



California State Board of Pharmacy
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 Sacramento, CA 95833
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 www.pharmacy.ca.gov

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



SURGICAL CLINIC SELF-ASSESSMENT FORM

Section 4192 of the Business and Professions Code requires 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 self-assessment must be completed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education and must assess the clinic’s compliance with current laws and regulations, including information on compounding practices as specified on the most recent version of the surgical clinic Self-Assessment Form approved by the board and posted on its internet website.

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available at the surgical clinic. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment. Note: In addition to this form, the consulting pharmacist must certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article.

All references to the board are to the California Board of Pharmacy. All references to the California Code of Regulations (CCR) are to the board’s regulations contained in Title 16 unless otherwise noted. Additionally, Business and Professions Code (BPC) are to Division 2 Healing Arts. Health and Safety Code (HSC) citations are contained in Division 10 Uniformed Controlled Substance Act. The Code of Federal Regulations (CFR) citations are to Title 21 Food and Drugs. United States Code (USC) citations are to Title 21 Food and Drugs.

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

Surgical Clinic Name: _____

Address: _____ Phone: _____

Fax: _____ Email: _____ Website: _____

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

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

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

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

Professional Director: _____ License #: _____ Exp. Date: _____

Professional Director Email: _____ Professional Director Phone: _____

Consulting Pharmacist: _____ RPH # _____ Exp. Date: _____

Consulting Pharmacist Email: _____ Consulting Pharmacist Phone: _____



Check the type of Clinic, pursuant to BPC 4190:

- 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.).

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. General Requirements

Yes No N/A

- 1.1 The clinic purchases or purchased drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic. (BPC 4190[b])
- 1.2 A separate license has been and will be issued for each clinic location. (BPC 4190[b].)
- 1.3 The clinic did or will notify the board of any change in the clinic’s address on a form furnished by the board. (BPC 4190[b])
- 1.4 The clinic keeps records of the kind and amounts of drugs purchased, administered, and dispensed, and the records are available and maintained for a minimum of three years for inspection by authorized officers of the law or representatives of the board. (BPC 4190[b], 4081, 4105)
- 1.5 The drug distribution service of the clinic is limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. (BPC 4190[c])
- 1.6 Drugs are not dispensed in an amount greater than that required to meet the patient’s needs for 72 hours. (BPC 4190[c])
- 1.7 Drugs for administration are those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of the patient for their immediate needs. (BPC 4190[c])
- 1.8 Any proposed change in ownership or beneficial interest in the licensee will be reported to the board, on a form to be furnished by 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. (BPC 4190[e])
- 1.9 The clinic complies with all applicable laws and regulations of the State Department of Public Health and the board related to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. (BPC 4191[a])



Yes No N/A

- 1.10 The clinic will or did notify the board within 30 days of any change in professional director on a form furnished by the board. (BPC4192[d])
- 1.11 If the clinic has or had a temporary closure, the clinic will or did notify the board of any temporary closure as soon as any closure exceeds or exceeded three consecutive calendar days. (CCR 1708.1)
 Note: A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless the closure exceeds four consecutive calendar days. (CCR 1708.1)
- 1.12 The clinic joined the board's email notification list within 60 days of obtaining its license or at time of license renewal. (BPC 4013[a])
- 1.13 The clinic updated its email address with the board's email notification list within 30 days of a change, if any, in the clinic's email address. (BPC 4013[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

2. Duties of the Professional Director

Yes No N/A

- 2.1 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 services are provided. (BPC 4192[c])
- 2.2 There is a professional director that is responsible for the safe, orderly, and lawful provision of pharmacy services. (BPC 4192[a])
- 2.3 In carrying out the professional director's responsibilities, a consulting pharmacist has been retained to approve the policies and procedures in conjunction with the professional director and administrator. (BPC 4192[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Duties of the Consulting Pharmacist

Yes No N/A

- 3.1 The consulting pharmacist visits the clinic regularly and at least quarterly. Nothing prohibits the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures. (BPC 4192[a])
- 3.2 The consulting pharmacist certifies in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of Article 14 for clinics. (BPC 4192[b])
- 3.3 Each written certification by the consulting pharmacist is kept on file in the clinic for three years and includes recommended corrective actions, if appropriate. (BPC 4192[b])



