BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

SUTTER FAIRFIELD SURGERY CENTER LLC
DBA SUTTER FAIRFIELD SURGERY CENTER
Clinic Permit No. CLN 1557

Respondent

Case No. 6900

OAH No. 2020090775

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 12, 2021.

It is so ORDERED on February 10, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board President

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
BRETT A. KINGSBURY
Deputy Attorney General
State Bar No. 243744
455 Golden Gate Avenue, Suite 11000
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **SUTTER FAIRFIELD SURGERY CENTER LLC D.B.A. SUTTER FAIRFIELD SURGERY CENTER** **2700 Low Court, 2nd Floor** **Fairfield, CA 94534** **Original Permit No. CLN 1557** Respondent.	Case No. 6900 OAH No. 2020090775 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Brett A. Kingsbury, Deputy Attorney General.

2. Respondent Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center (Respondent) is represented in this proceeding by attorney Jahmal T. Davis, whose address is: Hanson Bridgett LLP; 425 Market Street, 26th Floor; San Francisco 94105.

JURISDICTION

3. On or about December 22, 2004, the Board issued Original Permit Number CLN 1557 to Respondent. The Original Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6900 and will expire on December 1, 2021, unless renewed.

4. Accusation No. 6900 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 15, 2020. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6900 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6900. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent admits the truth of each and every charge and allegation in Accusation No. 6900. Respondent agrees that its Original Permit is subject to discipline and it agrees to be bound by the Disciplinary Order below.

RESERVATION

9. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

10. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

12. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Permit No. CLN 1557, issued to Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center (Respondent), shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6900, attached as exhibit A.

Consultant Pharmacist Review. For a period of one year following the effective date of this Disciplinary Order, Respondent shall retain an independent consultant at its own expense who shall be responsible for conducting a monthly, on-site physical inspection to review the operations of Respondent for compliance with state and federal laws and regulations governing the practice of pharmacy. During this period of one year, the Board or its designee retains the discretion to conduct an in-person inspection or a remote review, in lieu of the in-person inspection, and to reduce the frequency and/or form of the inspection of the pharmacist consultant's review. The independent consultant referred to herein shall be separate from the Pharmacy Consultant identified on Respondent's behalf in the Board's records.

The independent consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Failure to timely retain, seek approval of, or ensure timely reporting by the independent consultant shall be considered a violation of this order.

Quarterly Inventory Reconciliation of Controlled Substances Reports. For a period of one year following the effective date of this order, Respondent shall perform a quarterly inventory and inventory reconciliation to detect and prevent the loss of all federal Schedule II-V controlled substances. Respondent's Professional Director shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports in compliance with this term, as set forth in California Code of Regulations, title 16, section 1715.65.

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The compilation shall include: (1) A physical count, not an estimate, of all quantities of federal Schedule II-V controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories in compliance with this term 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 by this term; (2) A review of all acquisitions and dispositions of federal Schedule II-V controlled substances since the last inventory reconciliation report; (3) A comparison of (1) and (2) to determine if there are any variances; (4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy for at least three years in a readily retrievable form; and (5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Respondent shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If Respondent is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.

The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by Respondent's Professional Director, and be readily retrievable in the pharmacy for three years. A countersignature is not required if Respondent's Professional Director personally completed the inventory reconciliation report.

Any new Professional Director for Respondent shall complete an inventory reconciliation report within 30 days of becoming the Professional Director. An outgoing Professional Director must also complete an inventory reconciliation report, as required by this term.

The first of the four quarterly reports described herein is due within 45 days of the effective date of the Decision and Order adopting this stipulation.

Cost Recovery. Respondent shall pay $6,949.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3, with the full amount due six (6) months from the effective date of this decision.

Failure to timely pay costs shall be considered unprofessional conduct and shall subject Respondent to further discipline. In addition, if Respondent fails to pay, Respondent shall not be allowed to renew its Original Permit until Respondent pays costs in full. The Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6900, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure constitutes unprofessional conduct and cause for discipline, including outright revocation, of Respondent's Original Permit No. CLN 1557.

ACCEPTANCE

I am authorized to sign on behalf of Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center. I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center's attorney, Jahmal T. Davis, Esq. I understand the stipulation and the effect it will have on Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center's Original Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

BRADLEY R. HEATON
AUTHORIZED BOARD MEMBER
SUTTER FAIRFIELD SURGERY CENTER
for Respondent

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Failure to timely pay costs shall be considered unprofessional conduct and shall subject Respondent to further discipline. In addition, if Respondent fails to pay, Respondent shall not be allowed to renew its Original Permit until Respondent pays costs in full. The Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6900, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure constitutes unprofessional conduct and cause for discipline, including outright revocation, of Respondent's Original Permit No. CLN 1557.

