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

In the Matter of the Second Amended Accusation Against: **SAN YSIDRO PHARMACY, INC., dba SAN YSIDRO PHARMACY,** RAYMOND STEVE HOYT, President 1498 E. Valley Road Santa Barbara, CA 93108 Permit License No. PHY 46711 AND **RAYMOND STEVE HOYT** Pharmacist-in Charge 1463 Hosmer Lane Santa Barbara, CA 93108 Pharmacist License No. RPH 39935 Respondents.	Case No. 5737 OAH No. 2019040462 **SECOND AMENDED** **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about June 30, 2004, the Board of Pharmacy issued Permit License Number PHY 46711 to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt, President (Respondent Pharmacy). The Permit License was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.

3. On or about March 18, 1986, the Board of Pharmacy issued Pharmacist License Number RPH 39935 to Raymond Steve Hoyt (Respondent Hoyt). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2021, unless renewed.

JURISDICTION

4. The original Accusation in this matter was filed on September 12, 2017, and duly served on Respondents, each of whom filed a timely Notice of Defense. A First Amended Accusation was filed on February 20, 2019, and duly served on Respondents. This Second Amended 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.

5. Section **118,** subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the Uniform Controlled Substances Act (Health and Safety Code section 11000 et seq.).

7. Section **4052**, subdivision (b) of the Code states:

"(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration."

8. Section **4059**, subdivision (a) of the Code states:

"(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

9. Section **4126.5** of the code provides in pertinent part:

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

10. Section **4169** of the Code provides:

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

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

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

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

(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.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

11. Section **4210** of the Code provides:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

12. Section **4300** of the Code provides in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

13. 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."

14. 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:

. . .

"(c) Gross negligence.

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

. . .

"(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.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

"(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.

. . .

15. Section **4306.5** of the Code provides in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

16. Section **4307** of the Code states at sub-division (a) that:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, 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, director, associate, or partner had knowledge 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, or partner of a licensee as follows:

(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.

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

17. Section **4113** of the Code provides at sub-division (c):

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with the state and federal laws and regulations pertaining to the practice of pharmacy.

18. Section **4075** of the Code states in pertinent part:

No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity.

19. Health and Safety Code section **11153** states:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

20. Health and Safety Code section **111335** provides:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

21. Health and Safety Code section **111375** provides:

"Any drug or device is misbranded unless its labeling bears all of the following information:

(a) Adequate directions for use.

(b) Such adequate warnings against use of pathological conditions or by children where its use may be dangerous to health.

(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempt under Section 502(f) of the federal act (21 U.S.C. Sec 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

22. Health and Safety Code section **111400** provides:

Any drug or devise is misbranded if it is dangerous to health if used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

23. Health and Safety Code section 11150 states:

No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business

and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

24. Health and Safety Code section **11157** states:

No person shall issue a prescription that is false or fictitious in any respect.

25. Health and Safety Code section **111659**, subdivision (d) provides that the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice: "(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and the date of birth of the ultimate user. (2) the prescriber's category or licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government exempt facility. (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number. (4) National Drug Code (NDC) number of the controlled substance dispensed. (5) Quantity of the controlled substance dispensed. (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available. (7) Number of refills ordered. (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request. (9) Date of origin of the prescription. (10) Date of dispensing of the prescription."

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STATE REGULATIONS

26. California Code of Regulations, title 16, section **1715.5** provides in pertinent part:

"The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows: (a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility."

27. California Code of Regulations, title 16, section **1761** states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

28. California Code of Regulations, title 16 section **1735.2** states:

(a) Except as specified in (b) and (c), no drug preparation 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 preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists)

or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored,

transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding.

The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

29. California Code of Regulations, title 16 section **1735.2** states:

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

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

FEDERAL REGULATIONS

30. Code of Federal Regulations, title 21, section **1306.04** provides in pertinent part that a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacists who fills the prescription.

COST RECOVERY

31. Section **125.3** of the Code states, 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.

32. **DRUG CLASSIFICATIONS**

Brand Names	Generic Name	Dangerous Drug [Bus. & Prof. Code § 4022]	Scheduled Drug [Health & Safety Code (HSC)]	Indications For Use
Zithromax	Azithromycin	Yes	No	Antibiotic
Many	Betamethasone	Yes	No	Decrease swelling, Corticosteroid
Many	Clotrimazole	Yes	No	Antifungal
Many	Cyanocobalamin (B12)	Yes	No	Vitamin
None	DHEA (Dehydroepiandrosterone)	Yes	No	Vitamin/herb
Silenor	Doxepin	Yes	No	Antidepressant, sleep
Many	Estrogen, Estriol, Estradiol	Yes	No	Hormone replacement
	Fentanyl	Yes	Schedule II HSC § 11055 (c)(8)	Pain Control
Diflucan	Fluconazole	Yes	No	Antifungal
Many	Fludrocortisone	Yes	No	Antifungal

Many	Hydrocortisone	Yes	No	Decrease swelling, Corticosteroid
Dilaudid	Hydromorphone	Yes	Schedule II HSC § 11055 (b)(l)(J)	Pain Control
	Methadone	Yes	Yes 11055(c)(14)	Treatment of addiction and treatment of moderate to severe pain
Many	Naltrexone	Yes	No	To prevent the replace of opiod dependence
	Oxycodone	Yes	Yes 11055(b)(1)(M)	Moderate to severe pain
Pitocin	Oxytocin	Yes	No	Hormone
Many	Progesterone	Yes	No	Hormone replacement
Cialis	Tadalafil	Yes	No	Erectile dysfunction
Many	Testosterone	Yes	HSC 11056(f)(30)	Hormone replacement body building
Synthroid, Many	Thyrioid, Armour Thyroid, Nature-Thyroid, liothyronine, levothyroxine	Yes	No	Hormone replacement
Ultram	Tramadol	Yes	CFR 1308.14	Opiod Pain reliever

FACTUAL ALLEGATIONS

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

33. At all times relevant herein, Respondent Raymond Steve Hoyt was the President and 100% owner of corporate license holder, Respondent San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, as well as Pharmacist-in-Charge of San Ysidro Pharmacy – a retail pharmacy located in the city of Santa Barbara, CA.

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FACTS COMMON TO FIRST THROUGH SIXTH CAUSES FOR DISCIPLINE

34. **COMPOUNDING OF DOMPERIDONE PRODUCTS**

A. On or about June 7, 2004, the United States Food and Drug Administration (FDA) published its "FDA Talk Paper" identifying safety risks associated with use of the unapproved drug domperidone, which stated:

"In response to reports that women may be using an unapproved drug, domperidone, to increase milk production (lactation), the Food and Drug Administration (FDA) is warning breastfeeding women not to use this product because of safety concerns…

The Agency also is issuing an Import Alert which alerts FDA filed personnel to be on the lookout for attempts to import this drug so that it can be detained and refused admission into the U.S. if appropriate.

FDA took these actions because it has become aware that some women who breastfeed and/or pump breast milk are purchasing this drug, domperidone, from compounding pharmacies and from sources in foreign countries to increase breast milk production. Domperidone may increase the secretion of prolactin, a hormone that is needed for lactation.

Although domperidone is approved in several countries outside of the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is not approved in the U.S. for any indication.

The agency is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death of patients receiving an intravenous form of domperidone that has been withdrawn from marketing in a number of countries…

Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production…

[A]ll drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law."

B. At all times relevant herein, due to FDA restrictions, domperidone could not be legally compounded by pharmacies in the United States (with approved exceptions). 1

C. On or about April 1, 2015, the Board published a "subscriber alert" to all licensees, warning that domperidone was "not FDA approved for any use in humans in the United States," and summarizing the information in the 2004 FDA Talk Paper.

D. Following a Board investigative inquiry to Respondents for all compounding records, mater formulas and dispensing records for any products made with domperidone at Respondent Pharmacy between April 15, 2015 and August 25, 2015, Respondents admitted compounding the following products during the subject time period:

(1) Domperidone Products Compounded:

a. lot 04182015@4 for 300 capsules of domperidone 10 mg.

b. lot 04272015@12 for 200 capsules for domperidone 10 mg.

c. lot 06162015@12 for 100 capsules for domperidone 10 mg.

d. lot 07302015@12 for 200 capsules for domperidone 10 mg.

(2) Domperidone Dispensing Records:

4 prescriptions and 840 capsules were dispensed.

35. **PRESCRIPTIONS ISSUED TO PATIENTS AM and SM**

A. On or about January 25, 2014, a $12,500 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient AM, alleging improper management and dispensing of controlled substances resulting in AM's addiction and death on April 28, 2011. Payment was made without admission of allegations or liability.

B. On or about April 23, 2014, a $25,000 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient SM, alleging improper management and dispensing of controlled substances resulting in SM's

[1] FDA has a procedure for exception to this policy by an investigational new drug (IND) application filing. As of March 2015, only one such application to compound domperidone had been approved.

addiction and death on September 20, 2009. Payment was made without admission of allegation or liability.

C. Having received notice of both settlements, the Board sought to investigate allegations of misconduct related to AM and SM, and obtained a statement and related documents from Respondents.

Analysis of Prescription Records

D. As a part of the investigation, Board inspectors obtained and analyzed CURES2 data for Patients AM and SM.

E. All of the prescriptions filled by Respondents for Patients AM and SM were written by Dr. Julio Gabriel Diaz also known as Otero Julio Gabriel Diaz, MD (Dr. Diaz). a General Practice physician with secondary practice areas in Geriatrics and Pathology, who operated a practice in the city of Santa Barbara, CA.

F. On or about January 18, 2012, pursuant to a criminal complaint filed in United States District Court, Dr. Diaz was charged with illegal distribution of controlled substances. The affidavit in support of the criminal complaint stated that Dr. Dias wrote prescriptions for powerful painkillers, for "patients" who were drug addicts with no legitimate need for the drugs. Some of Dr. Diaz's "patients" diverted the pills they received to the black market and/or suffered fatal overdoses from the narcotics.3

G. Effective November 2, 2012, the California Medical Board revoked Dr. Diaz's medical license in the case entitled In the Matter of the Accusation Against Ortero Julio Gabriel Diaz, M.D., case no. 06-2010-209660. Dr. Diaz's license was revoked for committing gross negligent and impotence and for excessive prescribing narcotic medications to a patient.

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[2] CURES is an acronym for "California Utilization Review and Evaluation System." It contains over 100 million entries of controlled substance drugs that were dispensed in California. Pharmacists and prescribers can register with the Department of Justice to obtain access to the CURES data through the California Prescription Drug Monitoring Program (PDMP). Patient Activity Reports (PARs) are provided and reflect all controlled substances dispensed to an individual. CURES herein refers to CURES in general and PARs. Pharmacies are required to report to the California Department of Justice every schedule II, II and IV drug prescription under Health and Safety Code section 1165, subdivision (d).

[3] On August 28, 2015, following a jury trial, Dr. Diaz was found guilty in a federal district court of more than 25 counts of felony drug trafficking offenses, in *United States of America v. Julio Gabriel Diaz* (U.S.D.C. (CA Central), criminal case no. 8:11MJ00636

H. ANALYSIS OF PRESCRIPTION RECORDS - PATIENT AM

(1) AM (DOB 8/1984) initially came to Respondent Pharmacy on April 28, 2011, with prescriptions for chronic back pain. Over a period of six and a half months, he was dispensed prescriptions for methadone, hydromorphone and oxycodone. On the morning of November 25, 2011, he was found unresponsive and not breathing in his bedroom, and later pronounced dead. The coroner's investigation found nine syringes, several injection sites, a silver colored spoon, a cotton ball with heroin and burn marks on his thumb and fingers. His last methadone prescription dispensed by San Ysidro Pharmacy was filled on September 16, 2011.