CORRECTIVE ACTION OR ACTION PLAN: _____

4. Dangerous Drugs and Dangerous Device Inventory

- Yes No N/A
- 4.1 Dangerous drugs and dangerous devices transferred, sold, or delivered to the clinic are transferred, sold, or delivered only to the clinic. (BPC 4059.5[b])
 - 4.2 The clinic receiving the delivery of dangerous drugs and dangerous devices signs for the receipt of the dangerous drugs and dangerous devices. (BPC 4059.5[d])
 - 4.3 All stock of any dangerous drugs or dangerous devices is, at all times during business hours, open for inspection by authorized officers of the law. (BPC 4080)
 - 4.4 The clinic keeps a current inventory as defined by Section 1718 of the board's regulations. (BPC 4081[a], CCR 1718)
 - 4.5 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the clinic is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])
 - 4.6 The clinic captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])
 - 4.7 The clinic is aware of the requirements of the Drug Quality and Security Act (DQSA), to have lot level traceability and, unit-level traceability. (21 USC 360eee-1[d][2], [g][1]f)

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Controlled Substances

- Yes No N/A
- 5.1 The clinic has obtained a registration from DEA to engage in the distribution and dispensing of controlled substances. (21 CFR 1301.11)
 - 5.2 No Schedule II controlled substances are dispensed in the clinic. (BPC 4194)
 - 5.3 Controlled substance inventories required by Title 21; Code of Federal Regulations Section 1304.04 are available for inspection upon request for at least three (3) years after the date of the inventory. (CCR 1718, 21 CFR 1304.11[c])
 Date completed: _____
 - 5.4 Separate Schedule II records are maintained. This includes Schedule II invoices, U.S. official order forms, and inventory records. (21 CFR 1304.04[h])



Yes No N/A

- 5.5 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[h][3])
- 5.6 U.S. Official Order Form (DEA Form 222) or its electronic equivalent (CSOS) is utilized when ordering all Schedule II controlled substances. When Schedule II controlled substance orders are received by the clinic, for each item received, the date and quantity received is recorded. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])
- 5.7 For each prescription for a federally Schedule II, III, IV or V controlled substance, the clinic reports the specified information to the Department of Justice or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the Department of Justice. (HSC 11165[d])
- 5.8 The clinic or affected prescriber reports the theft or loss of prescription forms immediately to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. (HSC 11165.3)
- 5.9 The clinic's prescribers authorized to prescribe, order, administer, or furnish a controlled substance consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III or Schedule IV controlled substance to the 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. (HSC 11165.4[a][1][A][i])
- 5.10 The clinic took an initial inventory of all stocks of controlled substance on hand on the date the clinic first engaged in the distribution or dispensing of controlled substances. (21 CFR 1304.11[b])
- 5.11 The clinic takes a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory can be taken on any date that is within two years of the previous biennial inventory date. (21 CFR 1304.11[c])
- 5.12 The controlled substance inventory is taken either as of opening of business or as of the close of business on the inventory date and is indicated on the inventory. (21 CFR 1304.11[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Inventory Reconciliation

Yes No N/A

- 6.1 The clinic performs periodic inventory activities and prepares inventory reconciliation reports to detect and prevent the loss of federal controlled substances. (CCR 1715.65[a])
- 6.2 Inventory reconciliation reports are prepared on an ongoing basis for federal Schedule II controlled substances, at least once every three months. (CCR 1715.65[a][1])