ACCEPTANCE

I am authorized to sign on behalf of Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center. I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center's attorney, Jahmal T. Davis, Esq. I understand the stipulation and the effect it will have on Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center's Original Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/18/2020

DocuSigned by:
Bradley R. Heaton
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BRADLEY R. HEATON
AUTHORIZED BOARD MEMBER
SUTTER FAIRFIELD SURGERY CENTER
for Respondent

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I have read and fully discussed with Respondent Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____ _____

JAHMAL T. DAVIS, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

BRETT A. KINGSBURY
Deputy Attorney General
Attorneys for Complainant

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I have read and fully discussed with Respondent Sutter Fairfield Surgery Center L.L.C. d.b.a. Sutter Fairfield Surgery Center the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/21/2020

JAHMAL T. DAVIS, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 1/13/2021

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

BRETT A. KINGSBURY
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6900

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **SUTTER FAIRFIELD SURGERY CENTER LLC D.B.A. SUTTER FAIRFIELD SURGERY CENTER** **2700 Low Court, 2nd Floor** **Fairfield, CA 94534** **Original Permit No. CLN 1557** Respondent.	Case No. 6900 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about December 22, 2004, the Board of issued Original Permit Number CLN 1557 to Sutter Fairfield Surgery Center LLC d.b.a. Sutter Fairfield Surgery Center (Respondent). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2020, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

5. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

6. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

7. Section 4301 of the Code states:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

". . . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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8. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

9. Section 4333 of the Code states, in pertinent part, that all prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

REGULATORY PROVISIONS

10. Code of Federal Regulations, title 21, section 1304.11 provides:

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be

made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

. . . .

(e) Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors. Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) Inventories of manufacturers. Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10–milligram tablet or 10–milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10–milligram tablet or 10–milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100–tablet bottle or 3–milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100–tablet bottles or six 3–milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) Inventories of distributors. Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) Inventories of registrants that reverse distribute. Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance:

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: Each finished form of the substance (e.g., 10–milligram tablet or 10–milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100–tablet bottle or 3–milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100–tablet bottles or six 3–milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II, make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: The number and size (e.g., five 10–gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

. . . .

(6) Inventories of dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

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11. California Code of Regulations, title 16, section 1715.65 provides:

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:

(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section 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 by this section;

(2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and

(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.

(e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.

. . . .

(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

(h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

(1) All controlled substances added to an automated drug delivery system are accounted for;

(2) Access to automated drug delivery systems is limited to authorized facility personnel;

(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and

(4) Confirmed losses of controlled substances are reported to the board.

12. California Code of Regulations, title 16, section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

COST RECOVERY

13. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation of the licensing act to pay a sum not to exceed the reasonable costs of investigation and enforcement.

DRUGS

14. Fentanyl is a Schedule II controlled substance as designated by Health and Safety Code section 11055(c)(8) and is a dangerous drug per Code section 4022.

FACTUAL ALLEGATIONS

15. Respondent suffered a significant controlled substance loss due to employee diversion between July 3, 2018, and April 30, 2019. In reports to the Board, Respondent calculated its loss to include roughly 3,200 units of fentanyl in varying strengths.

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FIRST CAUSE FOR DISCIPLINE

(Schedule II Reconciliation)

16. Respondent is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1715.65, in that Respondent failed to comply with the requirements for inventory reconciliation to detect and prevent the loss of controlled substances.

17. Respondent failed to complete a Schedule II inventory reconciliation report every three months between July 3, 2018, and April 30, 2019, per section 1715.65(c).

18. To the extent such reports were prepared for a portion of that time (beginning in February 2019), preparation of the reports was necessarily not preceded by a complete physical count of Schedule II medications and a comparison of that count to all acquisitions and dispositions, per section 1715.65(c).

19. Respondent's Schedule II reconciliation reports dated February 28, 2019, March 28, 2019, and May 1, 2019, were not countersigned by Respondent's professional director, per section 1715.65(e).

SECOND CAUSE FOR DISCIPLINE

(Biennial Inventory)

20. Respondent is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1304.11(a) and/or (c), or in the alternative, under Code sections 4301(o) and 4081(a) in conjunction with California Code of Regulations, title 16, section 1718, in that Respondent failed to complete a biennial inventory of all controlled substances every two years and/or to maintain that inventory on location for three years after the date of the inventory. Specifically, upon inspection on July 25, 2019, Respondent's last completed biennial inventory was dated January 3, 2017.

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THIRD CAUSE FOR DISCIPLINE

(Current Inventory)

21. Respondent is subject to disciplinary action under Code sections 4301(o) and 4081(a), in conjunction with California Code of Regulations, title 16, section 1718, in that Respondent failed to maintain complete accountability for all dangerous drugs during the period of the diversion.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number CLN 1557, issued to Sutter Fairfield Surgery Center LLC d.b.a. Sutter Fairfield Surgery Center (Respondent);

2. Ordering Respondent to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as is deemed necessary and proper.

DATED: April 9, 2020

Anne Sodergren

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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