(2) Review of CURES Data - A review of CURES data for AM revealed that he filled a total of 175 controlled substance prescriptions between May 5, 2008 and November 15, 2011. In January 2009, the first prescriptions prescribed by Dr. Diaz for AM (for hydromorphone 8 mg and oxycodone 40 mg) were dispensed to AM. Dr. Diaz was the prescriber for 36 of the 38 controlled substance prescriptions in 2009, and 80 of the 81 controlled substance prescriptions in 2010. In 2011 AM was dispensed 43 controlled substance prescriptions. CURES data showed San Ysidro dispensed 9 out of the 43 prescriptions. However, AM's profile provided by Respondents showed additional dispensed prescriptions for AM not reported to CURES.4

[4] Board investigation disclosed that Respondent Pharmacy failed to report to CURES, 13 controlled substance prescriptions dispensed to AM between April 28, 2011 and August 18, 2011, in the following instances:

Date Filled	RX#	Drug Name	Strength	Quantity
04/28/2011	598197	oxycodone	30 mg	150
05/26/2011	600038	oxycodone	30 mg	120
05/26/2011	600039	hydromorphone	8 mg	120
05/26/2011	600042	methadone	10 mg	180
06/23/2011	601761	hydromorphone	8 mg	120
06/23/2011	601762	oxycodone	30 mg	120
06/23/2011	601764	methadone	10 mg	180
07/21/2011	603247	methadone	10 mg	180

(3) CURES data revealed 37 of the 43 prescriptions were paid in cash and not billed to a third party payer. Of the 9 out of the 43 prescriptions dispensed by Respondents – 5 of the 9 were for Schedule II controlled substances and paid for in cash.

(4) In 2011, AM was dispensed 56 controlled substances including those not reported to CURES. Dr. Diaz prescribed 55 of the 56 prescriptions. San Ysidro dispensed 22 of the 56 prescriptions. All 22 prescriptions were written by Dr. Diaz.

(5) The chart below is a summary of all prescriptions dispensed to AM by San Ysidro Pharmacy:

Date filled	RX#	Drug Name	Strength	Qty	EDS	Sig
04/28/2011	598195	methadone	10 mg	120	30	2 tablets every 12 hours
04/28/2011	598196	hydromorphone	8 mg	160	30	1-2 tablets every 2-4 hours
04/28/2011	598167	oxycodone	30 mg	150	7	2 tablets every 2-6 hours
05/26/2011	600038	oxycodone	30 mg	120	15	2 tablets every 6 hours
05/26/2011	600039	hydromorphone	8 mg	120	30	2 tablets every 6 hours
05/26/2011	600042	methadone	10 mg	180	30	3 tablets every 12 hours

07/21/2011	603248	oxycodone	30 mg	120
07/21/2011	603259	hydromorphone	8 mg	120
08/18/2011	604785	methadone	10 mg	160
08/18/2011	604787	hydromorphone	8 mg	120
08/18/2011	604788	oxycodone	30 mg	120
08/18/2011	604787	Hydromorphone	8 mg	120

06/23/2011	601761	hydromorphone	8 mg	120	30	2 tablets every 6 hours
06/23/2011	601762	oxycodone	30 mg	120	15	2 tablets every 6 hours
06/23/2011	601764	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603247	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603248	oxycodone	30 mg	120	15	2 tablets every 6 hours
07/21/2011	603259	hydromorphone	8 mg	120	30	1 tablet every 6 hours
08/18/2011	604785	methadone	10 mg	160	30	2-3 tablets every 12 hours
08/18/2011	604787	hydromorphone	8 mg	120	10	1-2 tablets every 4-6 hours
08/18/2011	604788	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
09/16/2011	606550	methadone	10 mg	160	26	3 tablets every 12 hours
09/16/2011	606551	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
09/16/2011	606552	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
10/14/2011	608213	oxycodone	30 mg	120	15	2 tablets every 6 hours
10/14/2011	608214	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
11/11/2011	609846	hydromorphone	8 mg	120	15	2 tablets every 6 hours
11/11/2011	609848	oxycodone	30 mg	97	12	2 tablets every 6 hours

(6) Hydromorphone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2300 tablets of hydromorphone 8 mg prescribed by Dr. Diaz. AM received methadone, oxycodone, and hydromorphone on every filled prescription written by Dr. Diaz except two (October 14, 2011 and November 11, 2011, for which methadone was not dispensed). A total of 17 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 1000 of the 2300 tablets as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
01/05/2011	324789	180	L M Caldwell Pharmacist	15	
01/07/2011	778577	180	L M Caldwell Pharmacist	30	13
04/28/2011	**598196**	**160**	**San Ysidro Pharmacy Inc**	**30**	
05/26/2011	**600039**	**120**	**San Ysidro Pharmacy Inc.**	**30**	
06/23/2011	**601761**	**120**	**San Ysidro Pharmacy Inc**	**30**	
06/27/2011	1175071	120	The Medicine Shoppe	15	26
07/21/2011	**603259**	**120**	**San Ysidro Pharmacy Inc**	**30**	
07/25/2011	1176649	120	The Medicine Shoppe	30	26
08/18/2011	**604787**	**120**	**San Ysidro Pharmacy Inc**	**10**	
08/22/2011	1178450	160	The Medicine Shoppe	14	6
09/16/2011	**606551**	**120**	**San Ysidro Pharmacy Inc**	**10**	
09/19/2011	1180096	150	The Medicine Shoppe	13	7

10/14/2011	**608214**	**120**	**San Ysidro Pharmacy Inc**	**10**	
10/17/2011	791700	150	L M Caldwell Pharmacist	12	7
11/11/2011	**609846**	**120**	**San Ysidro Pharmacy Inc**	**15**	
11/14/2011	793104	150	L M Caldwell Pharmacist	19	12
11/15/2011	793216	90	L M Caldwell Pharmacist	30	18
GRAND TOTAL		**2300**			

(7) Oxycodone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2267 tablets of oxycodone 30 mg prescribed by Dr. Diaz. A total of 17 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 967 of the 2267 tablets. as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Actual Days Supply	Days Early
01/05/2011	324788	180	L M Caldwell Pharmacist	15		
01/07/2011	778578	180	L M Caldwell Pharmacist	30		12
04/28/2011	**598197**	**150**	**San Ysidro Pharmacy Inc**	**30**	**7**	
05/26/2011	**600038**	**120**	**San Ysidro Pharmacy Inc.**	**30**	**15**	
06/23/2011	**601762**	**120**	**San Ysidro Pharmacy Inc**	**30**		
06/27/2011	1175072	120	The Medicine Shoppe	15		11
07/21/2011	**603248**	**120**	**San Ysidro Pharmacy Inc**	**30**		

07/25/2011	1176648	120	The Medicine Shoppe	30		11
08/18/2011	**604788**	**120**	**San Ysidro Pharmacy Inc**	**10**		**6**
08/22/2011	1178449	160	The Medicine Shoppe	14		6
09/16/2011	**606552**	**120**	**San Ysidro Pharmacy Inc**	**10**		
09/19/2011	1180095	150	The Medicine Shoppe	13		7
10/14/2011	**608213**	**120**	**San Ysidro Pharmacy Inc**	**10**		
10/17/2011	791701	150	L M Caldwell Pharmacist	12		12
11/11/2011	**609848**	**97**	**San Ysidro Pharmacy Inc**	**15**		
11/14/2011	793105	150	L M Caldwell Pharmacist	19		9
11/15/2011	793218	90	L M Caldwell Pharmacist	30		18
GRAND TOTAL		**2267**				

(8) Methadone dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 1320 tablets of methadone 10 mg prescribed by Dr. Diaz. A total of 8 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 6 of the 8 prescriptions and 980 of the 1320 tablets, as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
04/28/2011	**598195**	**120**	**San Ysidro Pharmacy Inc**	**30**	

05/26/2011	**600042**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
06/23/2011	**601764**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
07/21/2011	**603247**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
08/18/2011	**604785**	**160**	**San Ysidro Pharmacy Inc**	**25**	**2**
09/16/2011	**606550**	**160**	**San Ysidro Pharmacy Inc**	**26**	
10/24/2011	792078	160	L M Caldwell Pharmacist	30	
11/14/2011	793126	180	L M Caldwell Pharmacist	30	9
GRAND TOTAL		**1320**			

(9) AM - Corresponding Responsibility Analysis

(a) Respondents failed to meet their corresponding responsibility to assure legitimacy of prescriptions dispensed to AM, in that they ignored and/or failed to appropriately respond to numerous warning signs or red flags:

(i) AM was young – 27-years old

(ii) AM received duplicate therapy from multiple pharmacies for narcotics intended for severe pain - methadone, oxycodone, and hydromorphone

(iii) AM received repetitive combinations of narcotics

(iv) AM's diagnosis was chronic back pain – nonspecific diagnosis

(v) AM's primary method of payment was cash

(b) Respondents additionally failed to access the CURES reporting system, which would have shown that AM was using multiple pharmacies and insufficiently questioned prescriptions from Dr. Diaz.

I. ANALYSIS OF PRESCRIPTION RECORDS - PATIENT SM

(1) Patient SM filled prescriptions at San Ysidro Pharmacy on five occasions from March 30 through June 11, 2009 prior to his death on September 20,2009.

(2) SM was a laborer, with a history of on the job accidents who had been diagnosed with chronic cervical spine and lower back pain. On March 30, 2009, Respondents dispensed prescriptions for hydromorphone 8 mg (11-day supply) and corisoprodol 350 mg (30-day supply) to SM. Thereafter he only filled prescriptions for fentanyl troches (a compound medication) on four occasions:

(a) Prescription N552798(April 3, 2009) - 6-day supply
(b) Prescription N553545(April 16, 2009) - 15-day supply
(c) Prescription N555220 (May 15, 2009) - 5-day supply
(d) Prescription N556921(June 11, 2009) - 30-day supply

(3) Fentanyl 1600 mcg troche was a medication compounded for SM by San Ysidro Pharmacy. A troche is a lozenge that is dissolved in the mouth, typically for severe breakthrough pain in patients already taking a narcotic analgesic. The starting dose is 200 mcg for each pain episode. This may be repeated after waiting 15 minutes between doses, maximum of 4 units per day.

(a) Prescription number N555220 was issued with directions of one troche every 4-6 hours as needed for pain. This was a significant increase in dosage compared to two prior prescriptions (one troche every 12-24 hours) dispensed to SM. No documentation indicated the original prescriptions document was clarified with the physician.

(4) On July 1, 2009, SM initiated detox treatment, and was discharged on July 9, 2009 to a rehabilitation program. His prescription history shows he filled multiple prescriptions at other pharmacies on the day he was transferred to the rehabilitation program and in the days prior to his death.

FACTS COMMON TO

SEVENTH THROUGH EIGHTEENTH CAUSES FOR DISCIPLINE

36. **ILLEGAL ISSUANCE OF PRESCRIPTIONS**

In or about July 2017, JA visited Respondent Pharmacy to discuss compounding of her prescribed medication (doxepin), as she hoped to taper down her dosage. Following discussion with Respondent Hoyt, JA was persuaded to change her hormone replacement therapy instead. Hoyt prescribed compounded preparations with bioidentical hormones estradiol and

progesterone, then dispensed the prescription in two containers, labeled Rx 736829 and Rx 736830, and showing the prescriber as "Steve Hoyt-EEK-RPH". JA used the preparations one time at home, then discarded them after discussing Respondent Hoyt's advice with her physician. In Fall 2017, JA's physician filed a complaint with the Board regarding Respondent's conduct.

