California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

Surgical Clinic Self-Assessment

Business and Professions Code sections 4102 and 4192 require **the consulting pharmacist** of a surgical clinic licensed under section 4190 of the Business and Professions Code to complete a self-assessment of the surgical clinic's compliance with federal and state laws. **The assessment shall be performed by July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, and the self-assessment must assess the clinic's compliance with current laws and regulations and include information on compounding practices.**

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 surgical clinic, 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 surgical clinic 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 surgical clinic for three years after it is performed. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed shall also be provided to the Board.

Notes:

- This self-assessment is not an all-inclusive compilation of all laws and regulations that may apply to surgical clinics licensed under section 4190 of the Business and Professions Code. The professional director is responsible for the safe, orderly, and lawful provision of pharmacy services at the clinic, regardless of whether such laws or regulations are referenced on this self-assessment.
- In addition to completing this form, the consulting pharmacist must certify in writing quarterly that the clinic is, or is not, operating in compliance with Article 14 of Chapter 9 of Division 2 of the Business and Professions Code. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Further, as part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in section 4192.

Surgical Clinic Name:						
Address:			**Telephone:**			
License #:			**Expiration Date:**			
Pharmacy Name Operating ADDS:						
Pharmacy License # Operating ADDS:			**Expiration Date:**			
ADDS License #: [APDS operated by a pharmacy (BPC 4427.2, 4427.3)]			**Expiration Date:**			
CDPH License #: (If applicable)			**Expiration Date:**			
Accreditation by: (If applicable)			**Expiration Date**			
DEA Registration #			**Expiration Date:**			
Date of DEA Inventory:						
Hours:	Weekdays	Saturday	Sunday	24 Hours		
Professional Director:			**License #:**			
			Expiration Date:			
Consulting Pharmacist:			**License #:**			
			Expiration Date:			
Clinic Administrator			**License #:**			
			Expiration Date:			

Type of Surgical Clinic Check all that apply.	
	Licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code
	An outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code
	An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (41 U.S.C. Section 1395 et seq.)
Type of Services Provided	
	Medical Surgery
	Dental Surgery
	Podiatric Surgery
	List Others:

References:

Abbreviation	Full Reference
BPC	California Business and Professions Code
CC	California Civil Code
CCR	Title 16 California Code of Regulations
CDPH	California Department of Public Health
21 CFR	Code of Federal Regulations
HSC	California Health and Safety Code
21 USC	United States Code
USP 797	United States Pharmacopeia Chapter 797
USP 800	United States Pharmacopeia Chapter 800
WIC	California Welfare and Institutions Code

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Section 1: Facility Requirements

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.1	BPC 4190	Each clinic location has a separate license.				
1.2	BPC 4013 BPC 4190	The clinic notifies the Board of any change in the clinic's address or email address.				
1.3	BPC 4190	Any proposed change in ownership or beneficial interest in the clinic is reported to the Board at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.				
1.4	BPC 4192	The clinic notifies the Board within 30 days of any change in professional director.				

Section 2: Duties of the Professional Director

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4192	The professional director is a physician and surgeon acting in their capacity as medical director or a dentist or podiatrist acting in their capacity as a director in a clinic where only dental or podiatric service are provided.				
2.2	BPC 4192	The professional director is responsible for the safe, orderly, and lawful provision of pharmacy services.				

Section 3: Duties of the Consulting Pharmacist

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4192	A consulting pharmacist is retained to approve the policies and procedures in conjunction with the professional director and the administrator.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.2	BPC 4192	The consulting pharmacist visits the clinic regularly and at least quarterly to review the application of policies and procedures.				
3.3	BPC 4192	The consulting pharmacist certifies in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of Article 14 of Chapter 9 of Division 2 of the BPC. Each completed written certification includes recommended corrective actions, if appropriate.				

Section 4: Drug Inventory

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	BPC 4059 BPC 4059.5 BPC 4190	The clinic's purchases of drugs at wholesale are for administration or dispensing, under the direction of a physician or surgeon, to patients registered for care at the clinic.				
4.2	BPC 4059.5 BPC 4163	The clinic purchases and receives delivery of dangerous drugs consistent with legal requirements.				
4.3	21 USC 360eee-1	The clinic complies with applicable provisions of the Drug Supply Chain Security Act.				
4.4	BPC 4080 BPC 4195	During business hours, all stock of any dangerous drug is open to inspection by authorized officers of the law.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.5	21 USC 331 21 USC 351 21 USC 352 BPC 4081 BPC 4169 BPC 4342 CCR 1718 CCR 1718.1 HSC 111255 HSC 111335	The drug stock is within expiry and maintained to prevent misbranding and adulteration.				

Section: 5 Medication Administration

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 4190	Drugs are only administered to patients registered for care at the clinic and are directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of the patient for his or her immediate needs.				

Section 6: Drug Dispensing for Discharge

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	BPC 4190	The clinic's dispensing activities are limited to the dispensing of drugs for the control of pain and nausea for patients of the clinic.				
6.2	BPC 4190	Drugs are not dispensed in an amount greater than that required to meet the patient's needs for 72 hours.				
6.3	BPC 4191	The dispensing of drugs is performed only by a physician, pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.4	BPC 4193 7 WIC 14000 - 14199.87	The clinic is aware it is not eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the WIC), and the clinic does not offer drugs for sale or charge or bill for professional services for the dispensing or administering of drugs.				
6.5	BPC 4076.6	Upon the request of a patient or patient's representative, the clinic provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English language directions are provided on a supplemental document.				
6.6	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.				