Yes No N/A

- 6.3 Inventory reconciliation reports are prepared on an ongoing basis for the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months for the following: (CCR 1715.65[a][2])
- 6.3.1 Alprazolam, 1 milligram/unit
 - 6.3.2 Alprazolam, 2 milligram/unit
 - 6.3.3 Tramadol, 50 milligram/unit
 - 6.3.4 Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
- 6.4 Inventory reconciliation reports are prepared on an ongoing basis for any controlled substance not covered in 6.2 and 6.3. (CCR 1715.65[a][3][A])
- 6.4.1 The inventory reconciliation report is prepared for identified controlled substances lost no later than three months after discovery of the reportable loss of that controlled substance.
 - 6.4.2 The report is completed if the loss is discovered either by the inventory activities required by 6.2 and 6.3, or in any other manner.
 - 6.4.3 The report covers the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery.
 - 6.4.3 At a minimum, the reportable loss or any pattern(s) of loss(es) identified by the consulting pharmacist or professional director, as defined by the clinic's policies and procedures.
 - 6.4.4 There is an inventory reconciliation report for each pattern of loss identified.
- 6.5 Inventory activities for each controlled substance not covered in 6.2 and 6.3 are performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])
- Note: Inventory activities means inventory and all other functions sufficient to identify loss of controlled substance. The functions sufficient to identify loss outside of the inventory reconciliation process must be identified with the pharmacy's policies and procedures. (CCR 1715.65[a][3][B])
- 6.6 The consulting pharmacist reviews all the inventory activities performed and inventory reconciliation reports prepared and establishes and maintains secured methods to prevent losses of federal controlled substances. (CCR 1715.65[b])
- 6.7 The prepared inventory reconciliation report includes all of the following:
- 6.7.1 A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the clinic has an inventory. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required. (CCR 1715.65[c][1])
 - 6.7.2 The signature of the individual who performs the required inventory and date of the inventory or the report. (CCR 1715.65[c][1])



- 6.7.3 A review of all acquisitions and dispositions of each federal controlled substance covered by the report since the last inventory reconciliation report covering the controlled substance. (CCR 1715.65[c][2])
- 6.7.4 A comparison of 6.7.1 and 6.7.3 to determine if there are any variances. (CCR 1715.65[c][3])
- 6.7.5 Identification of all records used to compile the report, which, along with the records themselves, are maintained in the clinic and are readily retrievable in the clinic for three years. (CCR 1715.65[c][4], 1715.65[e][2])

Yes No N/A

- 6.8 The clinic submits to the board a report containing the identity, amount, and strength of each controlled substance lost, and the date of discovery of the loss, for all losses that have made the report necessary, no later than thirty days after the date of discovery. (CCR 1715.6[a], [b])
- 6.9 The clinic submits to the board a report for the discovery of the following controlled substance losses: (CCR 1715.6[a], [b])
 - 6.9.1 Any loss of a controlled substance in one of the following categories that causes the aggregated number of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: (CCR 1715.6[a][1][A]-[C])
 - 6.9.1.1 For tablets, capsules or other oral medication, 99 dosage units.
 - 6.9.1.2 For single-dose injectable medication, lozenges, film, such as oral, buccal and sublingual suppositories or patches, 10 dosage units.
 - 6.9.1.3 For Injectable multi-dose unit, two or more multi-dose vials, infusion bags, or other containers.
 - 6.9.2 Any loss of controlled substances, regardless of the amount, attributed to employee theft. (CCR 1715.6[a][2])
- 6.10 The clinic notifies the DEA in their area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. (21 CFR 1301.74[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Drug Dispensing

Yes No N/A

- 7.1 The dispensing of drugs in the clinic is performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations. (BPC 4191[b])
- 7.2 The clinic is aware that is it not eligible for any professional dispensing fee that is authorized under the Medi-Cal program (Chapter 7, commencing with Section 14000, of Part 3 of Division 9 of the Welfare and Institution Code). (BPC 4193)



Yes No N/A

- 7.3 The clinic does not offer drugs for sale or charge or bill for professional services for the dispensing or administering of drugs. (BPC 4193)
- 7.4 Does the clinic have a licensed automated drug dispensing system (ADDS) placed and operated inside an enclosed building, with a premise address, at a location approved by the board that is owned/leased and operated by a pharmacy? If yes, (BPC 4427.1, 4427.3[b][3])
 Name of Pharmacy: _____
 ADDS license number: _____
- 7.5 Does the clinic have an unlicensed ADDS pursuant to Business and Professions Code section 4427.2(i) that is owned/leased and operated by a hospital pharmacy? If yes, (BPC 4427.1, 4427.2[i], 4427.3[b][3])
 Name of Hospital Pharmacy: _____
 Hospital Pharmacy license number: _____
- 7.6 The prescription labels contain all the required information. (BPC 4076)
- 7.7 The prescription label is formatted in accordance with patient centered labeling requirements. (BPC 4076.5, CCR 1707.5)
- 7.8 Whenever requested by a patient or patient’s representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the 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. (BPC 4076.6[a])
- 7.9 The clinic provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].
- 7.10 Whenever an opioid prescription is dispensed to patient for outpatient use, the clinic prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” (BPC 4076.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Drug Compounding

Yes No N/A

- 8.1 Does a pharmacy deliver compounded preparation to the clinic at which a patient receives health care services? (CCR 1713[b].) If yes:
 Name of Pharmacy: _____
 Pharmacy license number: _____
 Sterile compounding license number: _____



Attach additional sheet if necessary.