37. The Board's subsequent investigation of the complaint resulted in the following findings related to other 'bio-identical hormone replacement therapy' (BHRT) prescriptions issued and filled by Respondents:

A. Between approximately January 1, 2017 and January 10, 2018, Respondent Hoyt issued 1,403 prescriptions, which were then dispensed by Respondent Pharmacy, under the ostensible authority of a collaborative practice agreement, for treatment of patients with bio-identical hormone replacement (BHRT), with "supervising physician" Dr. Bjorn Eek, an orthopedic surgeon residing in the city of Long Beach, pursuant to Business and Profession Code section 4052.2. The collaborative practice agreement relied on by Respondents was signed by Dr. Eek and Respondent Hoyt on or about June 12, 2014.

B. On the face of the statute, a section 4052.25 collaborative practice arrangement is only available to a pharmacist practicing at a health care facility, home health agency or *clinic*

[5] Business and Professions Code section 4052.2 provides as follows:
(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

– not a retail pharmacy. Moreover, Board investigators determined that between approximately January 1, 2017 and January 10, 2018, Respondents had no policies or protocols in place to comply with section 4052.2 requirements.

C. In his declaration signed on or about March 7, 2018, Dr. Eek stated that he did not see, examine, or review charts for any of the patients issued the subject 1,403 prescriptions by Respondent Hoyt, and stated that he did not authorize the subject prescriptions – and had never prescribed medications for the patients identified in the subject prescriptions.

38. The Board's investigation included review of pharmacy records related to compounded medications, resulting in the following findings:

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

A. Between approximately January 1, 2017 and January 10, 2018, Respondent Hoyt issued orders for 263 controlled substances, although he did not have a valid Drug Enforcement Administration (DEA) registration:

Controlled drug	Number of prescriptions	Amount sold (grams)
TESTOSTERONE 10MG/ML *** CREAM	4	120g
TESTOSTERONE 150MG/ML ** CREAM	19	675g
TESTOSTERONE 160MG/ML ** CREAM	27	870g
TESTOSTERONE *ATREVIS* 150MG/ML GEL	1	30g
TESTOSTERONE *ATREVIS* 160MG/ML GEL	5	150g
TESTOSTERONE *LB* 150MG/ML GEL	1	60g
TESTOSTERONE 2MG/ML** CREAM	9	270g
TESTOSTERONE (GLYCERIN) 4MG/ML** CREAM	12	360g
TESTOSTERONE *ATREVIS* 100MG/ML GEL	7	210g
TESTOSTERONE *ATREVIS* 200MG/ML** GEL	3	105g
TESTOSTERONE 100MG/ML** CREAM	11	330g
TESTOSTERONE 125MG/ML CREAM	10	300g
TESTOSTERONE 1MG/0.1ML CREAM	2	18g
TESTOSTERONE 4MG/ML CREAM	2	120g
TESTOSTERONE 4MG/ML** CREAM	111	3480g
TESTOSTERONE 5MG/ML CREAM	5	105g
TESTOSTERONE HRT 150MG/ML CREAM	8	255g
TESTOSTERONE HRT 200MG/ML** CREAM	14	585g
TESTOSTERONE HRT 2MG/ML CREAM	4	120g
TESTOSTERONE HRT 4MG/ML CREAM	4	120g
TESTOSTERONE 100MG+CHYRSIN-100MG/ML CREAM	3	100g
TRAMADOL HCL 50 MG TAB	1	**80 tablets**
Grand Total	**263**	**8383g and 80 tablets**

FACTS COMMON TO

NINETEENTH THROUGH TWENTY SEVENTH CAUSES FOR DISCIPLINE

39. ILLEGAL ISSUANCE OF PRESCRIPTIONS

On or about March 14, 2016, the Board received a complaint alleging Respondent Hoyt was prescribing a compound drug product, hydrocortisone 10 mg table, without the patient ever having seen a physician. Respondent Hoyt was prescribing and compounding hydrocortisone 10 mg for adrenal fatigue and purporting to be operating under a collaborated agreement.

40. The Board's subsequent investigation of the complaint resulted in the following findings related to other 'bio-identical hormone replacement therapy' (BHRT) prescriptions issued and filled by Respondents:

A. Between approximately July 21, 2015 and September 30, 2016, Respondent Hoyt issued 1,520 prescriptions, which were then dispensed by Respondent Pharmacy, under the ostensible authority of a collaborative practice agreement, for treatment of patients with bio-identical hormone replacement, with "supervising physician" Dr. Bjorn Eek, an orthopedic surgeon residing in the city of Long Beach, pursuant to Business and Profession Code section 4052.2. The collaborative practice agreement relied on by Respondents was signed by Dr. Eek and Respondent Hoyt on or about June 12, 2014.

B. A section 4052.6 collaborative practice arrangement is available to a pharmacist practicing at a health care facility, home health agency or clinic…or a physician, in accordance

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[6] Business and Professions Code section 4052.2 provides as follows:

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

with the policies and procedures or protocols of that....physician, and in accordance with subdivision (c)…. Board investigators determined that between approximately January 1, 2017 and January 10, 2018, Respondents had no policies or protocols in place to comply with section 4052.2 requirements.

C. In a responsive letter to the Board, Dr. Eek stated that Respondent Hoyt never involved him or discussed with him what he was doing.

41. The Board's investigation included review of pharmacy records related to compounded medications, resulting in the following findings:

A. Between approximately July 21, 2015 and September 30, 2016, Respondent Hoyt issued orders for 116 Schedule III controlled substances, although he did not have a valid Drug Enforcement Administration (DEA) registration, a requirement for prescribing controlled substance prescriptions:

Drug	Number of Prescriptions
KETA-10%GABA-10%AMIT-2%CLONIDINE-0.2% CREAM	3

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

KETAMINE 100MG/ML CREAM	2
TEST 150MG+CHRYSIN 100MG/ML CREAM	3
TESTOSTERONE 150MG/ML GEL	1
TESTOSTERONE 150MG/ML**CREAM	17
TESTOSTERONE 160MG/ML**CREAM	4
TESTOSTERONE (GLYCERIN) 4MG/ML**CREAM	4
TESTOSTERONE 100MG TROCHE	1
TESTOSTERONE 100MG/ML**CREAM	16
TESTOSTERONE 125MG/ML CREAM	3
TESTOSTERONE 1MG/0.1ML**CREAM	1
TESTOSTERONE 25MG TROCHE	3
TESTOSTERONE 4MG/ML GEL	1
TESTOSTERONE 4MG/ML**CREAM	53
TESTOSTERONE 5MG/ML CREAM	1
TESTOSTERONE CYPIONATE 200 MG/ML INJ	1
TESTOSTERONE HRT 200MG/ML**CREAM	2

CAUSES FOR DISCIPLINE

FIRST CAUSE FOR DISCIPLINE

Unlawful Manufacture and Sale of Misbranded Drugs – Domperidone

39. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, sub-divisions (j) and (o), in conjunction section 4169, sub–division (a)(3) and Health and Safety Code sections 111335 and 111400 due to their compounding of at least 4 batches of the unapproved drug domperidone, and their dispensing to two patients approximately 840 10 mg capsules of the unapproved drug domperidone between April 15 and August 25, 2015. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

SECOND CAUSE FOR DISCIPLINE

Unprofessional Conduct: Sale of Misbranded Drugs - Domperidome

40. Respondents are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with

section 4169, subdivision (a)(3) and Health and Safety Code sections 111335 and 111375, subdivision (c) due to their dispensing to two patients approximately 840 10 mg capsules of the unapproved drug domperidone (compounded by Respondents) between April 15 and August 25, 2015, without adequate warning or notification to consumers that such products were FDA unapproved and potentially dangerous. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

THIRD CAUSE FOR DISCIPLINE

Failure to Implement Electronic Monitoring of Schedule II Prescriptions

41. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations, section 1715.5 (a) (which mandates specific information be reported for each Schedule II prescription dispensed) in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 Schedule II controlled substance prescriptions dispensed to **Patient AM.** The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

FOURTH CAUSE FOR DISCIPLINE

Failure to Timely Comply with Department of Justice Reporting Requirements

42. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Health and Safety code section 11165(d) (requiring the dispensing pharmacy to report specific information about certain controlled substance transactions within seven days), in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 controlled substance prescriptions dispensed to **Patient AM**. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

FIFTH CAUSE FOR DISCIPLINE

Failure to Assume Corresponding Responsibility

43. Respondents are subject to discipline pursuant to Code section 4300 for unprofessional conduct as defined in section 4301, subdivision (d), (j) and (o), in conjunction

with Health and Safety Code section 11153(a) in that on dates approximately between April 28, 2011 and November 11, 2011, based on evidence reviewed by Board Inspectors, Respondents failed to meet their corresponding responsibility to assure legitimacy prescriptions, in that Respondents ignored and/or failed to appropriately respond to numerous warning signs or red flags that should put a reasonable and prudent dispensing pharmacist on notice that prescriptions for **Patient AM** may not have been legitimate, including but not limited to the patients age in relation to the combination of medications prescribed, the appropriateness of the therapy, the duplicate medications the patient received, the repetitive combination of medications, and the payment method of cash. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

Erroneous or Uncertain Prescriptions

44. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on May 15, 2009, Respondent dispensed prescription C555220, written by Dr. Diaz for **Patient SM** for fentanyl troche, without contacting the prescriber for clarification, despite instructions for dosage which exceeded the recommended maximum dose for this medication. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

SEVENTH CAUSE FOR DISCIPLINE

Unauthorized Practice as Advanced Practice Pharmacist

45. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4210, in that on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent practiced as an advanced practice pharmacist without obtaining certification as required under Business and Professions Code section 4210. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

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EIGHTH CAUSE FOR DISCIPLINE

Erroneous or Uncertain Prescriptions

46. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on at least 1,403 instances on dates between January 1, 2017 and January 10, 2018, Respondent compounded and/or dispensed prescriptions which contained significant errors, omissions, irregularities, uncertainties or ambiguities. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

NINTH CAUSE FOR DISCIPLINE

Furnishing Dangerous Drugs without a Valid Prescription

47. Respondents are subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4059, subdivision (a), in that on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent furnished dangerous drugs without a valid, properly authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

TENTH CAUSE FOR DISCIPLINE

Issuance of False or Fictitious Prescriptions

48. Respondents are subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 11157 in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent issued false or fictitious prescriptions. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

ELEVENTH CAUSE FOR DISCIPLINE

Failure to Obtain Requisite DEA Registration

49. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4052(b), due to his

issuance of an order for at least 263 controlled substances on dates between approximately January 1, 2017 through January 10, 2018, without a valid Drug Enforcement Administration (DEA) registration. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

TWELFTH CAUSE FOR DISCIPLINE

Failure to Maintain Required Compounding Records

50. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations (CCR), title 16, section 1735.3(a)(2), in that in each instance listed below, Respondents failed to comply with specific statutory requirements for a compounding log, which must be maintained for each drug preparation compounded in the pharmacy:

A. 16 CCR 1735.3(a)(2) (D) – the identity of the pharmacist reviewing the final drug preparation was not documented for: (1) HRT/water cream base lot 06272017@11, (2) Progesterone 160 mg/ml lot 06292017@8, (3) HRT/water cream base lot 07112017@7, and (4) Estradiol 4 mg/ml lot 07122017@8.

B. 16 CCR 1735.3(a)(2) (F) – the manufacturer, expiration dates and lot numbers of each component was not documented for: (1) Progesterone 160 mg/ml lot 06292017@8, (2) HRT/water cream base lot 07112017@7, and (3) Estradiol 4 mg/ml lot 07122017@8.

