

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

In the Matter of the Accusation Against:

PACIFIC SURGICAL INSTITUTE OF PAIN MANAGEMENT, INC.;
DAVID JAMES SMITH, CEO/PRES/SEC/TREAS/MEDICAL DIRECTOR,
Respondent

Clinic Permit No. CLN 720

Agency Case No. 7264

DECISION AND ORDER

The attached Stipulated Surrender of License Order 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 October 4, 2024.

It is so ORDERED on September 4, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh", is written over a light gray rectangular background.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 NICOLE R. TRAMA
Deputy Attorney General
4 State Bar No. 263607
600 West Broadway, Suite 1800
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Attorneys for Complainant
8

9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 7264

13 **PACIFIC SURGICAL INSTITUTE OF PAIN**
14 **MANAGEMENT, INC.; DAVID JAMES SMITH,**
15 **CEO/PRES/SECRETARY/TREASURER/**
16 **MEDICAL DIRECTOR**
3703 Camino Del Rio South, Ste. 101
San Diego, CA 92108

**STIPULATED SURRENDER OF
LICENSE AND ORDER**

17 **Clinic Permit No. CLN 720**

18 Respondent.
19
20

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

23 **PARTIES**

24 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
25 (Board). She brought this action solely in her official capacity and is represented in this matter by
26 Rob Bonta, Attorney General of the State of California, by Nicole R. Trama, Deputy Attorney
27 General.

28 ///

2. Respondent Pacific Surgical Institute of Pain Management, Inc., is represented in this proceeding by attorney Matthew D. Rifat, whose address is: Post Office Box 19879, San Diego, California, 92159.

3. On or about November 16, 1998, the Board issued Clinic Permit No. CLN 720 to Respondent Pacific Surgical Institute of Pain Management, Inc., with David James Smith, M.D., as Owner, Chief Executive Officer, President, Secretary, Treasurer, and Medical Director and Joyce L. Norman as the Administrator. The Clinic Permit was in full force and effect at all times relevant to the charges brought in Second Amended Accusation No. 7264, and expired on November 1, 2023.

JURISDICTION

4. Second Amended Accusation No. 7264 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 5, 2022. Respondent timely filed its Notice of Defense contesting the Accusation. First Amended Accusation No. 7264 was filed on October 17, 2023. Second Amended Accusation No. 7264 was filed on July 15, 2024. A copy of Second Amended Accusation No. 7264 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Second Amended Accusation No. 7264. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

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 Second Amended Accusation; 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 understands that the charges and allegations in Second Amended Accusation No. 7264, if proven at a hearing, constitute cause for imposing discipline upon Clinic Permit No. CLN 720.

9. For the purpose of resolving the Second Amended Accusation without the expense and uncertainty of further proceeding, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Second Amended Accusation and that those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of their Clinic Permit without further process.

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 surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they 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 Surrender and Disciplinary Order 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 Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

12. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement.

1 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
2 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order
3 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
4 executed by an authorized representative of each of the parties.

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

7 **ORDER**

8 IT IS HEREBY ORDERED that Clinic Permit No. CLN 720, issued to Respondent Pacific
9 Surgical Institute of Pain Management, Inc. with David James Smith, M.D., as Owner, Chief
10 Executive Officer, President, Secretary, Treasurer, and Medical Director and Joyce L. Norman as
11 the Administrator, is surrendered and accepted by the Board.

12 1. The surrender of Respondent's Clinic Permit and the acceptance of the surrendered
13 license by the Board shall constitute the imposition of discipline against Respondent. This
14 stipulation constitutes a record of the discipline and shall become a part of Respondent's license
15 history with the Board. Respondent and David James Smith, M.D., understand and agree that for
16 purposes of Business and Professions Code section 4307, the surrender shall be construed the
17 same as revocation.

18 2. Respondent shall lose all rights and privileges as a clinic in California as of the
19 effective date of the Board's Decision and Order.