Section 7 Controlled Substances

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.1	21 CFR 1301.11 21 CFR 1301.12 21 USC 802 21 USC 822	If controlled substances are dispensed at the clinic, the clinic has obtained its own separate DEA registration.[1]				
7.2	BPC 4194	No Schedule II controlled substances are dispensed in the clinic except as permitted by BPC 4194.				
7.3	BPC 4081 BPC 4105 CCR 1715.6 CCR 1715.65 CCR 1718 21 CFR 1304.04 21 CFR 1304.11	The clinic completes an inventory of all controlled substances at least every two years, and otherwise complies with requirements to perform periodic inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of federal controlled substances.				
7.4	21 CFR 1301.75 21 CFR 1304.04 21 CFR 1304.21 21 CFR 1305.03 21 CFR 1305.12 21 CFR 1305.13 21 CFR 1305.21 21 CFR 1305.22	The clinic complies with applicable federal laws related to the ordering and storing of, and maintenance of records regarding, controlled substances.				

[1] For this purpose, "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. (See 21 USC 802(10).)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.5	HSC 11165	Except as provided in subdivision (k) of HSC 11165, the clinic reports to the CURES system within one working day after the date a controlled substance is released to the patient or patient's representative.				
7.6	HSC 11165.3	The clinic reports the theft or loss of prescription forms immediately to the CURES Prescription Drug Monitoring Program, no later than three days after the discovery of the theft or loss.				
7.7	HSC 11165.4	The clinic prescribers consult the CURES database before prescribing a Schedule II, III, or IV controlled substance to a discharged patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.				
7.8	CCR 1715.6 21 CFR 1301.74	The clinic reports drug losses to the Board and the DEA within the time limits required by law and regulation.				

Section 8: Drug Compounding

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.1	BPC 4059.5 CCR 1713	A pharmacy delivers ***patient specific*** compounded preparations to the clinic. Name of Pharmacy: _____ Pharmacy License #: _____ Sterile Compounding License # (if applicable): _____ (Attach additional sheet if necessary)				
8.2	BPC 4129 BPC 4129.2	The clinic purchases compounded drugs from an outsourcing facility licensed by the Board. Name of Outsourcing Facility: _____ Outsourcing Facility License #: _____ (Attach additional sheet if necessary)				
8.3	21 USC 353a	The clinic performs nonsterile compounding of drugs in compliance with current USP 795 and applicable law and regulations.				
8.4	21 USC 353a	The clinic performs sterile compounding of drugs in compliance with current USP 797 and applicable law and regulations.				
8.5	21 USC 353a	The clinic performs hazardous drug compounding in compliance with current USP 800 and applicable law and regulations.				

Section 9: Policies and Procedures

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.1	BPC 4191	The clinic has developed policies and procedures that are approved by the consulting pharmacist, professional director, and clinic administrator.				
9.2	CCR 1715.65	The clinic has written policies and procedures for performing the inventory activities and preparing the inventory reconciliation reports required by CCR 1715.65.				

Section 10: Record Keeping

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.1	BPC 4190	The clinic keeps records of the kind and amounts of drugs purchased, administered, and dispensed.				
10.2	BPC 4105 CCR 1707	All records or other documentation required to be maintained by the clinic are retained on the licensed premises, or, if not, the clinic has received a waiver from the Board to store records off-site.				
10.3	BPC 4192	Each written certification completed by the consulting pharmacist is kept on file in the clinic for three years.				
10.4	BPC 4192	Completed self-assessments are signed under penalty of perjury and are kept on file in the clinic for three years.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.5	BPC 4081 BPC 4105 BPC 4190 CCR 1715.6 CCR 1715.65 CCR 1718 21 CFR 1304.11 21 CFR 1305.13 21 CFR 1305.05 21 CFR 1301.74	The clinic records are maintained, able to be readily retrieved, and retained as required by law.				
10.6	BPC 4081	The clinic has digitized its records consistent with legal provisions.				
10.7	CCR 1715.65	Controlled substance inventory reconciliation reports and all records used to compile the reports are readily retrievable in the clinic for three years.				

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 4427.1 BPC 4427.3 BPC 4427.6	Automated Patient Dispensing Systems (APDS) installed by a pharmacy in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment.
BPC 688 21 CFR 1306.08 21 CFR 1311	Electronic Prescription Requirements
HSC 150200	Facilities licensed by State Department of Public Health: Voluntary Drug Repository and Distribution Program
BPC 4115	Pharmacist supervision of pharmacy technicians compounding outside a licensed pharmacy.
CCR 1708.1	Temporary closure.

CONSULTING PHARMACIST CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this surgical clinic of which I am the consulting pharmacist to the best of my professional ability. Any deficiency identified herein will be corrected by _____(date). I understand that failure to correct any deficiency identified herein could result in action by the California State Board of Pharmacy (Board). I further understand that all responses are subject to verification by the Board. 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: _____
(Consulting Pharmacist)

ACKNOWLEDGEMENT BY PROFESSIONAL DIRECTOR:

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: _____
(Professional Director)

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