C. 16 CCR 1735.3(a)(2) (J) – quality reviews and required post-compounding processes and procedures were not documented for: (1) Progesterone 160 mg/ml lot 06292017@8, (2) HRT/water cream base lot 07112017@7, and (3) Estradiol 4 mg/ml lot 07122017@8.

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

THIRTEENTH CAUSE FOR DISCIPLINE

Failure to Support Extend Beyond Use Assignments

51. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1735.2 (i), in that, for each of compounded drug preparation listed below, Respondents assigned a 180 beyond use date was assigned without the support of method

suitability test, container closure integrity test, or stability studies, as required by section 1735.2(i):

A. HRT/water cream base lot 06272017@11,

B. Progesterone 160 mg/ml lot 06292017@8;

C. HRT/water cream base lot 07112017@7;

D. Estradiol 4 mg/ml lot 07122017@8

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

FOURTEENTH CAUSE FOR DISCIPLINE

Gross Negligence

52. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (c) in that on dates between January 1, 2017 and January 10, 2018, Respondent committed gross negligence in his practice as a pharmacist, due his acts and/or omissions which were an extreme departure from the standard of care, which under similar circumstances, would have been ordinarily exercised by a competent pharmacist, by reason of his dispensing at least 1,403 prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

FIFTEENTH CAUSE FOR DISCIPLINE

Acts Involving Dishonesty, Fraud, or Deceit

53. Respondent Hoyt is subject to disciplinary action under section 4301, subdivision (f), in that Respondent committed acts involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, or substantially injure another, by reason of his acts and/or omissions in dispensing at least 1,403 prescriptions while knowing that the prescriber had not examined, diagnosed nor prescribed dangerous drugs. Each of the 1,403 prescriptions were fraudulently obtained under dishonest and deceitful practices by Respondent Hoyt. The allegations of paragraphs 33,and 36-38 above are realleged as though fully set forth.

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SIXTEEN CAUSE FOR DISCIPLINE

Knowingly Making False Representations

54. Respondent Hoyt is subject to disciplinary action under section 4301, subdivision (g), in that on or about March 13, 2018, Respondent knowingly made false representations regarding the existence or nonexistence of a state of facts, in a written document submitted to the Board in March, 2018, Respondent made the following representations, which he knew were false and untrue:

1. Dr. Eek visited San Ysidro on 2/15/18.

2. Dr. Eek incorporated extensively anti-aging science of identical hormone replacement therapy into his practice, as it provided significant improvement in patient outcomes.

3. He provided help and support for Dr. Eek's patients through discussion and recommendations that formed the basis for the therapeutic regimen dispensed by San Ysidro Pharmacy.

4. Dr. Eek and I discussed the guideline for BHRT diagnosis based on laboratory results and patient-reported symptoms during patient interviews.

5. Respondent Hoyt documented at least 1,403 times on a written prescription that Dr. Eek had authorized a prescription for dangerous drugs.

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

SEVENTEENTH CAUSE FOR DISCIPLINE

Inappropriate Exercise of Education

55. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent dispensed at least 1,403 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

EIGHTEENTH CAUSE FOR DISCIPLINE

Failure to Exercise Professional Judgement

56. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent dispensed at least 1,403 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

NINETEENTH CAUSE FOR DISCIPLINE

Unauthorized Practice as Advanced Practice Pharmacist

57. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4210, in that on at least 1,520 instances on dates approximately between July 2015 and September 2016, Respondent practiced as an advanced practice pharmacist without obtaining certification as required under Business and Professions Code section 4210. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTIETH CAUSE FOR DISCIPLINE

Erroneous or Uncertain Prescriptions

58. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on at least 1,520 instances on dates between July 2015 and September 2016, Respondents compounded and/or dispensed prescriptions which contained significant errors, omissions, irregularities, uncertainties or ambiguities. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY FIRST CAUSE FOR DISCIPLINE

Furnishing Dangerous Drugs without a Valid Prescription

59. Respondents are subject to disciplinary action under section 4300 for unprofessional

as defined in section 4301, subdivision (j) and (o), for violating section 4059, subdivision (a), in that on at least 1,520 instances on dates approximately between July 2015 and September 2016, Respondents furnished dangerous drugs without a valid, properly authorized prescription. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY SECOND CAUSE FOR DISCIPLINE

Issuance of False or Fictitious Prescriptions

60. Respondents are subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 11157 in that, that in on at least 1,520 instances on dates approximately between July 2015 and September 2016, Respondents issued false or fictitious prescriptions. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY THIRD CAUSE FOR DISCIPLINE

Failure to Obtain Requisite DEA Registration

61. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4052(b), due to his issuance of an order for at least 116 controlled substances on dates between approximately July 2015 and September 2016, without a valid Drug Enforcement Administration (DEA) registration. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY FOURTH CAUSE FOR DISCIPLINE

Gross Negligence

62. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (c) in that on dates between July 2015 and September 2016, Respondent committed gross negligence in his practice as a pharmacist, due his acts and/or omissions which were an extreme departure from the standard of care, which under similar circumstances, would have been ordinarily exercised by a competent pharmacist, by reason of his dispensing at least 1,520 prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY FIFTH CAUSE FOR DISCIPLINE

Acts Involving Dishonesty, Fraud, or Deceit

63. Respondent Hoyt is subject to disciplinary action under section 4301, subdivision (f), in that Respondent committed acts involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, or substantially injure another, by reason of his acts and/or omissions in dispensing at least 1,520 prescriptions while knowing that the prescriber had not examined, diagnosed nor prescribed dangerous drugs. Each of the 1,520 prescriptions were fraudulently obtained under dishonest and deceitful practices by Respondent Hoyt. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY SIXTH CAUSE FOR DISCIPLINE

Inappropriate Exercise of Education

64. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,520 instances on dates approximately between July 2015 and September 2016, Respondent dispensed at least 1,520 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

TWENTY SEVENTH CAUSE FOR DISCIPLINE

Failure to Exercise Professional Judgement

65. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,520 instances on dates approximately between July 2015 and September 2016, Respondent dispensed at least 1,520 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 39-41 above are realleged as though fully set forth.

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DISCIPLINARY CONSIDERATIONS

66. To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

A. **Prior Citation** (Respondent San Ysidro Pharmacy, Inc.) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 2012 56574** was issued to Respondent Pharmacy for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,125.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Offense	Amount of Fine
1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	None
2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date . . .	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

B. **Prior Citation** (Respondent Raymond Steve Hoyt) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 201359523** was issued to Respondent Hoyt for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,625.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Offense	Amount of Fine
1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	$500.
2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

OTHER MATTERS

67. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, San Ysidro Pharmacy, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if it is revoked.

68. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, while Raymond Steve Hoyt has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 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 Permit License Number PHY 46711, issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President);

2. Revoking or suspending Pharmacist License Number RPH 39935, issued to Raymond Steve Hoyt;

3. Prohibiting Respondent San Ysidro Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc.is revoked;

4. Prohibiting Respondent Raymond Steve Hoyt from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc., is revoked;

5. Ordering San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President) and Raymond Steve Hoyt, as an individual licensee, 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;

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

DATED: September 27, 2019

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

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

In the Matter of the First Amended Accusation Against**:** **SAN YSIDRO PHARMACY, INC., dba SAN YSIDRO PHARMACY,** RAYMOND STEVE HOYT, President 1498 E. Valley Road Santa Barbara, CA 93108 Permit License No. PHY 46711 **AND** **RAYMOND STEVE HOYT** Pharmacist-in Charge 1463 Hosmer Lane Santa Barbara, CA 93108 Pharmacist License No. RPH 39935 Respondents.	Case No. 5737 **FIRST AMENDED** **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about June 30, 2004, the Board of Pharmacy issued Permit License Number PHY 46711 to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt, President (Respondent Pharmacy). The Permit License was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2019, unless renewed.

3. On or about March 18, 1986, the Board of Pharmacy issued Pharmacist License Number RPH 39935 to Raymond Steve Hoyt (Respondent Hoyt). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2019, unless renewed.

JURISDICTION

4. The original Accusation in this matter was filed on September 12, 2017, and duly served to Respondents, each of whom filed a timely Notice of Defense. This First Amended 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.

5. Section **118,** subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the Uniform Controlled Substances Act (Health and Safety Code section 11000 et seq.).

7. Section **4052**, subdivision (b) of the Code states:

"(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration."

8. Section **4059**, subdivision (a) of the Code states:

"(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section

3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

9. Section **4126.5** of the code provides in pertinent part:

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

10. Section **4169** of the Code provides:

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

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

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

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

(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.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

11. Section **4210** of the Code provides:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

12. Section **4300** of the Code provides in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

13. 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."

14. 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:

. . .

"(c) Gross negligence.

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

. . .

"(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.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

"(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.

. . .

15. Section **4306.5** of the Code provides in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

16. Section **4307** of the Code states at sub-division (a) that:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, 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, director, associate, or partner had knowledge 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, or partner of a licensee as follows:

(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.

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

17. Section **4113** of the Code provides at sub-division (c):

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with the state and federal laws and regulations pertaining to the practice of pharmacy.

18. Section **4075** of the Code states in pertinent part:

No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity.

19. Health and Safety Code section **11153** states:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

20. Health and Safety Code section **111335** provides:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

21. Health and Safety Code section **111375** provides:

"Any drug or device is misbranded unless its labeling bears all of the following information:

(a) Adequate directions for use.

(b) Such adequate warnings against use of pathological conditions or by children where its use may be dangerous to health.

(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempt under Section 502(f) of the federal act (21 U.S.C. Sec 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

22. Health and Safety Code section **111400** provides:

Any drug or devise is misbranded if it is dangerous to health if used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

23. Health and Safety Code section 11150 states:

No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

24. Health and Safety Code section **11157** states:

No person shall issue a prescription that is false or fictitious in any respect.

25. Health and Safety Code section **111659**, subdivision (d) provides that the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice: "(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and the date of birth of the ultimate user. (2) the prescriber's category or licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government exempt facility. (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number. (4) National Drug Code (NDC) number of the controlled substance dispensed. (5) Quantity of the controlled substance dispensed. (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available. (7) Number of refills ordered. (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request. (9) Date of origin of the prescription. (10) Date of dispensing of the prescription."

STATE REGULATIONS

26. California Code of Regulations, title 16, section **1715.5** provides in pertinent part:

"The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows: (a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility."

27. California Code of Regulations, title 16, section **1761** states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

28. California Code of Regulations, title 16 section **1735.2** states:

(a) Except as specified in (b) and (c), no drug preparation 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 preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to

the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

29. California Code of Regulations, title 16 section **1735.2** states:

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

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

FEDERAL REGULATIONS

30. Code of Federal Regulations, title 21, section **1306.04** provides in pertinent part that a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacists who fills the prescription.