20 3. Respondent shall cause to be delivered to the Board its pocket license and, if one was
21 issued, its wall certificate on or before the effective date of the Decision and Order.

22 4. Respondent's clinic may be sold prior to the effective date of the decision. In the
23 event that Respondent's clinic is not sold before the effective date of the decision, Respondent
24 shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale
25 of or storage in a facility licensed by the Board of all controlled substances and dangerous drugs
26 and devices that were purchased under the clinic permit. Respondent shall further provide written
27 proof of such disposition and shall submit a completed Discontinuance of Business form
28 according to Board guidelines.

5. Respondent may not apply for any license, permit, or registration from the Board for three years from the effective date of this decision. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Second Amended Accusation No. 7264 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

6. Respondent shall pay the agency its costs of investigation and enforcement in the amount of \$11,842.50 prior to issuance of a new or reinstated license.

7. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Second Amended Accusation No. 7264 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney Matthew D. Rifat. I understand the stipulation and the effect it will have on my Clinic Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

DAVID JAMES SMITH, M.D., as the
Director and authorized agent on behalf of:
PACIFIC SURGICAL INSTITUTE OF PAIN
MANAGEMENT, INC.
Respondent

5. Respondent may not apply for any license, permit, or registration from the Board for three years from the effective date of this decision. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Second Amended Accusation No. 7264 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

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ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney Matthew D. Rifat. I understand the stipulation and the effect it will have on my Clinic Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: July 18, 2024

David J. Smith, M.D.

DAVID JAMES SMITH, M.D., as the
Director and authorized agent on behalf of:
PACIFIC SURGICAL INSTITUTE OF PAIN
MANAGEMENT, INC.

Respondent

1 I have read and fully discussed with Respondent Pacific Surgical Institute of Pain
2 Management Inc., the terms and conditions and other matters contained in this Stipulated
3 Surrender of License and Order. I approve its form and content.

4
5 DATED: _____

MATTHEW D. RIFAT
Attorney for Respondent

6
7
8 **ENDORSEMENT**

9 The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted
10 for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

11 DATED: _____

Respectfully submitted,

12 ROB BONTA
13 Attorney General of California
14 GREGORY J. SALUTE
Supervising Deputy Attorney General

15
16 NICOLE R. TRAMA
17 Deputy Attorney General
Attorneys for Complainant

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1 I have read and fully discussed with Respondent Pacific Surgical Institute of Pain
2 Management Inc., the terms and conditions and other matters contained in this Stipulated
3 Surrender of License and Order. I approve its form and content.

4
5 DATED: July 18, 2024



6 MATTHEW D. RIFAT
7 Attorney for Respondent

8 **ENDORSEMENT**

9 The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted
10 for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

11 DATED: 7/19/2024

Respectfully submitted,

12 ROB BONTA
13 Attorney General of California
14 GREGORY J. SALUTE
15 Supervising Deputy Attorney General

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16 Nicole R. Trama

17 NICOLE R. TRAMA
18 Deputy Attorney General
19 Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 7264

1 ROB BONTA
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2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 NICOLE R. TRAMA
Deputy Attorney General
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Attorneys for Complainant
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17 **MEDICAL DIRECTOR**
18 **3703 Camino Del Rio South, Ste. 101**
19 **San Diego, CA 92108**

20 **Clinic Permit No. CLN 720**

21 Respondent.

Case No. 7264

**SECOND AMENDED
ACCUSATION**

22 **PARTIES**

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

26 2. On or about November 16, 1998, the Board of Pharmacy issued Clinic Permit
27 Number CLN 720 to Respondent Pacific Surgical Institute of Pain Management, Inc. with David
28 James Smith, M.D., as Owner, Chief Executive Officer, President, Secretary, Treasurer, and

1 Medical Director and Joyce L. Norman as the Administrator. The Clinic Permit was in full force
2 and effect at all times relevant to the charges brought herein and expired on November 1, 2023,
3 and has not been renewed.

