspection of the emergency drug supply.				
8.14	BPC 4115 BPC 4119.7 22 CCR 70263	Written policies and procedures for inspection of drug supply throughout the hospital.				
8.15	BPC 4119.7 22 CCR 70263	Written policies and procedures for storing and maintaining drugs in accordance with national standards regarding the storage area and refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines.				
8.16	22 CCR 70263	Policies regarding investigational drug use.				

Section 9: Controlled Substances

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.1	21 CFR 1304.04 21 CFR 1304.11	The pharmacy completes an inventory of all controlled substances every two years.				
9.2	16 CCR 1715.65	The pharmacy complies with inventory activities and reconciliation requirements.				
9.3	16 CCR 1715.6	The pharmacy reports drug losses to the Board within the time limits required by law and regulation.				
9.4	21 CFR 1304.04 21 CFR 1305.03 21 CFR 1305.12 21 CFR 1305.13 21 CFR 1305.21 21 CFR 1305.22	The pharmacy complies with applicable federal laws related to the ordering and storing of controlled substances.				
9.5	21 CFR 1307.11 BPC 4160	The pharmacy's 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.				

Section 10: Pharmacy Operations

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.1	BPC 4169 HSC 111250 et seq. HSC 111330 et seq.	The automated drug delivery system used within the pharmacy to select, count, package and label dangerous drugs, is used consistent with legal provisions to avoid misbranding and adulteration.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.2	21 CFR Part 200 21 CFR Part 210 BPC 4119.3 BPC 4342 HSC 110105 HSC 111430	Drugs are repackaged for dispensing consistent with Current Good Manufacturing Practices and labeling requirements.				
10.3	21 CFR Part 210 21 CFR Part 211	A log is maintained for drugs pre-packed for future dispensing.				

Section 11: Emergency Room Dispensing by Prescriber Provisions

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.1	BPC 4068 HSC 11165	When the hospital pharmacy is closed and there is no pharmacist available in the hospital, if a prescriber dispenses to an emergency room patient a dangerous drug acquired by the hospital pharmacy, the dispensing information is recorded and provided to the pharmacy when the pharmacy reopens, and the pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to HSC 11165 .				
11.2	BPC 4068 BPC 4076	The pharmacy is aware that a prescriber may dispense the unused portion of a single patient use multidose dose packaging for self-administration, acquired by the hospital pharmacy, upon discharge.				

Section 12: Furnishes Drugs to Outpatients, Employees or Walk-in Customers

*** Complete this section if your hospital pharmacy furnishes drugs to outpatients, employees or walk-in customers.**

You are not required to complete this section if: (1) your pharmacy solely furnishes drugs for administration to patients of the hospital, or (2) your hospital has a separate PHY community pharmacy license from the Board for outpatient dispensing.

	Reference	Item	Yes	No	N/A	Corrective Action Plan
12.1	16 CCR 1710	If the pharmacy dispenses prescriptions to outpatients or employees of the hospital, or to walk-in customers, sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.				
12.2	BPC 4122 BPC 4058 BPC 4032 16 CCR 1707.6	The pharmacy has required notices and licenses posted in public view allowing for use of the notices as intended.				
12.3	BPC 4052 16 CCR 1707.2 16 CCR 1707.3 16 CCR 1707.5 16 CCR 1764	A pharmacist provides patient consultation as required by law, including any time a pharmacist deems it warranted in the exercise of his or her professional judgment, and in a confidential manner.				
12.4	16 CCR 1707.5	There are policies and procedures in place to help patients with limited or no English proficiency understand information on the prescription label.				
12.5	BPC 4076.8	If a person informs the pharmacy that the person identifies as a person who is blind, has low-vision, or is otherwise print disabled, the pharmacy provides the person or their authorized representative, at no additional cost, an accessible prescription label that meets the requirements of BPC 4076.8.				

