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

In the Matter of the Accusation Against: **SAN DIEGO HOSPICE CORP.** **DBA SAN DIEGO HOSPICE PHARMACY** **4311 Third Avenue** **San Diego, CA 92103** **Retail Pharmacy Permit No. PHY 37157** **Sterile Compounding License No. LSC 99299** **and** **ROSENE DOBNICK PIRRELLO** **3863-3 California Street** **San Diego, CA 92110** **Pharmacist License No. RPH 36880** Respondents.	Case No. 4461 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about February 10, 1982, the Board of Pharmacy issued Pharmacist License Number RPH 36880 to Rosene Dobnick Pirrello (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2016, unless renewed.

3. On or about July 24, 1991, the Board of Pharmacy issued Hospital Pharmacy Permit Number HSP 37157 to San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent). On February 4, 2013, the Hospital Pharmacy Permit was changed to a Retail Pharmacy Permit (PHY 37157). The Permit was in full force and effect at all times relevant to the charges brought herein and expired on June 1, 2013.

4. On or about May 26, 2005, the Board of Pharmacy issued Sterile Compounding License Number LSC 99299 to San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and expired on June 1, 2013.

JURISDICTION

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

6. 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.].

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

8. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, 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

9. Section 4022 of the Code states:

> Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Section 4105, subdivision (a) of the Code states: "All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."

11. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

12. Section 4301 of the Code states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . . .
>
> (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.
>
> . . . .

13. Section 4333, subdivision (a) of the Code states: "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

14. California Code of Regulations, title 16, section 1707 states:

...

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing. . . .

15. California Code of Regulations, title 16, section 1735, subdivision (a) states in pertinent part:

"Compounding" means any of the following activates occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

...

16. California Code of Regulations, title 16, section 1735.2(a) states:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

17. California Code of Regulations, title 16, section 1735.3 states in pertinent part:[1]

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) The equipment used in compounding the drug product.

(8) A pharmacy assigned reference or lot number for the compounded drug product.

(9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded. . . .

18. California Code of Regulations, title 16, section 1751.7 states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

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[1] The California Code of Regulations sections listed above are from the prior version of the Regulations, which was in effect at the time of the facts giving rise to the allegations asserted herein. In 2013, the Regulations were renumbered and reorganized.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

...

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

...

COST RECOVERY

19. 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 or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

20. Chlorpromazine is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of psychiatric illness and nausea or vomiting.

21. Dexamethasone is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of swelling.

22. Diazepam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(9) and a dangerous drug pursuant to Business and Professions Code section 4022. Diazepam is used for the treatment of anxiety and seizures.

23. Fentanyl is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c)(8), and a dangerous drug pursuant to Business and Professions Code section 4022. Fentanyl is used for the treatment of pain.

24. Haloperidol is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of psychiatric illness.

25. Indomethacin is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of inflammation.

26. Ketoprofen is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of pain.

27. Metoclopramide is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of nausea and vomiting.

28. Mexiletine is a dangerous drug pursuant to Business and Professions Code section 4022 and is used in the treatment of heart arrhythmias and prevent transplanted organ rejection.

29. Phenobarbital is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(26), and a dangerous drug pursuant to Business and Professions Code section 4022. Phenobarbital is used in the treatment of seizures.

30. Phenytoin is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of seizures.

FACTUAL ALLEGATIONS

31. Since August 21, 2002 and at all times referenced herein, Rosene Pirrello (Respondent) was the Pharmacist-in-Charge (PIC) of San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent). On or about May 15, 2012, the Board conducted an annual licensed sterile compounder inspection of Respondents.

32. During the inspection, the Board inspector discovered that Respondents did not maintain the records for the acquisition of dangerous drugs and controlled substances on the licensed premises as required by law.

33. During the inspection, the Board inspector also reviewed Respondents' compounding records and discovered that Respondents had not followed the regulations required for compounding sterile injectable drugs.[2] Specifically, from February 22, 2012 through May 4,

[2] "Sterile" compounds require sterility and are typically in the form of injectables for the direct administration into a sterile organ or fluid in the body. It is imperative these products contain little to no contaminants for the safety of the patient.

2012, Respondents compounded six batches of stock fentanyl 1000mcg/ml-1000mls (Assigned Lot Numbers STK178-0, STK178-2, STK178-3, STK220-0, STK220-1, and STK220-2) without quarantine of those six batches until end-product testing, in order to confirm sterility and acceptable levels of pyrogens. Respondents did not examine on a periodic basis the end-product of those six batches to ensure that they met the required specifications.

34. Respondents also did not perform periodic sampling to determine if the end-product met required specifications for another nine lots of sterile to sterile compounded fentanyl 50mcg/ml aliquots, as follows:

Compounded date	Assigned Beyond Use Date	Assigned Lot #	Stock Lot # Used
2/22/12	3/22/12	STK179-0	STK 178-0
2/29/12	3/30/12	STK179-2	STK 178-2
3/12/12	4/11/12	STK128-12	STK 178-3
4/11/12	5/11/12	STK219-0	STK 220-0
4/12/12	5/12/12	STK219-1	STK 220-0
4/19/12	5/11/12	STK219-2	STK 220-0
4/26/12	5/26/12	STK219-3	STK 220-1
5/4/12	6/3/12	STK219-5	STK 220-2
5/7/12	6/3/12	STK219-6	STK 220-2

These nine lots were dispensed to patients without Respondents' verification of the test results.

35. The Board inspector also determined based on her review of compounding logs that Respondents did not properly record the required manufacturer and lot numbers in their compounding logs for another three lots of stock fentanyl 1000 mcg/ml (Assigned Lot Numbers STK178-3, STK220-0, and STK220-2) and another five lots of fentanyl 50 mcg/ml (Assigned Lot Numbers STK219-0, STK219-1, STK219-2, STK219-3, and STK219-6).