4 **JURISDICTION, STATUTORY, & REGULATORY PROVISIONS**

5 3. This Second Amended Accusation is brought before the Board of Pharmacy (Board),
6 Department of Consumer Affairs, under the authority of the following laws. All section
7 references are to the Business and Professions Code (Code) unless otherwise indicated.

8 4. Section 480 states in part:

9 (a) Notwithstanding any other provision of this code, a board may deny a
10 license regulated by this code on the grounds that the applicant has been convicted of
11 a crime or has been subject to formal discipline only if either of the following
12 conditions are met:

13 (1) The applicant has been convicted of a crime within the preceding seven
14 years from the date of application that is substantially related to the qualifications,
15 functions, or duties of the business or profession for which the application is made,
16 regardless of whether the applicant was incarcerated for that crime, or the applicant
17 has been convicted of a crime that is substantially related to the qualifications,
18 functions, or duties of the business or profession for which the application is made
19 and for which the applicant is presently incarcerated or for which the applicant was
20 released from incarceration within the preceding seven years from the date of
21 application. However, the preceding seven-year limitation shall not apply in either of
22 the following situations:

23 . . .

24 (2) The applicant has been subjected to formal discipline by a licensing board in
25 or outside California within the preceding seven years from the date of application
26 based on professional misconduct that would have been cause for discipline before
27 the board for which the present application is made and that is substantially related to
28 the qualifications, functions, or duties of the business or profession for which the
present application is made. However, prior disciplinary action by a licensing board
within the preceding seven years shall not be the basis for denial of a license if the
basis for that disciplinary action was a conviction that has been dismissed pursuant to
Section 1203.4, 1203.4a, 1203.41, 1203.42, or 1203.425 of the Penal Code or a
comparable dismissal or expungement.

. . . .

5. 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.].

1 6. Section 4300, subdivision (a) of the Code provides that every license issued by the
2 Board may be suspended or revoked.

3 7. Section 4300.1 of the Code states:

4 The expiration, cancellation, forfeiture, or suspension of a board-issued license
5 by operation of law or by order or decision of the board or a court of law, the
6 placement of a license on a retired status, or the voluntary surrender of a license by a
7 licensee shall not deprive the board of jurisdiction to commence or proceed with any
8 investigation of, or action or disciplinary proceeding against, the licensee or to render
9 a decision suspending or revoking the license.

10 8. Code section 4022 states:

11 “Dangerous drug” or “dangerous device” means any drug or device unsafe for
12 self-use in humans or animals, and includes the following:

13 (a) Any drug that bears the legend: “Caution: federal law prohibits
14 dispensing without prescription,” “Rx only,” or words of similar import.

15 (b) Any device that bears the statement: “Caution: federal law restricts this
16 device to sale by or on the order of a _____,” “Rx only,” or words of similar import,
17 the blank to be filled in with the designation of the practitioner licensed to use or
18 order use of the device.

19 (c) Any other drug or device that by federal or state law can be lawfully
20 dispensed only on prescription or furnished pursuant to Section 4006.

21 9. Code section 4081 states in part:

22 (a) All records of manufacture and of sale, acquisition, receipt, shipment, or
23 disposition of dangerous drugs or dangerous devices shall be at all times during
24 business hours open to inspection by authorized officers of the law, and shall be
25 preserved for at least three years from the date of making. A current inventory
26 shall be kept by every manufacturer, wholesaler, third-party logistics provider,
27 pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician,
28 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.

...

10 10. Section 4105, subdivision (a) of the Code states:

11 All records or other documentation of the acquisition and disposition of
12 dangerous drugs and devices by any entity licensed by the board shall be retained on
13 the licensed premises in a readily retrievable form.

1 11. Code section 4112 states in part:

2 (a) Any pharmacy located outside this state that ships, mails, or delivers, in any
3 manner, controlled substances, dangerous drugs, or dangerous devices into this state
4 shall be considered a nonresident pharmacy.

