California State Board of Pharmacy
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www.pharmacy.ca.gov

Business and Consumer Services Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment

Business and Professions Code section 4102 requires the pharmacist-in-charge of each 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:

- 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.

Pharmacy Name:				
Address:		**Telephone:**		
License #:		**Expiration Date:**		
Other Permit #:		**Expiration Date:**		
Licensed Sterile Compounding License#		**Expiration Date:**		
Licensed Remote Dispensing Site Pharmacy License #		**Expiration Date:**		
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.	
☐	Chain Community
☐	Non-Chain Community
☐	Mail Order
☐	Call Center
☐	Board and Care
☐	Skilled Nursing Facility
☐	Correctional Facility
☐	Central Fill
☐	Specialty Pharmacy
☐	Home Health Care/ Infusion Center
☐	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 **TCH**=Technician)

Name:		**RPH#:**		**Expiration Date:**	
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		DEA#:		**Expiration Date:**	
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Name:		**TCH#:**		**Expiration Date:**	
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References:

Abbreviation	Full Reference
BPC	Business and Professions Code
CCR	Title 16 California Code of Regulations
CC	Civil Code
HSC	Health and Safety Code
USC	United State Code
CFR	Code of Federal Regulations

Table of Contents

Section 1: Facility Requirements/Operations Standards/Security

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.1	CCR 1764 CCR 1714	The pharmacy has an area suitable for confidential patient consultation.				
1.2	BPC 4116 BPC 4059.5 CCR 1714	The pharmacy is secure to prevent unauthorized access and effective control to prevent theft.				
1.3	CCR 1714	The pharmacy is clean, orderly, and free of pests.				
1.4	CCR 1714	The pharmacy is equipped with a sink with hot and cold running water for pharmaceutical purposes.				
1.5	BPC 4122 BPC 4058 BPC 4032 CCR 1707.6	The pharmacy has required notices and licenses posted in public view allowing for use of the notices as intended.				
1.6	BPC 4013	The pharmacy is subscribed to the Board's email notification system.				
1.7	BPC 4113.7 BPC 4317	If the pharmacy is a chain community pharmacy, as defined in BPC 4001(c), it does not establish quotas related to the duties for which a pharmacist or pharmacy technician license is required.				
1.8	BPC 4113	The Pharmacy notifies the Board when a change in PIC occurs.				
1.9	CC 56.10 CC 56.101 CCR 1717.1 CCR 1717.4 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.				

Section 2: Delivery of Drugs/Drug Stock

	Reference	Item	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 Drug Supply Chain Security Act provisions.				
2.3	21 USC 331 21 USC 351 21 USC 352 BPC 4059.5 BPC 4169 BPC 4342 HSC 111255 HSC 111335 CCR 1714	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	Dangerous drugs and devices are only obtained from or furnished to persons or entities authorized by pharmacy law.				

Section 3: Pharmacist-in-Charge (PIC)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4113 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	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.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.3	BPC 4113	The PIC has adequate authority to establish staffing levels, and actually makes staffing decisions.				
3.4	BPC 4113	The PIC has adequate authority to establish the pharmacist to pharmacy technician ratio, and actually determines the ratio in accordance with law.				

Section 4: Pharmacy Personnel

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	BPC 4113.5 BPC 4113.6 BPC 4114 BPC 4115 BPC 4115.5 BPC 4301 CCR 1714.3	The pharmacy complies with applicable staffing requirements.				
4.2	BPC 680 CCR 1793.7	Pharmacy personnel are appropriately identified.				
4.3	BPC 4113	The PIC or pharmacist on duty (1) immediately notifies store management or the building owner of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, and (2) if the conditions are not resolved within 24 hours, ensures the Board is timely notified.				
4.4	BPC 4052 BPC 4301	Pharmacists have adequate authority to exercise professional judgement and comply with the law.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.5	BPC 4023.5 BPC 4038 BPC 4114 BPC 4115 BPC 4115.5 CCR 1726 CCR 1793 CCR 1793.2 CCR 1793.7	Intern pharmacists, pharmacy technicians and pharmacy technician trainees are solely performing authorized duties under the supervision of a pharmacist.				
4.6	CCR 1717 CCR 1712 CCR 1793.7	All prescriptions filled or refilled by nonpharmacist authorized personnel are checked by a pharmacist and documented.				
4.7	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.				
4.8	CCR 1793.7	The pharmacy has a job description for pharmacy technicians.				
4.9	CCR 1793.3	Non-licensed personnel are supervised by pharmacists and are permitted to perform the duties specified in CCR section 1793.3(a).				