12.6	16 CCR 1707.2	If prescription medication is mailed or delivered, written notice about the availability of consultation is provided.				
12.7	16 CCR 1707.3	A pharmacist reviews a patient's drug therapy and medication record prior to consultation.				
12.8	BPC 4073 BPC 4074 BPC 4076 BPC 4076.5 BPC 4076.6 BPC 4076.7 16 CCR 1707.5 16 CCR 1717 16 CCR 1744 21 CFR 290.5	Prescriptions are appropriately labeled and appropriate warning labels affixed.				
12.9	BCP 4073 BCP 4073.5 22 CCR 70263	The pharmacy complies with generic substitution requirements.				
12.10	15 USC 1473 16 CFR 1700.15 16 CCR 1717	The pharmacy complies with child-resistant container and senior-adult ease-of-opening tested container requirements.				
12.11	21 CFR 310.515 21 CFR 208.24	Medication guides and package inserts are provided as required by law.				
12.12	BPC 4062 BPC 4064	The pharmacy follows emergency refill provisions.				
12.13	BPC 688 BPC 733 BPC 4115 16 CCR 1717 16 CCR 1717.1	A prescription is transferred at the request of the patient.				
12.14	HSC 11165	The pharmacy reports to the CURES system within one working day.				

12.15	HSC 11200	Controlled substance prescriptions are not filled or refilled more than six months from the date written.				
12.16	HSC 11200	Refills for schedule III-IV controlled substance prescriptions are limited to a maximum of five times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply.				
12.17	HSC 11200	Refills for schedule II controlled substances are prohibited.				
12.18	HSC 11167	The pharmacy is in compliance with the limitations for dispensing a schedule II prescription upon an oral order, in an emergency.				
12.19	HSC 11159.2 16 CCR 1745 21 CFR 1306.11	Controlled substance written with the "11159.2 exemption" for terminally ill are only dispensed when the original prescription is received consistent with legal requirements.				
12.20	HSC 11159.2 HSC 11159.3 HSC 11162.1 HSC 11164 HSC 11167.5	All written controlled substances prescriptions are on California Security Prescription Forms and signed and dated by the prescriber, unless otherwise exceptions exist.				
12.21	HSC 11166	No controlled substance prescription is filled after six months have elapsed from the date written on the prescription by the provider.				
12.22	16 CCR 1745 21 CFR 1306.13	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.				

12.23	21 USC 829 BPC 4052.10	Where requested by the patient or the patient's prescriber, the pharmacist partially fills a schedule II prescription and maintains the records for each such fill (filled within 30 days from the date of prescription issuance).				
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Additional References

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Item
BPC 4016.5 BPC 4052.6 BPC 4210	Advanced Pharmacist Practitioner Provisions
BPC 4128 BPC 4128.2 BPC 4128.3 BPC 4128.4 BPC 4128.5 BPC 4128.6 BPC 4128.7	Centralized Hospital Packaging Pharmacy Provisions
HSC 11153 Precedential Decision 21 CFR 1306.04	Corresponding Responsibility Requirements
BPC 4107.5	Counterfeit Drug Provisions; Required Notice to Board
BPC 688 21 CFR 1306.08 21 CFR Part 1311	Electronic Prescription Requirements
BPC 4119	Furnishing of Emergency Medical Supplies for Local Emergency Medical Service Agency
BPC 4145.5	Hypodermic Needles and Syringes Furnished without a Prescription

Reference	Item
16 CCR 1776 16 CCR 1776.1 16 CCR 1776.2 16 CCR 1776.3 16 CCR 1776.4 16 CCR 1776.5 16 CCR 1776.6 21 CFR 1317.30 21 CFR 1317.40	Prescription Drug Take Back Services
HSC 150200	Voluntary Drug Repository and Distribution Program

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this hospital pharmacy of which I am the pharmacist-in-charge to the best of my professional ability. Any deficiency identified herein will be corrected by _____ (date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. 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* _____
(Pharmacist-in-Charge)

Date: _____

ACKNOWLEDGEMENT BY PHARMACY OWNER OR AUTHORIZED OFFICER:

I, (please print) _____, hereby certify 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 action by the California State Board of Pharmacy.

Signature* _____
Pharmacy Owner or Authorized Officer

Date: _____

*Consistent with [16 CCR Section 1700](#), the Board will accept digital signatures.