5 (b) A person may not act as a nonresident pharmacy unless he or she has
6 obtained a license from the board. The board may register a nonresident pharmacy
7 that is organized as a limited liability company in the state in which it is licensed.

8 ...

9 12. Code section 4161 states in part:

10 (a) A person located outside this state that (1) ships, sells, mails, warehouses,
11 distributes, or delivers dangerous drugs or dangerous devices into this state or (2)
12 sells, brokers, warehouses, or distributes dangerous drugs or devices within this state
13 shall be considered a nonresident wholesaler or a nonresident third-party logistics
14 provider.

15

16 13. Code section 4169 states in part:

17 (a) A person or entity shall not do any of the following:

18 (1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or
19 dangerous devices at wholesale with a person or entity that is not licensed with the
20 board as a wholesaler, third-party logistics provider, or pharmacy.

21 (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or
22 reasonably should have known were adulterated, as set forth in Article 2
23 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the
24 Health and Safety Code.

25 (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or
26 reasonably should have known were misbranded, as defined in Section 111335 of the
27 Health and Safety Code.

28 (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after
the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs
or dangerous devices for at least three years.

....

14. Code section 4190 states in part:

(a) For the purposes of this article, "clinic" means a surgical clinic 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, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal

Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) A clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(c) The drug distribution service of a clinic shall be 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. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board.

(e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall 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.

(f) Nothing in this section shall limit the ability of a physician and surgeon to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

15. Code section 4191 states:

(a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating 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. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be 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.

16. Code section 4192 states:

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's

responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit 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.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

17. Code section 4195 states:

The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law.

18. Code section 4301 states in part:

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 includes, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties

1 of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea
2 of nolo contendere is deemed to be a conviction within the meaning of this provision. The
3 board may take action when the time for appeal has elapsed, or the judgment of conviction
4 has been affirmed on appeal or when an order granting probation is made suspending the
imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal
Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not
guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
indictment.

5 . . .

6 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
7 abetting the violation of or conspiring to violate any provision or term of this chapter
8 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.

9 (p) Actions or conduct that would have warranted denial of a license.

10 . . .

11
12 19. Code section 4302 states in part:

13 The board may deny, suspend, or revoke any license where conditions exist in
14 relation to any person holding 10 percent or more of the ownership interest or where
15 conditions exist in relation to any officer, director, or other person with management
or control of the license that would constitute grounds for disciplinary action against a
licensee.

16
17 20. Code section 4307 states in part:

18 (a) Any person who has been denied a license or whose license has been
19 revoked or is under suspension, or who has failed to renew his or her license while it
20 was under suspension, or who has been a manager, administrator, owner, member,
21 officer, director, associate, partner, or any other person with management or control
22 of any partnership, corporation, trust, firm, or association whose application for a
license has been denied or revoked, is under suspension or has been placed on
probation, and while acting as the manager, administrator, owner, member, officer,
23 director, associate, partner, or any other person with management or control had
knowledge of or knowingly participated in any conduct for which the license was
denied, revoked, suspended, or placed on probation, shall be prohibited from serving
as a manager, administrator, owner, member, officer, director, associate, partner, or in
any other position with management or control of a licensee as follows:

24
25 (1) Where a probationary license is issued or where an existing license is
placed on probation, this prohibition shall remain in effect for a period not to exceed
five years.

26
27 (2) Where the license is denied or revoked, the prohibition shall continue until
the license is issued or reinstated.

28 (b) "Manager, administrator, owner, member, officer, director, associate,

1 partner, or any other person with management or control of a license” as used in this
2 section and Section 4308, may refer to a pharmacist or to any other person who serves
3 in such capacity in or for a licensee.

4 (c) The provisions of subdivision (a) may be alleged in any pleading filed
5 pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
6 the Government Code. However, no order may be issued in that case except as to a
7 person who is named in the caption, as to whom the pleading alleges the applicability
8 of this section, and where the person has been given notice of the proceeding as
9 required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
10 the Government Code. The authority to proceed as provided by this subdivision
11 shall be in addition to the board's authority to proceed under Section 4339 or any
12 other provision of law.