Section 5: Prescription Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 4052 BPC 4069 CCR 1707.2 CCR 1707.3 CCR 1707.5 CCR 1714 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.				
5.2	CCR 1707.2	If prescription medication is mailed or delivered, written notice about the availability of consultation is provided.				
5.3	CCR 1707.1	The pharmacy maintains medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.				
5.4	BPC 688	The pharmacy has the capability to receive an electronic prescription on behalf of a patient.				
5.5	CCR 1707.3	A pharmacist reviews a patient's drug therapy and medication record prior to consultation.				
5.6	BPC 4073 BPC 4074 BPC 4076 BPC 4076.5 BPC 4076.6 BPC 4076.7 BPC 4076.8 CCR 1707.5 CCR 1717 CCR 1744 21 CFR 290.5	Prescriptions are appropriately labeled, and appropriate warning labels are affixed.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.7	BPC 4040 BPC 4070 BPC 4071 CCR 1712 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.				
5.8	BPC 4067	Internet prescriptions for delivery in this state are only dispensed or furnished pursuant to an appropriate prior examination of the human or animal.				
5.9	BCP 4073 BCP 4073.5	The pharmacy complies with generic substitution requirements.				
5.10	15 USC 1473 16 CFR 1700.15 CCR 1717	The pharmacy complies with child-resistant container and senior-adult ease-of-opening tested container requirements.				
5.11	21 CFR 310.515 21 CFR 208.24	Medication guides and package inserts are provided as required by law.				
5.12	BPC 4119.2 BPC 4119.4 BPC 4119.8 BPC 4119.9 EDC 49414 EDC 49414.3 EDC 49414.7	The pharmacy furnishes albuterol, naloxone hydrochloride and/or epinephrine to a school or other authorized entity pursuant to a standing order or as otherwise authorized by law.				
5.13	BPC 4062 BPC 4064	The pharmacy follows emergency refill provisions.				
5.14	CCR 1717.5	The pharmacy's auto-refill program meets the requirements of the law.				
5.15	CCR 1761	Prior to dispensing a prescription, where necessary, a pharmacist contacts the prescriber to obtain information needed to validate the prescription.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.16	BPC 688 BPC 733 BPC 4115 CCR 1717 CCR 1717.1	A prescription is transferred at the request of the patient.				

Section 6: Quality Assurance/Medication Error Reporting Requirements

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	BPC 4125 CCR 1711	The pharmacy has a quality assurance program that meets the requirements of the law and regulation.				
6.2	BPC 4113.1	The pharmacy reports medication errors to an entity approved by the Board as required by law.				
6.3	CCR 1711	The pharmacist communicates with the patient or patient's agent and physician that a medication error has occurred.				

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 CCR 1717.1 CCR 1717.5 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.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.3	BPC 4105 CCR 1707	The pharmacy has received a waiver to store records off-site and maintains records on the licensed premises 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.				
8.3	CCR 1714.1	Operation of the pharmacy during the temporary absence of a pharmacist for breaks and meal periods.				
8.4	CCR 1717.1 CC 56.10 CC 56.101	Confidentiality of medical information.				
8.5	BPC 4059.5	Delivery of dangerous drugs to a secure storage facility when the pharmacy is closed.				
8.6	BPC 733	Actions to be taken to ensure that patients have timely access to prescribed drugs and devices despite a pharmacist's refusal to dispense on ethical, moral or religious grounds.				
8.7	CCR 1707.5	Helping patients with limited or no English proficiency to understand information on the prescription label.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.8	CCR 1715.65	Inventory reconciliation reporting requirements.				
8.9	BPC 4081 CCR 1793.7	Pharmacy personnel and operations.				
8.10	CCR 1717.5	Auto-refill program.				
8.11	CCR 1711	Quality assurance for medication errors.				
8.12	BPC 4113.5 CCR 1714.3	Community pharmacy staffing.				
8.13	BPC 4119.3[1]	Repackaging services.				

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	CCR 1715.65	The pharmacy complies with inventory activities and reconciliation requirements.				
9.3	CCR 1715.6	The pharmacy reports drug losses to the Board within the time limits required by law and regulation.				
9.4	HSC 11165	The pharmacy reports to the CURES system within one working day.				