COST RECOVERY

31. Section **125.3** of the Code states, 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.

32. **DRUG CLASSIFICATIONS**

Brand Names	Generic Name	Dangerous Drug [Bus. & Prof. Code § 4022]	Scheduled Drug [Health & Safety Code (HSC)]	Indications For Use
Zithromax	Azithromycin	Yes	No	Antibiotic
Many	Betamethasone	Yes	No	Decrease swelling, Corticosteroid
Many	Clotrimazole	Yes	No	Antifungal
Many	Cyanocobalamin (B12)	Yes	No	Vitamin
None	DHEA (Dehydroepiandrosterone)	Yes	No	Vitamin/herb
Silenor	Doxepin	Yes	No	Antidepressant, sleep
Many	Estrogen, Estriol, Estradiol	Yes	No	Hormone replacement
	Fentanyl	Yes	Schedule II HSC § 11055 (c)(8)	Pain Control
Diflucan	Fluconazole	Yes	No	Antifungal
Many	Fludrocortisone	Yes	No	Antifungal
Many	Hydrocortisone	Yes	No	Decrease swelling, Corticosteroid
Dilaudid	Hydromorphone	Yes	Schedule II HSC § 11055 (b)(l)(J)	Pain Control
	Methadone	Yes	Yes 11055(c)(14)	Treatment of addiction and treatment of moderate to severe pain
Many	Naltrexone	Yes	No	To prevent the replace of opiod dependence
	Oxycodone	Yes	Yes 11055(b)(1)(M)	Moderate to severe pain
Pitocin	Oxytocin	Yes	No	Hormone
Many	Progesterone	Yes	No	Hormone replacement
Cialis	Tadalafil	Yes	No	Erectile dysfunction
Many	Testosterone	Yes	HSC 11056(f)(30)	Hormone replacement body

				building
Synthroid, Many	Thyrioid, Armour Thyroid, Nature-Thyroid, liothyronine, levothyroxine	Yes	No	Hormone replacement
Ultram	Tramadol	Yes	CFR 1308.14	Opiod Pain reliever

FACTUAL ALLEGATIONS

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

33. At all times relevant herein, Respondent Raymond Steve Hoyt was the President and 100% owner of corporate license holder, Respondent San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, as well as Pharmacist-in-Charge of San Ysidro Pharmacy – a retail pharmacy located in the city of Santa Barbara, CA.

FACTS COMMON TO FIRST THROUGH SIXTH CAUSES FOR DISCIPLINE

34. **COMPOUNDING OF DOMPERIDONE PRODUCTS**

A. On or about June 7, 2004, the United States Food and Drug Administration (FDA) published its "FDA Talk Paper" identifying safety risks associated with use of the unapproved drug domperidone, which stated:

"In response to reports that women may be using an unapproved drug, domperidone, to increase milk production (lactation), the Food and Drug Administration (FDA) is warning breastfeeding women not to use this product because of safety concerns…

The Agency also is issuing an Import Alert which alerts FDA filed personnel to be on the lookout for attempts to import this drug so that it can be detained and refused admission into the U.S. if appropriate.

FDA took these actions because it has become aware that some women who breastfeed and/or pump breast milk are purchasing this drug, domperidone, from compounding pharmacies and from sources in foreign countries to increase breast milk production. Domperidone may increase the secretion of prolactin, a hormone that is needed for lactation.

Although domperidone is approved in several countries outside of the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for

enhancing breast milk production in lactating women and is not approved in the U.S. for any indication.

The agency is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death of patients receiving an intravenous form of domperidone that has been withdrawn from marketing in a number of countries…

Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production…

[A]ll drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law."

B. At all times relevant herein, due to FDA restrictions, domperidone could not be legally compounded by pharmacies in the United States (with approved exceptions). [1]

C. On or about April 1, 2015, the Board published a "subscriber alert" to all licensees, warning that domperidone was "**not FDA approved** for any use in humans in the United States," and summarizing the information in the 2004 FDA Talk Paper.

D. Following a Board investigative inquiry to Respondents for all compounding records, mater formulas and dispensing records for any products made with domperidone at Respondent Pharmacy between April 15, 2015 and August 25, 2015, Respondents admitted compounding the following products during the subject time period:

(1) Domperidone Products Compounded:

a. lot 04182015@4 for 300 capsules of domperidone 10 mg.

b. lot 04272015@12 for 200 capsules for domperidone 10 mg.

c. lot 06162015@12 for 100 capsules for domperidone 10 mg.

[1] FDA has a procedure for exception to this policy by an investigational new drug (IND) application filing. As of March 2015, only one such application to compound domperidone had been approved.

d. lot 07302015@12 for 200 capsules for domperidone 10 mg.

(2) Domperidone Dispensing Records:

4 prescriptions and 840 capsules were dispensed.

35. **PRESCRIPTIONS ISSUED TO PATIENTS AM and SM**

A. On or about January 25, 2014, a $12,500 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient AM, alleging improper management and dispensing of controlled substances resulting in AM's addiction and death on April 28, 2011. Payment was made without admission of allegations or liability.

B. On or about April 23, 2014, a $25,000 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient SM, alleging improper management and dispensing of controlled substances resulting in SM's addiction and death on September 20, 2009. Payment was made without admission of allegation or liability.

C. Having received notice of both settlements, the Board sought to investigate allegations of misconduct related to AM and SM, and obtained a statement and related documents from Respondents.

Analysis of Prescription Records

D. As a part of the investigation, Board inspectors obtained and analyzed CURES[2] data for Patients AM and SM.

E. All of the prescriptions filled by Respondents for Patients AM and SM were written by Dr. Julio Gabriel Diaz also known as Otero Julio Gabriel Diaz, MD (Dr. Diaz). a

[2] CURES is an acronym for "California Utilization Review and Evaluation System." It contains over 100 million entries of controlled substance drugs that were dispensed in California. Pharmacists and prescribers can register with the Department of Justice to obtain access to the CURES data through the California Prescription Drug Monitoring Program (PDMP). Patient Activity Reports (PARs) are provided and reflect all controlled substances dispensed to an individual. CURES herein refers to CURES in general and PARs. Pharmacies are required to report to the California Department of Justice every schedule II, II and IV drug prescription under Health and Safety Code section 1165, subdivision (d).

General Practice physician with secondary practice areas in Geriatrics and Pathology, who operated a practice in the city of Santa Barbara, CA.

F. On or about January 18, 2012, pursuant to a criminal complaint filed in United States District Court, Dr. Diaz was charged with illegal distribution of controlled substances. The affidavit in support of the criminal complaint stated that Dr. Dias wrote prescriptions for powerful painkillers, for "patients" who were drug addicts with no legitimate need for the drugs. Some of Dr. Diaz's "patients" diverted the pills they received to the black market and/or suffered fatal overdoses from the narcotics.[3]

G. Effective November 2, 2012, the California Medical Board revoked Dr. Diaz's medical license in the case entitled In the Matter of the Accusation Against Ortero Julio Gabriel Diaz, M.D., case no. 06-2010-209660. Dr. Diaz's license was revoked for committing gross negligent and impotence and for excessive prescribing narcotic medications to a patient.

H. **ANALYSIS OF PRESCRIPTION RECORDS - PATIENT AM**

(1) AM (DOB 8/1984) initially came to Respondent Pharmacy on April 28, 2011, with prescriptions for chronic back pain. Over a period of six and a half months, he was dispensed prescriptions for methadone, hydromorphone and oxycodone. On the morning of November 25, 2011, he was found unresponsive and not breathing in his bedroom, and later pronounced dead. The coroner's investigation found nine syringes, several injection sites, a silver colored spoon, a cotton ball with heroin and burn marks on his thumb and fingers. His last methadone prescription dispensed by San Ysidro Pharmacy was filled on September 16, 2011.

(2) **Review of CURES Data** - A review of CURES data for AM revealed that he filled a total of 175 controlled substance prescriptions between May 5, 2008 and November 15, 2011. In January 2009, the first prescriptions prescribed by Dr. Diaz for AM

[3] On August 28, 2015, following a jury trial, Dr. Diaz was found guilty in a federal district court of more than 25 counts of felony drug trafficking offenses, in *United States of America v. Julio Gabriel Diaz* (U.S.D.C. (CA Central), criminal case no. 8:11MJ00636

(for hydromorphone 8 mg and oxycodone 40 mg) were dispensed to AM. Dr. Diaz was the prescriber for 36 of the 38 controlled substance prescriptions in 2009, and 80 of the 81 controlled substance prescriptions in 2010. In 2011 AM was dispensed 43 controlled substance prescriptions. **CURES data** showed San Ysidro dispensed 9 out of the 43 prescriptions. However, AM's profile *provided by Respondents* showed additional dispensed prescriptions for AM not reported to CURES.[4]

(3) CURES data revealed 37 of the 43 prescriptions were paid in cash and not billed to a third party payer. Of the 9 out of the 43 prescriptions dispensed by Respondents – 5 of the 9 were for Schedule II controlled substances and paid for in cash.

[4] Board investigation disclosed that Respondent Pharmacy failed to report to CURES, 13 controlled substance prescriptions dispensed to AM between April 28, 2011 and August 18, 2011, in the following instances:

Date Filled	RX#	Drug Name	Strength	Quantity
04/28/2011	598197	oxycodone	30 mg	150
05/26/2011	600038	oxycodone	30 mg	120
05/26/2011	600039	hydromorphone	8 mg	120
05/26/2011	600042	methadone	10 mg	180
06/23/2011	601761	hydromorphone	8 mg	120
06/23/2011	601762	oxycodone	30 mg	120
06/23/2011	601764	methadone	10 mg	180
07/21/2011	603247	methadone	10 mg	180
07/21/2011	603248	oxycodone	30 mg	120
07/21/2011	603259	hydromorphone	8 mg	120
08/18/2011	604785	methadone	10 mg	160
08/18/2011	604787	hydromorphone	8 mg	120
08/18/2011	604788	oxycodone	30 mg	120
08/18/2011	604787	Hydromorphone	8 mg	120

(4) In 2011, AM was dispensed 56 controlled substances including those not reported to CURES. Dr. Diaz prescribed 55 of the 56 prescriptions. San Ysidro dispensed 22 of the 56 prescriptions. All 22 prescriptions were written by Dr. Diaz.

(5) The chart below is a summary of **all** prescriptions dispensed to AM by San Ysidro Pharmacy:

Date filled	RX#	Drug Name	Strength	Qty	EDS	Sig
04/28/2011	598195	methadone	10 mg	120	30	2 tablets every 12 hours
04/28/2011	598196	hydromorphone	8 mg	160	30	1-2 tablets every 2-4 hours
04/28/2011	598167	oxycodone	30 mg	150	7	2 tablets every 2-6 hours
05/26/2011	600038	oxycodone	30 mg	120	15	2 tablets every 6 hours
05/26/2011	600039	hydromorphone	8 mg	120	30	2 tablets every 6 hours
05/26/2011	600042	methadone	10 mg	180	30	3 tablets every 12 hours
06/23/2011	601761	hydromorphone	8 mg	120	30	2 tablets every 6 hours
06/23/2011	601762	oxycodone	30 mg	120	15	2 tablets every 6 hours
06/23/2011	601764	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603247	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603248	oxycodone	30 mg	120	15	2 tablets every 6 hours
07/21/2011	603259	hydromorphone	8 mg	120	30	1 tablet every 6 hours
08/18/2011	604785	methadone	10 mg	160	30	2-3 tablets every 12 hours
08/18/2011	604787	hydromorphone	8 mg	120	10	1-2 tablets every 4-6 hours
08/18/2011	604788	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
09/16/2011	606550	methadone	10 mg	160	26	3 tablets every 12 hours

09/16/2011	606551	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
09/16/2011	606552	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
10/14/2011	608213	oxycodone	30 mg	120	15	2 tablets every 6 hours
10/14/2011	608214	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
11/11/2011	609846	hydromorphone	8 mg	120	15	2 tablets every 6 hours
11/11/2011	609848	oxycodone	30 mg	97	12	2 tablets every 6 hours