13 21. California Code of Regulations, title 16, section 1770 provides:

14 (a) For the purpose of denial, suspension, or revocation of a personal or facility
15 license pursuant to Section 141 or Division 1.5 (commencing with Section 475) of the
16 Business and Professions Code, a crime, professional misconduct, or act shall be
17 considered substantially related to the qualifications, functions or duties of the
18 practice, profession, or occupation that may be performed under the license type
19 sought or held if to a substantial degree it evidences present or potential unfitness of
20 an applicant or licensee to perform the functions authorized by the license in a
21 manner consistent with the public health, safety, or welfare.

22 (b) In making the substantial relationship determination required under
23 subdivision (a) for a crime, the board will consider the following criteria:

24 (1) The nature and gravity of the offense;

25 (2) The number of years elapsed since the date of the offense; and

26 (3) The nature and duties of the practice, profession, or occupation that may be
27 performed under the license type sought or held.

28 (c) For purposes of subdivision (a), substantially related crimes, professional
misconduct, or acts shall include, but are not limited to, those which:

(1) Violate or attempt to violate, directly or indirectly, or to aid, abet or
conspire to violate, any provision of law of this state, or any other jurisdiction,
governing the practice of pharmacy.

(2) Violate or attempt to violate, directly or indirectly, or to aid, abet or
conspire to violate, any provision of Chapter 13 (commencing with Section 801) of
Title 21 of the United States Code regulating controlled substances or any law of this
state, or any other jurisdiction, relating to controlled substances or dangerous drugs.

(3) Violate or attempt to violate, directly or indirectly, or to aid, abet or
conspire to violate, any provision of law of this state, or any other jurisdiction,
relating to government provided or government supported healthcare.

(4) Involve dishonesty, fraud, deceit, or corruption related to money, items,
documents, or personal information.

(5) Involve a conviction for driving under the influence of drugs or alcohol.

1 **COST RECOVERY**

2 22. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
3 administrative law judge to direct a licensee found to have committed a violation or violations of
4 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
5 enforcement of the case.

6 **FACTUAL ALLEGATIONS**

7 23. David James Smith, M.D., (Dr. Smith) has been the Director of the Respondent
8 Pacific Surgical Institute of Pain Management, Inc., (hereinafter Clinic) located in San Diego,
9 since the issuance of the Clinic's license.

10 **Dr. Smith's Disciplinary Actions**

11 24. In a disciplinary case entitled, *In the Matter of the Accusation Against David James*
12 *Smith, M.D.*, Case Number 800-2015-013651, the Medical Board of California issued a decision
13 and order effective September 24, 2020, revoking Dr. Smith's Physician and Surgeon's
14 Certificate, staying the revocation, and placing him on probation for five years with certain terms
15 and conditions. The circumstances of the discipline were that Dr. Smith committed acts of gross
16 negligence in the care and treatment of one patient, and acts of repeated negligence in the care
17 and treatment of two patients; excessively prescribed drugs to one patient; failed to maintain
18 adequate and accurate medical records in the care and treatment of two patients; and engaged in
19 unprofessional conduct in the care and treatment of two patients. As part of the discipline, Dr.
20 Smith was required to maintain a record of all controlled substances ordered, prescribed,
21 dispensed, administered, or possessed and any recommendations or approvals to possess or
22 cultivate marijuana; complete an education course, a prescribing practices course, a medical
23 record keeping course, and an ethics course; complete a clinical competence assessment program
24 prohibited him from ordering, prescribing, dispensing, administering, furnishing or possessing
25 Schedule II, III, or IV drugs until after proof of successful completion of the clinical competence
26 assessment program has been provided to the Board; and prohibited him from performing any
27 care or treatment with patients involving the use, management or any surgical procedures related
28 to intrathecal pumps until after successful completion of the clinical competence assessment

1 program has been provided to the Board; obtain a practice monitor; prohibited him from
2 supervising physician assistants and advanced practice nurses, among other terms.