[1] Formerly BPC 4052.7

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.5	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.				
9.6	21 CFR 1307.11 BPC 4160	The pharmacy's sales of controlled substances to other pharmacies or prescribers does not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year.				
9.7	HSC 11200	Controlled substance prescriptions are not filled or refilled more than six months from the date written.				
9.8	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.				
9.9	HSC 11200	Refills for schedule II controlled substances are prohibited.				
9.10	HSC 11167	The pharmacy is in compliance with the limitations for dispensing a schedule II prescription upon an oral order, in an emergency.				
9.11	HSC 11159.2 CCR 1745 21 CFR 1306.11	Controlled substance prescriptions written with the "11159.2 exemption" for terminally ill patients are only dispensed when the original prescription is received consistent with legal requirements.				
9.12	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 other exceptions exist.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.13	HSC 11166	No controlled substance prescription is filled after six months have elapsed from the date written on the prescription by the provider.				
9.14	HSC 11167.5 21 CFR 1306.11	An oral or electronically transmitted prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only after the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form and obtained a signature of the prescriber.				
9.15	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.				
9.16	21 USC 829 21 CFR 1306.13 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).				
9.17	HSC 11159.2 21 CFR 1306.13 CCR 1745	For patients in a skilled nursing facility or terminally ill, the pharmacist partially fills a schedule II prescription and maintains the records for each such fill (filled within 60 days from the date of prescription issuance).				

Section 10: 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.				
10.2	21 CFR Part 210 BPC 4119.3[2] 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.				
10.4	BPC 4119.3[3]	Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and labeled to include the names and addresses of both pharmacies and meet other requirements.				

[2] Formerly BPC 4052.7
[3] Formerly BPC 4052.7

Section 11: Prescription Drug Take Back Services

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.1	CCR 1776 CCR 1776.1 CCR 1776.2 CCR 1776.3 CCR 1776.4 CCR 1776.5 CCR 1776.6	The pharmacy participates in a Prescription Drug Take-Back Program and adheres to all federal, state and local requirements.				
11.2	CCR 1776.1 CCR 1776.2 CCR 1776.6	The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location and complies with all legal requirements.				
11.3	21 CFR 1317.30 21 CFR 1317.40 CCR 1776	The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle.				
11.4	CCR 1776.1	The pharmacy has notified the board in writing within 30 days of establishing the collection program.				
11.5	CCR 1776.1 CCR 1776.6	The pharmacy has notified the board in writing within 30 days of ceasing to maintain a drug take-back receptacle.				
11.6	CCR 1776.1 CCR 1776.6	If the pharmacy provides take-back services to consumers neither the pharmacy nor the PIC is on probation with the board.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.7	CCR 1776.4 CCR 1776.6	The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or persons lawfully entitled to dispose of a resident decedent's property to dispose of unwanted or unused prescription drugs and complies with all legal requirements.				
11.8	CCR 1776.4 CCR 1776.6	The pharmacy has established a collection receptacle in a skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs and complies with all legal requirements.				
11.9	CCR 1776.1	Only prescription drugs dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of the drug take-back services maintained by the pharmacy.				

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	Topic
BPC 4016.5 BPC 4052.6 BPC 4210	Advanced Pharmacist Practitioners
HSC 150200	Voluntary Drug Repository and Distribution Program
CCR 1707.4	Refill Pharmacies
HSC 125286.10 HSC 125286.20 HSC 125286.25	Standards of Service for Providers of Blood-Clotting Products for Home Use
BPC 4067	Internet; Dispensing Dangerous Drugs and Dangerous Devices without Prescription
BPC 4130 BPC 4131 BPC 4132 BPC 4133 BPC 4134 BPC 4135	Remote Dispensing Site Pharmacies
CCR 1708.4 CCR 1708.5 CCR 1751 et al	Nuclear Pharmacies
BPC 4119	CLIA-waived testing
BPC 4115	Technician Administration of Vaccines
CCR 1708.1	Temporary Closures
BPC 22949.92.1	Pharmacy Closures
BPC 4107.5	Counterfeit Drugs; Required Notice to Board
CCR 1709.1	Serving as a PIC in more than one Location
BPC 4119	Furnishing of Emergency Medical Supplies for Local Emergency Medical Services Agency
BPC 4076	Expedited Partner Therapy
BPC 4145.5	Hypodermic Needles and Syringes Furnished without a Prescription

Reference	Topic
HSC 11153 Precedential Decision 21 CFR 1306.04	Corresponding Responsibility Requirements
BPC 688 21 CFR 1306.08 21 CFR Part 1311	Electronic Prescription Requirements
BPC 4064	Emergency Refill of Prescription without Prescriber Authorization
BPC 4064.5	Refill Consolidation by a Pharmacist; Requirements and Exceptions

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 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* _____ Date: _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

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* _____ Date: _____
Pharmacy Owner or Hospital Administrator

*Consistent with 16 CCR Section 1700, the Board will accept digital signatures.