36. In addition, the Board inspector determined that Respondents had ordered and purchased non-patient specific compounded drugs (drugs compounded by pharmacies prior to receipt by those pharmacies of valid prescriptions for individual patients where the prescribers had approved use of a compounded drug either orally or in writing) from two pharmacies, UCP and VDC.

37. Respondents' records show that from January 2009 to April 2012, Respondents ordered and purchased the following units of non-patient specific compounded drug products from UCP:

Compounded Drug	Total Units Purchased
Chlorpromazine 50mg Suppository (number)	78,474
Chlorpromazine 25mg Suppository (number)	2,850
Chlorpromazine 100mg Suppository (number)	6,840
Chlorpromazine 100mg/ml Sol (ml)	7,344
Diph 25-Methel 10- dex 2mg Suppository (number)	360
Ketoprofen 20% PLO (grams)	11,552
Ketoprofen 10% PLO (grams)	7,800
MOHS Paste (grams)	300
Phenytoin 300mg Suppository (number)	930
Valproic Acid 250mg/5ml suspension (ml)	1,700
Ketamine 5% keto 10% Lido 5% PLO (grams)	180
Indomethacin 50mg Suppository (number)	48
Sal Acid 2% sulfur 3% HCT 0.05% Cream (grams)	60
Mexiletine 50 mg Capsules (number)	300
APAP 650MG Suppository (number)	3,000

38. Respondents' records further show that from January 2009 to April 2012, Respondents ordered and purchased the following units of non-patient specific compounded drug products from VDC:

Compounded Drug	Total Units Purchased
Chlorpromazine (unknown)	20
Chlorpromazine 50mg/ml PLO gel 10ml (each)	795
Chlorpromazine 100mg/ml PLO gel 10ml (each)	1,477
Mexiletine 50mg capsules (number)	1,286
Mexiletine 100mg capsules (number)	100
Mexiletine 150mg capsules (number)	550
Dexamethasone/ diphen/ metoclopramide 2mg/25mg/10mg (1 ml) PLO (each)	1,415
Phenobarbital 60mg Suppository	490
Phenobarbital 30mg Suppository	30
Phenobarbital 180mg Suppository	72
Diazepam 5mg Suppository	30
Diazepam 10mg Suppository	150
Lorazepam 1mg/ml PLO	5
Metoclopramide 10mg/0.1ml PLO gel	44
Haloperidol 1mg/ml PLO Gel	63
Carbamazepine 200mg Suppository (each)	12

39. The total number of each type of non-patient specific compounded drug products which Respondents ordered and purchased from UCP and VDC, were as follows:

Compounded Product	Total Units Purchased
Suppositories (number)	93,290
PLO Gel	19,535gms and 10,954 mls
Creams (grams)	60
Solutions/suspension (mls)	9,044
Pastes (grams)	300
Capsules	2,236

40. Subsequently, Respondents comingled these non-patient specific compounded drugs into their pharmacy stock and then dispensed those drugs to patients.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Records)

41. Respondents are subject to disciplinary action under Code sections 4301(o), for violating Code sections 4105(a) and 4333(a) and California Code of Regulations, title 16, sections 1707(e) and (f) for failing to maintain records of acquisition of dangerous drugs and controlled substances onsite at the address listed on its pharmacy license, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Perform End Product Testing)

42. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7(c) in that they compounded six batches of stock fentanyl 1000mcg/ml-1000mls without documentation of end product testing for sterility and pyrogens and without a quarantine of products until the end product testing confirmed sterility and acceptable levels of pyrogens, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failure to Keep Proper Compounding Records)

43. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1735.3(a)(6), in that Respondents' compounding logs for three lots of stock fentanyl 1000mcg/ml and five lots of fentanyl 50 mcg/ml lacked the manufacturer and lot numbers, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Complete Process Validation)

44. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7(a), in that Respondents compounded nine lots of sterile to sterile fentanyl 50mcg/ml aliquots where no periodic sampling was performed in order to determine if the product met required specifications and dispensed those nine lots to patients without verifying the test results, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Aiding and Abetting Compounding of Drugs Prior to Receipt of Valid Prescriptions for Individual Patients)

45. Respondents are subject to disciplinary action under Code section 4301(o), for aiding and abetting the violation of California Code of Regulations, title 16, section 1735.2(a), in that Respondents ordered and purchased drugs which were compounded by UCP and VDC prior to receipt by UCP and VDC of valid prescriptions either orally or in writing, for individual patients where the prescribers had approved use of a compounded drug product, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

DISCIPLINARY CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. On or about June 5, 2012, the Board issued Citation number CI 2011 52741 against Rosene Dobnick Pirrello for violating California Code of Regulations, title 16, section 1714(d), for failing to provide security against theft or diversion of dangerous drugs, and ordered Respondent Pirrello to pay a fine in the amount of $1,000.00. Respondent Pirrello complied with the citation.

b. On or about June 5, 2012, the Board issued Citation number CI 2011 52740 against San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy, for violating California Code of Regulations, title 16, section 1714(b), for failing to account for 4,950 tablets of hydrocodone/apap 5/500 mg, and ordered payment of a fine in the amount of $1,500.00. Respondent San Diego Hospice Corp. complied with the citation.

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 Pharmacist License Number 36880, issued to Rosene Dobnick Pirrello, RPH;

2. Revoking or suspending Retail Pharmacy Permit Number PHY 37157 (formerly HSP 37157), issued to San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy;

3. Revoking or suspending Sterile Compounding License Number LSC 99299, issued to San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy;

4. Ordering Respondents 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;

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

DATED: 2/6/14

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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