3 25. In a subsequent disciplinary matter, *In the Matter of the Accusation Against David*
4 *James Smith, M.D.*, Case Number 800-2018-042234, the Medical Board of California issued a
5 decision and order effective January 21, 2022, revoking Dr. Smith's Physician and Surgeon's
6 Certificate, staying the revocation, and placing him on probation for the duration of Dr. Smith's
7 probation in case No. 800-2015-013651, with the following additional term: prohibited from
8 performing any care or treatment with patients involving the use, management, or any surgical
9 procedure related to intrathecal pumps, or advising any medical provider on the care or treatment
10 of patients involving the use, management, or any surgical procedure related to intrathecal pumps,
11 for the duration of Dr. Smith's probation in case No. 800-2015-013651.

12 **Inspection of Clinic**

13 26. On October 6, 2021, a Board of Pharmacy Inspector inspected the Clinic. At the front
14 window, the Inspector identified herself and stated her purpose. The Inspector was informed by
15 an employee that Director Dr. Smith and Administrator Matt Rifat (Administrator Rifat) were in a
16 meeting for the next two weeks. The Inspector asked to speak to Dr. M.R. and Dr. D.D., who
17 each had a California Department of Public Health certificate posted in the lobby of the Clinic.
18 The Inspector was informed that Dr. M.R. left employment at the Clinic two weeks prior and that
19 Dr. D.D. only comes in when needed. The Inspector was further informed that Dr. S.T. would
20 often come into the Clinic. The Inspector was informed that the FBI, IRS and DEA had taken
21 records with them when they came to the Clinic in August 2021. The Inspector requested to see
22 where the drugs were housed and any paperwork that was available.

23 27. A licensed vocational nurse (LVN) escorted the Inspector to the patient care areas.
24 She showed the Inspector where the drugs were housed by unlocking the cabinets and opening the
25 safe to the controlled substances. The LVN then introduced the Inspector to an operating room
26 technician who was responsible for ordering the drugs. He informed the Inspector that he ordered
27 mainly from Nationwide Medical Surgical Inc., but that the Clinic also purchased from Direct
28 Compounding and Outsourcing before they closed. Direct Compounding and Outsourcing is not

licensed with the Board as a wholesaler, third-party logistics provider, or pharmacy. The Board Inspector reviewed and took photographs of invoices from Direct Compounding and Outsourcing that showed from at least May 27, 2020 to at least August 19, 2020, the Clinic purchased, traded, or transferred the following dangerous drugs from Direct Compounding and Outsourcing:

Date	Invoice Number	Item
8/19/20	1688	Compounded dexameth/triamcin/bupivacaine in a 6ml vial
8/13/20	1669	Sodium Chloride 50ml vial (PF) X 50 Bupivacaine HCL(PF) 0.25 10 ml vials X 50
6/25/20	1486	Sodium Chloride 20ml vial (PF) X 75 Lidocaine 1% 50ml vial X 75
6/17/20	1458	Dantrolene 20mg SDV X 4 Ondanestron 4ml SDV X 50 Verapamil 10ml/4ml SDV X 4 Hydrazine 25mg/ml SDV X 25 Succinylcholine 200ml SDV X 25 Compounded dexameth/triamcin/bupivacaine in a 6 ml vial
6/16/20	1451	Phenylephrine 10mg/ml 1ml vial
5/27/20	1379	Lidocaine 1% 50ml vial X 10 Lidocaine 2% 50ml vial X 10 Bupivacaine w/EPI 50 ml vial X 25 Sodium Chloride 0.9 100ml bag X 96

28. During the inspection, the Inspector was informed that the Clinic was using Dr. M.R.'s DEA license for the ordering of controlled substances. When asked who owned the controlled substances now that Dr. M.R. had left the practice, nobody could answer. The Inspector asked additional questions about the practice and was informed that a registered nurse was performing the anesthesia, a second registered nurse would perform the IVPs and the LVN would provide the IM injections.