Yes No N/A

- 8.2 Does the clinic purchase compounded drugs from a facility registered as an outsourcing facility with the federal Food and Drug Administration and concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution? (BPC 4129) If yes:

Name of outsourcing facility: _____

Outsourcing Facility license #: _____

Attach additional sheet if necessary.

- 8.3 The clinic compounds for immediate use in compliance with the current United States Pharmacopeia Chapter 797 (USP 797). (USC 503A[b][A][i][I])
- 8.4 The clinic compounds for future use in compliance with the current USP 797. (USC 503A[b][A][i][I])
- 8.5 The clinic handles hazardous drugs in compliance with the current United State Pharmacopeia Chapter 800 (USP 800). (USP 800)

CORRECTIVE ACTION OR ACTION PLAN: _____

9. Policies and Procedures

Yes No N/A

- 9.1 The clinic has developed and approved policies and procedures to implement the laws and regulations by the consulting pharmacist, professional director, and the clinic administrator. (BPC 4191[a])
- 9.2 The clinic has policies and procedures that were developed and approved by the consulting pharmacist, the professional director, and the clinic administrator to implement the laws and regulations: (BPC 4191[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

10. Record Keeping Requirements

Yes No N/A

- 10.1 Inventory reports and all records used to compile the report are readily retrievable in the clinic for three years. (CCR 1715.65[e][2])
- 10.2 All records of manufacture and of sales, acquisition, receipt, shipment, or disposition of dangerous drugs and dangerous devices, at all times, during business hours are open for inspection by authorized officers of the law and are preserved for at least three years from the date of making. This also includes the kind and amounts of drugs purchased, administered, and dispensed. (BPC 4081, BPC 4190[b])



- 10.2.1 Purchase invoices for all prescription drugs. (BPC 4081[a])
- 10.2.2 Biennial controlled substance inventory. (21 CFR 1304.11[c], CCR 1718)
- 10.2.3 U.S. Official Order Forms (DEA Form 222). (21 CFR 1305.13)
- 10.2.4 Power of Attorney for completion of DEA Forms 222. (21 CFR 1305.05)
- 10.2.5 Theft and loss reports (DEA Form 106). (BPC 4081, 21 CFR 1301.74[c])
- 10.2.6 Records documenting return of drugs to wholesaler or manufacturer. (BPC 4081[a])
- 10.2.7 Records documenting transfers or sales to other clinics or reverse distributors. (BPC 4081, 4105, CCR 1718)
- 10.2.8 Records of receipt and shipment. (BPC 4081)

Yes No N/A

- 10.3 All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by the clinic is retained on the licensed premises in a readily retrievable form. (BPC 4105)
- 10.4 Each completed quarterly written certification by the consulting pharmacist is kept on file in the clinic for three years. (BPC 4192[b])
- 10.5 Completed Surgical Clinic self-assessments signed under penalty of perjury are kept on file in the clinic for three years. (BPC 4192[b])

CORRECTIVE ACTION OR ACTION PLAN: _____



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CONSULTING PHARMACIST CERTIFICATION:

I, (please print) _____, RPH # _____
 hereby certify that I have read, reviewed and completed the self-assessment of this clinic of
 which I am the Consulting Pharmacist. Any deficiency identified herein will be corrected by
 _____(date). The self-assessment was completed to the best of my professional
 ability and acknowledge failure to correct any deficiency identified could result in action by the
 board. 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 _____
 (Consulting Pharmacist)

PROFESSIONAL DIRECTOR CERTIFICATION:

I, (please print) _____, Professional License # _____
 hereby certify that I have read and reviewed the completed self-assessment of this clinic of
 which I am the Professional Director. Any deficiency identified herein will be corrected by
 _____(date). The self-assessment was completed to the best of my professional
 ability and acknowledge failure to correct any deficiency identified could result in action by the
 board. 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 is provided in this self-assessment form is true and correct.

Signature _____ Date _____
 (Professional Director)



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.

- Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General.
- CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
- HSC, Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
- USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control
- United States Pharmacopeia, Chapters 795, 797, 800, and 825