(6) Hydromorphone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2300 tablets of hydromorphone 8 mg prescribed by Dr. Diaz. AM received methadone, oxycodone, and hydromorphone on *every* filled prescription written by Dr. Diaz except two (October 14, 2011 and November 11, 2011, for which methadone was not dispensed). A total of 17 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 1000 of the 2300 tablets as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
01/05/2011	324789	180	L M Caldwell Pharmacist	15	
01/07/2011	778577	180	L M Caldwell Pharmacist	30	13
04/28/2011	**598196**	**160**	**San Ysidro Pharmacy Inc**	**30**	
05/26/2011	**600039**	**120**	**San Ysidro Pharmacy Inc.**	**30**	
06/23/2011	**601761**	**120**	**San Ysidro Pharmacy Inc**	**30**	
06/27/2011	1175071	120	The Medicine Shoppe	15	26
07/21/2011	**603259**	**120**	**San Ysidro Pharmacy Inc**	**30**	
07/25/2011	1176649	120	The Medicine Shoppe	30	26
08/18/2011	**604787**	**120**	**San Ysidro Pharmacy Inc**	**10**	
08/22/2011	1178450	160	The Medicine Shoppe	14	6
09/16/2011	**606551**	**120**	**San Ysidro Pharmacy Inc**	**10**	
09/19/2011	1180096	150	The Medicine Shoppe	13	7

10/14/2011	**608214**	**120**	**San Ysidro Pharmacy Inc**	**10**	
10/17/2011	791700	150	L M Caldwell Pharmacist	12	7
11/11/2011	**609846**	**120**	**San Ysidro Pharmacy Inc**	**15**	
11/14/2011	793104	150	L M Caldwell Pharmacist	19	12
11/15/2011	793216	90	L M Caldwell Pharmacist	30	18
GRAND TOTAL		**2300**			

(7) Oxycodone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2267 tablets of **oxycodone** 30 mg prescribed by Dr. Diaz. A total of 17 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 967 of the 2267 tablets. as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Actual Days Supply	Days Early
01/05/2011	324788	180	L M Caldwell Pharmacist	15		
01/07/2011	778578	180	L M Caldwell Pharmacist	30		12
04/28/2011	**598197**	**150**	**San Ysidro Pharmacy Inc**	**30**	**7**	
05/26/2011	**600038**	**120**	**San Ysidro Pharmacy Inc.**	**30**	**15**	
06/23/2011	**601762**	**120**	**San Ysidro Pharmacy Inc**	**30**		
06/27/2011	1175072	120	The Medicine Shoppe	15		11
07/21/2011	**603248**	**120**	**San Ysidro Pharmacy Inc**	**30**		
07/25/2011	1176648	120	The Medicine Shoppe	30		11
08/18/2011	**604788**	**120**	**San Ysidro Pharmacy Inc**	**10**		**6**
08/22/2011	1178449	160	The Medicine Shoppe	14		6
09/16/2011	**606552**	**120**	**San Ysidro Pharmacy Inc**	**10**		
09/19/2011	1180095	150	The Medicine Shoppe	13		7
10/14/2011	**608213**	**120**	**San Ysidro Pharmacy Inc**	**10**		
10/17/2011	791701	150	L M Caldwell Pharmacist	12		12
11/11/2011	**609848**	**97**	**San Ysidro Pharmacy Inc**	**15**		
11/14/2011	793105	150	L M Caldwell	19		9

			Pharmacist			
11/15/2011	793218	90	L M Caldwell Pharmacist	30		18
GRAND TOTAL		**2267**				

(8) Methadone dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 1320 tablets of methadone 10 mg prescribed by Dr. Diaz. A total of 8 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 6 of the 8 prescriptions and 980 of the 1320 tablets, as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
04/28/2011	**598195**	**120**	**San Ysidro Pharmacy Inc**	**30**	
05/26/2011	**600042**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
06/23/2011	**601764**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
07/21/2011	**603247**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
08/18/2011	**604785**	**160**	**San Ysidro Pharmacy Inc**	**25**	**2**
09/16/2011	**606550**	**160**	**San Ysidro Pharmacy Inc**	**26**	
10/24/2011	792078	160	L M Caldwell Pharmacist	30	
11/14/2011	793126	180	L M Caldwell Pharmacist	30	9
GRAND TOTAL		**1320**			

(9) **AM - Corresponding Responsibility Analysis**

(a) Respondents failed to meet their corresponding responsibility to assure legitimacy of prescriptions dispensed to AM, in that they ignored and/or failed to appropriately respond to numerous warning signs or red flags:

(i) AM was young – 27-years old
(ii) AM received duplicate therapy from multiple pharmacies for narcotics intended for severe pain - methadone, oxycodone, and hydromorphone
(iii) AM received repetitive combinations of narcotics
(iv) AM's diagnosis was chronic back pain – non specific diagnosis
(v) AM's primary method of payment was cash

(b) Respondents additionally failed to access the CURES reporting system, which would have shown that AM was using multiple pharmacies and insufficiently questioned prescriptions from Dr. Diaz.

I. ANALYSIS OF PRESCRIPTION RECORDS - PATIENT SM

(1) Patient SM filled prescriptions at San Ysidro Pharmacy on five occasions from March 30 through June 11, 2009 prior to his death on September 20,2009.

(2) SM was a laborer, with a history of on the job accidents who had been diagnosed with chronic cervical spine and lower back pain. On March 30, 2009, Respondents dispensed prescriptions for hydromorphone 8 mg (11 day supply) and corisoprodol 350 mg (30 day supply) to SM. Thereafter he only filled prescriptions for fentanyl troches (a compound medication) on four occasions:

(a) Prescription N552798(April 3, 2009) - 6 day supply
(b) Prescription N553545(April 16, 2009) - 15 day supply
(c) Prescription N555220 (May 15, 2009) - 5 day supply
(d) Prescription N556921(June 11, 2009) - 30 day supply

(3) Fentanyl 1600 mcg troche was a medication compounded for SM by San Ysidro Pharmacy. A troche is a lozenge that is dissolved in the mouth, typically for severe breakthrough pain in patients already taking a narcotic analgesic. The starting dose is 200 mcg for each pain episode. This may be repeated after waiting 15 minutes between doses, maximum of 4 units per day.

(a) Prescription number N555220 was issued with directions of one troche every 4-6 hours as needed for pain. This was a significant increase in dosage compared to two prior prescriptions (one troche every 12-24 hours) dispensed to SM. No documentation indicated the original prescriptions document was clarified with the physician.

(4) On July 1, 2009, SM initiated detox treatment, and was discharged on July 9, 2009 to a rehabilitation program. His prescription history shows he filled multiple prescriptions at other pharmacies on the day he was transferred to the rehabilitation program and in the days prior to his death.

/ / /

FACTS COMMON TO

SEVENTH THROUGH EIGHTEENTH CAUSES FOR DISCIPLINE

36. **ILLEGAL ISSUANCE OF PRESCRIPTIONS**

In or about July 2017, JA visited Respondent Pharmacy to discuss compounding of her prescribed medication (doxepin), as she hoped to taper down her dosage. Following discussion with Respondent Hoyt, JA was persuaded to change her hormone replacement therapy instead. Hoyt prescribed compounded preparations with bioidentical hormones estradiol and progesterone, then dispensed the prescription in two containers, labeled Rx 736829 and Rx 736830, and showing the prescriber as "Steve Hoyt-EEK-RPH". JA used the preparations one time at home, then discarded them after discussing Respondent Hoyt's advise with her physician. In Fall 2017, JA's physician filed a complaint with the Board regarding Respondent's conduct.

37. The Board's subsequent investigation of the complaint resulted in the following findings related to other 'bio-identical hormone replacement therapy' (BHRT) prescriptions issued and filled by Respondents:

A. Between approximately January 1, 2017 and January 10, 2018, Respondent Hoyt issued 1,403 prescriptions, which were then dispensed by Respondent Pharmacy, under the ostensible authority of a *collaborative practice agreement,* for treatment of patients with bio-identical hormone replacement (BHRT), with "supervising physician" Dr. Bjorn Eek, an orthopedic surgeon residing in the city of Long Beach, pursuant to Business and Profession Code section 4052.2. The *collaborative practice agreement* relied on by Respondents was signed by Dr. Eek and Respondent Hoyt on or about June 12, 2014.

B. On the face of the statute, a section 4052.2[5] collaborative practice arrangement is only available to a pharmacist practicing at a *health care facility, home health agency or*

[5] Business and Professions Code section 4052.2 provides as follows:
(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(continued…)

clinic – not a retail pharmacy. Moreover, Board investigators determined that between approximately January 1, 2017 and January 10, 2018, Respondents had no policies or protocols in place to comply with section 4052.2 requirements.

C. In his declaration signed on or about March 7, 2018, Dr. Eek stated that he did not see, examine, or review charts for any of the patients issued the subject 1,403 prescriptions by Respondent Holt, and stated that he did not authorize the subject prescriptions – and had never prescribed medications for the patients identified in the subject prescriptions.

(…continued)
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.
(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.
(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:
(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.
(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.
(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.
(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.
(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:
(1) Successfully completed clinical residency training.
(2) Demonstrated clinical experience in direct patient care delivery.

38. The Board's investigation included review of pharmacy records related to compounded medications, resulting in the following findings:

A. Between approximately January 1, 2017 and January 10, 2018, Respondent Hoyt issued orders for 263 controlled substances, although he did not have a valid Drug Enforcement Administration (DEA) registration:

Controlled drug	Number of prescriptions	Amount sold (grams)
TESTOSTERONE 10MG/ML *** CREAM	4	120g
TESTOSTERONE 150MG/ML ** CREAM	19	675g
TESTOSTERONE 160MG/ML ** CREAM	27	870g
TESTOSTERONE *ATREVIS* 150MG/ML GEL	1	30g
TESTOSTERONE *ATREVIS* 160MG/ML GEL	5	150g
TESTOSTERONE *LB* 150MG/ML GEL	1	60g
TESTOSTERONE 2MG/ML** CREAM	9	270g
TESTOSTERONE (GLYCERIN) 4MG/ML** CREAM	12	360g
TESTOSTERONE *ATREVIS* 100MG/ML GEL	7	210g
TESTOSTERONE *ATREVIS* 200MG/ML** GEL	3	105g
TESTOSTERONE 100MG/ML** CREAM	11	330g
TESTOSTERONE 125MG/ML CREAM	10	300g
TESTOSTERONE 1MG/0.1ML CREAM	2	18g
TESTOSTERONE 4MG/ML CREAM	2	120g
TESTOSTERONE 4MG/ML** CREAM	111	3480g
TESTOSTERONE 5MG/ML CREAM	5	105g
TESTOSTERONE HRT 150MG/ML CREAM	8	255g
TESTOSTERONE HRT 200MG/ML** CREAM	14	585g
TESTOSTERONE HRT 2MG/ML CREAM	4	120g
TESTOSTERONE HRT 4MG/ML CREAM	4	120g
TESTOSTERONE 100MG+CHYRSIN-100MG/ML CREAM	3	100g
TRAMADOL HCL 50 MG TAB	1	**80 tablets**
Grand Total	**263**	**8383g and 80 tablets**

CAUSES FOR DISCIPLINE

FIRST CAUSE FOR DISCIPLINE

(Unlawful Manufacture and Sale of Misbranded Drugs – Domperidone)

39. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, sub-divisions (j) and (o), in conjunction section 4169, sub–division (a)(3) and Health and Safety Code sections 111335 and 111400 due to their compounding of at least 4 batches of the unapproved drug domperidone, and their dispensing to

two patients approximately 840 10 mg capsules of the unapproved drug domperidone between April 15 and August 25, 2015. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Sale of Misbranded Drugs - Domperidome)

40. Respondents are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with section 4169, subdivision (a)(3) and Health and Safety Code sections 111335 and 111375, subdivision (c) due to their dispensing to two patients approximately 840 10 mg capsules of the unapproved drug domperidone (compounded by Respondents) between April 15 and August 25, 2015, without adequate warning or notification to consumers that such products were FDA unapproved and potentially dangerous. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

THIRD CAUSE FOR DISCIPLINE

(Failure to Implement Electronic Monitoring of Schedule II Prescriptions)

41. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations, section 1715.5 (a) (which mandates specific information be reported for each Schedule II prescription dispensed) in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 Schedule II controlled substance prescriptions dispensed to **Patient AM.** The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Timely Comply with Department of Justice Reporting Requirements)

42. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Health and Safety code section 11165(d) (requiring the dispensing pharmacy to report specific information

about certain controlled substance transactions within seven days), in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 controlled substance prescriptions dispensed to **Patient AM**. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Assume Corresponding Responsibility)

43. Respondents are subject to discipline pursuant to Code section 4300 for unprofessional conduct as defined in section 4301, subdivision (d), (j) and (o), in conjunction with Health and Safety Code section 11153(a) in that on dates approximately between April 28, 2011 and November 11, 2011, based on evidence reviewed by Board Inspectors, Respondents failed to meet their corresponding responsibility to assure legitimacy prescriptions, in that Respondents ignored and/or failed to appropriately respond to numerous warning signs or red flags that should put a reasonable and prudent dispensing pharmacist on notice that prescriptions for **Patient AM** may not have been legitimate, including but not limited to the patients age in relation to the combination of medications prescribed, the appropriateness of the therapy, the duplicate medications the patient received, the repetitive combination of medications, and the payment method of cash. The allegations of paragraphs 33 through 35 above are realleged as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

44. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on May 15, 2009, Respondent dispensed prescription C555220, written by Dr. Diaz for **Patient SM** for fentanyl troche, without contacting the prescriber for clarification, despite instructions for dosage which exceeded the recommended maximum dose for this medication. The allegations of paragraphs 33 through 35 above are

realleged as though fully set forth.