1 29. The Inspector sent a request for information to Administrator Rifat after she left the
2 Clinic. The Inspector requested several items including, the name and contact information for the
3 consulting pharmacist, all acquisition records for any dangerous drugs and devices from Direct
4 Compounding and Outsourcing from January 1, 2020 to October 6, 2021, and the names of the
5 physicians present at the Clinic on September 17, 2021. The Board Inspector also asked for the
6 relationship between the Clinic and Direct Compounding and Outsourcing, and information about
7 the controlled substances and DEA license for the Clinic.

8 30. In response, Administrator Rifat provided a letter to the Board Inspector on
9 November 1, 2021. In response to the Inspector's question about whether the Clinic had its own
10 DEA registration or if the Clinic used a provider's DEA registration, Administrator Rifat stated
11 that the center had its own DEA registration and then provided the Board Inspector with the DEA
12 number that actually belonged to Dr. M.R. (even though Dr. M.R. had left the practice weeks
13 prior.) In response to the Board's request for records, Administrator Rifat told the Board
14 Inspector that all records were in the custody of law enforcement, and did not provide copies of
15 multiple invoices previously photographed by the Inspector, which showed the purchase of
16 dangerous drugs and medical supplies from May to August 2020 from Direct Compounding and
17 Outsourcing, as well as other records related to Direct Compounding and Outsourcing which
18 were not seized by law enforcement. In addition, Administrator Rifat told the Inspector that the
19 Clinic was only a vendor of Direct Compounding and Outsourcing, even though there was a
20 relationship between the Clinic and Direct Compounding and Outsourcing.¹ Administrator Rifat
21 told the Board inspector that only Dr. Smith was present at the Clinic on September 17, 2021.
22 However, records showed that Dr. M.R. was also present. As for the pharmacist consultant,
23 Administrator Rifat stated it was Pharmacist H.K., however, she no longer provided pharmacy
24 services to the center and a replacement search was underway.

25 31. In a subsequent communication on November 17, 2021, Administrator Rifat told the
26 Board Inspector that the Clinic's new pharmacist consultant was Pharmacist V.Z., and that she

27
28 ¹ Direct Compounding and Outsourcing's managing member (with 85% control) is Dr.
Smith's wife.

1 “has met with and been oriented by the surgery center team.” He further informed the Board
2 Inspector that the consulting pharmacist “is preparing her report.” However, Pharmacist V.Z. told
3 the Board Inspector on November 26, 2021, that she was not going to be the Clinic’s pharmacist
4 consultant. The Clinic never sent the Board Inspector a consulting pharmacist report.

5 32. The Board Inspector concluded that the Clinic did not have a consulting pharmacist
6 retained from on or about April 13, 2021 to on or about November 24, 2021. No consulting
7 pharmacist was available to certify in writing that the Clinic was operating in compliance with the
8 requirements during that timeframe.

9 **Dr. Smith’s Criminal Conviction**

10 33. On or about April 3, 2024, in the criminal case entitled, *United States of America v.*
11 *David J. Smith*, United States District Court Southern District of California, Case No. 22-CR-
12 2842, Dr. Smith was convicted on his plea of guilty to violation of Title 21, United States Code,
13 Section 331(k) (Adulteration of Controlled Substances (Misdemeanor)), in that beginning on a
14 date unknown but no later than May 2018 and continuing until at least December 2021, Dr. Smith
15 caused a drug that was held for sale after shipment in interstate commerce to be adulterated
16 within the meaning of Title 21, United States Code, Section 351(a)(2)(A), to wit: N-phenyl-N-[1-
17 (2-phenylethyl)-4-piperidinyl] propenamide (commonly known as fentanyl), by preparing,
18 packing or holding such drug under insanitary conditions whereby it may have been contaminated
19 with filth, or whereby it may have been rendered injurious to health.