SEVENTH CAUSE FOR DISCIPLINE

Unauthorized Practice as Advanced Practice Pharmacist

45. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4210, in that on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent practiced as an advanced practice pharmacist without obtaining certification as required under Business and Professions Code section 4210. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

EIGHTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

46. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on at least 1,403 instances on dates between January 1, 2017 and January 10, 2018, Respondent compounded and/or dispensed prescriptions which contained significant errors, omissions, irregularities, uncertainties or ambiguities. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

NINTH CAUSE FOR DISCIPLINE

Furnishing Dangerous Drugs without a Valid Prescription

47. Respondents are subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4059, subdivision (a), in that on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent furnished dangerous drugs without a valid, properly authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

TENTH CAUSE FOR DISCIPLINE

Issuance of False or Fictitious Prescriptions

48. Respondents are subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 11157 in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent issued false or fictitious prescriptions. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

ELEVENTH CAUSE FOR DISCIPLINE

Failure to Obtain Requisite DEA Registration

49. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in 4301, subdivision (j) and (o), for violating section 4052(b), due to his issuance of an order for at least 263 controlled substances on dates between approximately January 1, 2017 through January 10, 2018, without a valid Drug Enforcement Administration (DEA) registration. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

TWELFTH CAUSE FOR DISCIPLINE

Failure to Maintain Required Compounding Records

50. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations (CCR), title 16, section 1735.3(a)(2), in that in each instance listed below, Respondents failed to comply with specific statutory requirements for a compounding log, which must be maintained for each drug preparation compounded in the pharmacy:

A. 16 CCR 1735.3(a)(2) (D) – the identity of the pharmacist reviewing the final drug preparation was not documented for: (1) HRT/water cream base lot 06272017@11, (2) Progesterone 160 mg/ml lot 06292017@8, (3) HRT/water cream base lot 07112017@7, and (4) Estradiol 4 mg/ml lot 07122017@8.

B. 16 CCR 1735.3(a)(2) (F) – the manufacturer, expiration dates and lot numbers of

each component was not documented for: (1) Progesterone 160 mg/ml lot 06292017@8, (2) HRT/water cream base lot 07112017@7, and (3) Estradiol 4 mg/ml lot 07122017@8.

C. 16 CCR 1735.3(a)(2) (J) – quality reviews and required post-compounding processes and procedures were not documented for: (1) Progesterone 160 mg/ml lot 06292017@8, (2) HRT/water cream base lot 07112017@7, and (3) Estradiol 4 mg/ml lot 07122017@8.

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

THIRTEENTH CAUSE FOR DISCIPLINE

Failure to Support Extend Beyond Use Assignments

51. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1735.2 (i), in that, for each of compounded drug preparation listed below, Respondents assigned a 180 beyond use date was assigned without the support of method suitability test, container closure integrity test, or stability studies, as required by section 1735.2(i):

A. HRT/water cream base lot 06272017@11,

B. Progesterone 160 mg/ml lot 06292017@8;

C. HRT/water cream base lot 07112017@7;

D. Estradiol 4 mg/ml lot 07122017@8

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

FOURTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence)

52. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (c) in that on dates between January 1, 2017 and January 10, 2018, Respondent committed gross negligence in his practice as a pharmacist, due his acts and/or omissions which were an extreme departure from the standard of care, which under similar circumstances, would have been ordinarily exercised by a competent pharmacist, by reason of his dispensing at least 1,403 prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of

paragraphs 33, and 36-38 above are realleged as though fully set forth.

FIFTEENTH CAUSE FOR DISCIPLINE

Acts Involving Dishonesty, Fraud, or Deceit

53. Respondent Hoyt is subject to disciplinary action under section 4301, subdivision (f), in that Respondent committed acts involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, or substantially injure another, by reason of his acts and/or omissions in dispensing at least 1,403 prescriptions while knowing that the prescriber had not examined, diagnosed nor prescribed dangerous drugs. Each of the 1,403 prescriptions were fraudulently obtained under dishonest and deceitful practices by Respondent Hoyt. The allegations of paragraphs 33,and 36-38 above are realleged as though fully set forth.

SIXTEEN CAUSE FOR DISCIPLINE

Knowingly Making False Representations

54. Respondent Hoyt is subject to disciplinary action under section 4301, subdivision (g), in that on or about March 13, 2018, Respondent knowingly made false representations regarding the existence or nonexistence of a state of facts, in a written document submitted to the Board in March, 2018, Respondent made the following representations, which he knew were false and untrue:

1. Dr. Eek visited San Ysidro on 2/15/18

2. Dr. Eek incorporated extensively anti-aging science of identical hormone replacement therapy into his practice, as it provided significant improvement in patient outcomes

3. He provided help and support for Dr. Eek's patients through discussion and recommendations that formed the basis for the therapeutic regimen dispensed by San Ysidro Pharmacy

4. Dr. Eek and I discussed the guideline for BHRT diagnosis based on laboratory results and patient-reported symptoms during patient interviews

5. Respondent Hoyt documented at least 1,403 times on a written prescription that Dr. Eek had authorized a prescription for dangerous drugs.

The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

SEVENTEENTH CAUSE FOR DISCIPLINE

Inappropriate Exercise of Education

55. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent dispensed at least 1,403 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

EIGHTEENTH CAUSE FOR DISCIPLINE

Failure to Exercise Professional Judgement

56. Respondent Hoyt is subject to disciplinary action under section 4300 for unprofessional as defined in section 4301, subdivision (j) and (o), for violating section 4306.5(a) in that, that in on at least 1,403 instances on dates approximately between January 1, 2017 and January 10, 2018, Respondent dispensed at least 1,403 fraudulent prescriptions that he knew or should have known were not supported by a valid, legally authorized prescription. The allegations of paragraphs 33, and 36-38 above are realleged as though fully set forth.

DISCIPLINARY CONSIDERATIONS

57. To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

A. **Prior Citation** (Respondent San Ysidro Pharmacy, Inc.) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 2012 56574** was issued to Respondent Pharmacy for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,125.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Offense	Amount of Fine
1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	None

2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date . . .	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

B. **Prior Citation** (Respondent Raymond Steve Hoyt) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 201359523** was issued to Respondent Hoyt for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,625.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Offense	Amount of Fine
1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	$500.
2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

OTHER MATTERS

58. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, San Ysidro Pharmacy, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if it is revoked.

59. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, while Raymond Steve Hoyt has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for

five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 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 Permit License Number PHY 46711, issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President);

2. Revoking or suspending Pharmacist License Number RPH 39935, issued to Raymond Steve Hoyt;

3. Prohibiting Respondent San Ysidro Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc.is revoked;

4. Prohibiting Respondent Raymond Steve Hoyt from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc., is revoked;

5. Ordering San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President) and Raymond Steve Hoyt, as an individual licensee, 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;

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

DATED: February 20, 2019

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

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

In the Matter of the Accusation Against: **SAN YSIDRO PHARMACY, INC., dba SAN YSIDRO PHARMACY,** RAYMOND STEVE HOYT, President 1498 E. Valley Road Santa Barbara, CA 93108 Permit License No. PHY 46711 **AND** **RAYMOND STEVE HOYT** Pharmacist-in Charge 1463 Hosmer Lane Santa Barbara, CA 93108 Pharmacist License No. RPH 39935 Respondents.	Case No. 5737 **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 June 30, 2004, the Board of Pharmacy issued Permit License Number PHY 46711 to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt,

President (Respondent Pharmacy). The Permit License was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2018, unless renewed.

3. On or about March 18, 1986, the Board of Pharmacy issued Pharmacist License Number RPH 39935 to Raymond Steve Hoyt (Respondent Hoyt). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.

JURISDICTION

4. 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.

5. Section **118,** subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section **4011** of the code provides that the Board shall administer and enforce both the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the Uniform Controlled Substances Act (Health and Safety Code section 11000 et seq.).

7. Section **4169** of the Code provides:

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

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

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

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

(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.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

8. Section **4300** of the Code provides in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

9. 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."

10. 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:

. . .

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

. . .

"(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.

. . .

11. Section **4307** of the Code states at sub-division (a) that :

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, 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, director, associate, or partner had knowledge 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, or partner of a licensee as follows:

(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.

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

12. Section **4113** of the Code provides at sub-division (c):

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with the state and federal laws and regulations pertaining to the practice of pharmacy.

13. Section **4075** of the Code states in pertinent part:

No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity.

14. Health and Safety Code section **11153** states:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

15. Health and Safety Code section **111335** provides:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

16. Health and Safety Code section **111375** provides:

"Any drug or device is misbranded unless its labeling bears all of the following information:

(a) Adequate directions for use.

(b) Such adequate warnings against use of pathological conditions or by children where its use may be dangerous to health.

(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempt under Section 502(f) of the federal act (21 U.S.C. Sec 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

17. Health and Safety Code section **111400** provides:

Any drug or devise is misbranded if it is dangerous to health if used in the dosage, or with the frequency or duration prescribed, recommended , or suggested in its labeling.

18. Health and Safety Code section **111659**, subdivision (d) provides that the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice: " (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and the date of birth of the ultimate user. (2) the prescriber's category or licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government exempt facility. (3) Pharmacy prescription number, license number, NPI number, and federal controlled

substance registration number. (4) National Drug Code (NDC) number of the controlled substance dispensed. (5) Quantity of the controlled substance dispensed. (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available. () Number of refills ordered. (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.(9) Date of origin of the prescription. (10) Date of dispensing of the prescription. "

STATE REGULATIONS

19. California Code of Regulations, title 16, section **1715.5** provides in pertinent part:

"The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows: (a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility."

20. California Code of Regulations, title 16, section **1761** states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

FEDERAL REGULATIONS

21. Code of Federal Regulations, title 21, section **1306.04** provides in pertinent part that a prescription for a controlled substance to be effective must be issued for a legitimate medical

purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacists who fills the prescription.