20 **FIRST CAUSE FOR DISCIPLINE**

21 **(Failure to Meet the Duties of a Professional Director)**

22 34. Respondent is subject to disciplinary action under Code section 4301, subdivision (o),
23 for violating Code section 4192, in that Dr. Smith as the Medical Director, failed to retain a
24 consulting pharmacist from April 13, 2021 to November 24, 2021 and no consultant was
25 available to certify in writing during that time that the Clinic was operating in compliance with
26 the requirements, as set forth in paragraphs 23 through 33, incorporated herein.

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1 (a) Respondent's Owner, Chief Executive Officer, President, Secretary, Treasurer, and
2 Medical Director, Dr. Smith, was formally disciplined by the Medical Board of California in two
3 disciplinary actions, which would have warranted denial of licensure under Code section
4 480(a)(2) and 4302.

5 (b) Respondent failed to retain a consulting pharmacist and ensure the provisions of Code
6 section 4192 were met, which would have warranted a denial of licensure.

7 (c) Respondent's Owner, Chief Executive Officer, President, Secretary, Treasurer, and
8 Medical Director, Dr. Smith, was convicted of a crime, which would have warranted denial of
9 licensure under Code section 480(a)(1) and 4302.

10 **SEVENTH CAUSE FOR DISCIPLINE**

11 **(Substantially Related Conviction)**

12 40. Respondent is subject to disciplinary action under Code section 4301, subdivision (1),
13 as it relates to Code section 4302 in that Dr. Smith was convicted on his plea of guilty to violation
14 of Title 21, United States Code, Section 331(k) (Adulteration of Controlled Substances
15 (Misdemeanor)), as set forth in paragraphs 23 through 33, incorporated herein.

16 **OTHER MATTERS**

17 41. Pursuant to Code section 4307, if discipline is imposed on Clinic Permit Number
18 CLN 720, issued to Pacific Surgical Institute of Pain Management Inc., Respondent Pacific
19 Surgical Institute of Pain Management Inc., shall be prohibited from serving as a manager,
20 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
21 Clinic Permit Number CLN 720, issued to Pacific Surgical Institute of Pain Management Inc., is
22 reinstated if it is revoked.

23 42. Pursuant to Code section 4307, if discipline is imposed on Clinic Permit Number
24 CLN 720, issued to Pacific Surgical Institute of Pain Management Inc., while Dr. Smith has been
25 an officer and owner and had knowledge of or knowingly participated in any conduct for which
26 the licensee was disciplined, Dr. Smith shall be prohibited from serving as a manager,
27 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
28

Clinic Permit Number CLN 720, issued Pacific Surgical Institute of Pain Management Inc., is reinstated if it is revoked.

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 Clinic Permit Number CLN 720, issued to Pacific Surgical Institute of Pain Management, Inc., with David James Smith, M.D., as Owner, Chief Executive Officer, President, Secretary, Treasurer;

2. Prohibiting Pacific Surgical Institute of Pain Management Inc., from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Clinic Permit Number CLN 720 is placed on probation or until Clinic Permit Number CLN 720 is reinstated if Clinic Permit Number CLN 720 issued to Pacific Surgical Institute of Pain Management Inc., is revoked;

3. Prohibiting Dr. Smith from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Clinic Permit Number CLN 720, is placed on probation or until Clinic Permit Number CLN 720 is reinstated if Clinic Permit Number CLN 720 issued to Pacific Surgical Institute of Pain Management Inc., is revoked;

4. Ordering Pacific Surgical Institute of Pain Management Inc., 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,

5. Taking such other and further action as deemed necessary and proper.

DATED: 7/15/2024

**Sodergren,
Anne@DCA**

Digitally signed by
Sodergren, Anne@DCA
Date: 2024.07.15 11:28:47
-07'00'

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

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