COST RECOVERY

22. Section **125.3** of the Code states, 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.

23. **DRUG CLASSIFICATIONS**

Brand Names	Generic Name	Dangerous Drug [Bus. & Prof. Code § 4022]	Scheduled Drug [Health & Safety Code (HSC)]	Indications For Use
	Fentanyl	Yes	Schedule II HSC § 11055 (c)(8)	Pain Control
Dilaudid	Hydromorphone	Yes	Schedule II HSC § 11055 (b)(l)(J)	Pain Control
	Methadone	Yes	Yes 11055(c)(14)	Treatment of addiction and treatment of moderate to severe pain
	Oxycodone	Yes	Yes 11055(b)(1)(M)	Moderate to severe pain

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

24. At all times relevant herein, Respondent Raymond Steve Hoyt was the President and 100% owner of corporate license holder, Respondent San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, as well as Pharmacist-in-Charge of San Ysidro Pharmacy – a retail pharmacy located in the city of Santa Barbara, CA.

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25. **COMPOUNDING OF DOMPERIDONE PRODUCTS**

A. On or about June 7, 2004, the United States Food and Drug Administration (FDA) published its "FDA Talk Paper" identifying safety risks associated with use of the unapproved drug domperidone, which stated:

"In response to reports that women may be using an unapproved drug, domperidone, to increase milk production (lactation), the Food and Drug Administration (FDA) is warning breastfeeding women not to use this product because of safety concerns...

The Agency also is issuing an Import Alert which alerts FDA filed personnel to be on the lookout for attempts to import this drug so that it can be detained an refused admission into the U.S. if appropriate.

FDA took these actions because it has become aware that some women who breastfeed and/or pump breast milk are purchasing this drug, domperidone, from compounding pharmacies and from sources in foreign countries to increase breast mile production. Domperidone may increase the secretion of prolactin, a hormone that is needed for lactation.

Although domperidone is approved in several countries outside of the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is not approved in the U.S. for any indication.

The agency is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death of patients receiving an intravenous form of domperidone that has been withdrawn from marketing in a number of countries...

Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production...

[A]ll drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug and Cosmetic Act (the Act) because they are unapproved new drugs

and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law."

B. At all times relevant herein, because of FDA restrictions, domperidone could not be legally compounded by pharmacies in the United States (with approved exceptions). [1]

C. On or about April 1, 2015, the Board published a "subscriber alert" to all licensees, warning that domperidone was "**not FDA approved** for any use in humans in the United States," and summarizing the information in the 2004 FDA Talk Paper.

D. Following a Board investigative inquiry to Respondents for all compounding records, mater formulas and dispensing records for any products made with domperidone at Respondent Pharmacy between April 15, 2015 and August 25, 2015, Respondents admitted compounding the following products during the subject time period:

(1) Domperidone Products Compounded:

a. lot 04182015@4 for 300 capsules of domperidone 10 mg.

b. lot 04272015@12 for 200 capsules for domperidone 10 mg.

c. lot 06162015@12 for 100 capsules for domperidone 10 mg.

d. lot 07302015@12 for 200 capsules for domperidone 10 mg.

(2) Domperidone Dispensing Records:

4 prescriptions and 840 capsules were dispensed.

26. **PRESCRIPTIONS ISSUED TO PATIENTS AM and SM**

A. On or about January 25, 2014, a $12,500 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient AM, alleging improper management and dispensing of controlled substances resulting in AM's addiction and death on April 28, 2011. Payment was made without admission of allegations or liability.

[1] FDA has a procedure for exception to this policy by an investigational new drug (IND) application filing. As of March 2015, only one such application to compound domperidone had been approved.

B. On or about April 23, 2014, a $25,000 payment was made by an insurance company on behalf of Respondents to settle a malpractice suit brought by the family of deceased patient SM, alleging improper management and dispensing of controlled substances resulting in SM's addiction and death on September 20, 2009. Payment was made without admission of allegation or liability.

C. Having received notice of both settlements, the Board sought to investigate allegations of misconduct related to AM and SM, and obtained a statement and related documents from Respondents.

Analysis of Prescription Records

D. As a part of the investigation, Board inspectors obtained and analyzed CURES[2] data for Patients AM and SM.

E. All of the prescriptions filled by Respondents for Patients AM and SM were written by Dr. Julio Gabriel Diaz also known as Otero Julio Gabriel Diaz, MD (Dr. Diaz). a General Practice physician with secondary practice areas in Geriatrics and Pathology, who operated a practice in the city of Santa Barbara, CA.

F. On or about January 18, 2012, pursuant to a criminal complaint filed in United States District Court, Dr. Diaz was charged with illegal distribution of controlled substances. The affidavit in support of the criminal complaint stated that Dr. Dias wrote prescriptions for powerful painkillers, for "patients" who were drug addicts with no legitimate need for the drugs. Some of Dr. Diaz's "patients" diverted the pills they received to the black market and/or suffered fatal overdoses from the narcotics.[3]

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[2] CURES is an acronym for "California Utilization Review and Evaluation System." It contains over 100 million entries of controlled substance drugs that were dispensed in California. Pharmacists and prescribers can register with the Department of Justice to obtain access to the CURES data through the California Prescription Drug Monitoring Program (PDMP). Patient Activity Reports (PARs) are provided and reflect all controlled substances dispensed to an individual. CURES herein refers to CURES in general and PARs. Pharmacies are required to report to the California Department of Justice every schedule II, II and IV drug prescription under Health and Safety Code section 1165, subdivision (d).

[3] On August 28, 2015, following a jury trial, Dr. Diaz was found guilty in a federal district court of more than 25 counts of felony drug trafficking offenses, in *United States of America v. Julio Gabriel Diaz* (U.S.D.C. (CA Central), criminal case no. 8:11MJ00636

G. Effective November 2, 2012, the California Medical Board revoked Dr. Diaz's medical license in the case entitled In the Matter of the Accusation Against Ortero Julio Gabriel Diaz, M.D., case no. 06-2010-209660. Dr. Diaz's license was revoked for committing gross negligent and impotence and for excessive prescribing narcotic medications to a patient.

H. **ANALYSIS OF PRESCRIPTION RECORDS - PATIENT AM**

(1) AM (DOB 8/1984) initially came to Respondent Pharmacy on April 28, 2011, with prescriptions for chronic back pain. Over a period of six and a half months, he was dispensed prescriptions for methadone, hydromorphone and oxycodone. On the morning of November 25, 2011, he was found unresponsive and not breathing in his bedroom, and later pronounced dead. The coroner's investigation found nine syringes, several injection sites, a silver colored spoon, a cotton ball with heroin and burn marks on his thumb and fingers. His last methadone prescription dispensed by San Ysidro Pharmacy was filled on September 16, 2011.

(2) **Review of CURES Data** - A review of CURES data for AM revealed that he filled a total of 175 controlled substance prescriptions between May 5, 2008 and November 15, 2011. In January 2009, the first prescriptions prescribed by Dr. Diaz for AM (for hydromorphone 8 mg and oxycodone 40 mg) were dispensed to AM. Dr. Diaz was the prescriber for 36 of the 38 controlled substance prescriptions in 2009, and 80 of the 81 controlled substance prescriptions in 2010. In 2011 AM was dispensed 43 controlled substance prescriptions. **CURES data** showed San Ysidro dispensed 9 out of the 43 prescriptions. However, AM's profile *provided by Respondents* showed additional dispensed prescriptions for AM not reported to CURES.[4]

[4] Board investigation disclosed that Respondent Pharmacy failed to report to CURES, 13 controlled substance prescriptions dispensed to AM between April 28, 2011 and August 18, 2011, in the following instances:

Date Filled	RX#	Drug Name	Strength	Quantity
04/28/2011	598197	oxycodone	30 mg	150
05/26/2011	600038	oxycodone	30 mg	120

(continued...)

(3) CURES data revealed 37 of the 43 prescriptions were paid in cash and not billed to a third party payer. Of the 9 out of the 43 prescriptions dispensed by Respondents – 5 of the 9 were for Schedule II controlled substances and paid for in cash.

(4) In 2011, AM was dispensed 56 controlled substances including those not reported to CURES. Dr. Diaz prescribed 55 of the 56 prescriptions. San Ysidro dispensed 22 of the 56 prescriptions. All 22 prescriptions were written by Dr. Diaz.

(5) The chart below is a summary of **all** prescriptions dispensed to AM by San Ysidro Pharmacy:

Date filled	RX#	Drug Name	Strength	Qty	EDS	Sig
04/28/2011	598195	methadone	10 mg	120	30	2 tablets every 12 hours
04/28/2011	598196	hydromorphone	8 mg	160	30	1-2 tablets every 2-4 hours
04/28/2011	598167	oxycodone	30 mg	150	7	2 tablets every 2-6 hours

(...continued)

05/26/2011	600039	hydromorphone	8 mg	120
05/26/2011	600042	methadone	10 mg	180
06/23/2011	601761	hydromorphone	8 mg	120
06/23/2011	601762	oxycodone	30 mg	120
06/23/2011	601764	methadone	10 mg	180
07/21/2011	603247	methadone	10 mg	180
07/21/2011	603248	oxycodone	30 mg	120
07/21/2011	603259	hydromorphone	8 mg	120
08/18/2011	604785	methadone	10 mg	160
08/18/2011	604787	hydromorphone	8 mg	120
08/18/2011	604788	oxycodone	30 mg	120

05/26/2011	600038	oxycodone	30 mg	120	15	2 tablets every 6 hours
05/26/2011	600039	hydromorphone	8 mg	120	30	2 tablets every 6 hours
05/26/2011	600042	methadone	10 mg	180	30	3 tablets every 12 hours
06/23/2011	601761	hydromorphone	8 mg	120	30	2 tablets every 6 hours
06/23/2011	601762	oxycodone	30 mg	120	15	2 tablets every 6 hours
06/23/2011	601764	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603247	methadone	10 mg	180	30	3 tablets every 12 hours
07/21/2011	603248	oxycodone	30 mg	120	15	2 tablets every 6 hours
07/21/2011	603259	hydromorphone	8 mg	120	30	1 tablet every 6 hours
08/18/2011	604785	methadone	10 mg	160	30	2-3 tablets every 12 hours
08/18/2011	604787	hydromorphone	8 mg	120	10	1-2 tablets every 4-6 hours
08/18/2011	604788	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
09/16/2011	606550	methadone	10 mg	160	26	3 tablets every 12 hours
09/16/2011	606551	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
09/16/2011	606552	oxycodone	30 mg	120	10	1-2 tablets every 4-6 hours
10/14/2011	608213	oxycodone	30 mg	120	15	2 tablets every 6 hours
10/14/2011	608214	hydromorphone	8 mg	120	10	2 tablets every 4-6 hours
11/11/2011	609846	hydromorphone	8 mg	120	15	2 tablets every 6 hours
11/11/2011	609848	oxycodone	30 mg	97	12	2 tablets every 6 hours

(6) Hydromorphone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2300 tablets of hydromorphone 8 mg prescribed by Dr. Diaz. AM received methadone, oxycodone, and hydromorphone on *every* filled prescription written by Dr. Diaz except two (October 14,

2011 and November 11, 2011, for which methadone was not dispensed).A total of 17 prescriptions were dispensed to AM.

San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 1000 of the 2300 tablets as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
01/05/2011	324789	180	L M Caldwell Pharmacist	15	
01/07/2011	778577	180	L M Caldwell Pharmacist	30	13
04/28/2011	**598196**	**160**	**San Ysidro Pharmacy Inc**	**30**	
05/26/2011	**600039**	**120**	**San Ysidro Pharmacy Inc.**	**30**	
06/23/2011	**601761**	**120**	**San Ysidro Pharmacy Inc**	**30**	
06/27/2011	1175071	120	The Medicine Shoppe	15	26
07/21/2011	**603259**	**120**	**San Ysidro Pharmacy Inc**	**30**	
07/25/2011	1176649	120	The Medicine Shoppe	30	26
08/18/2011	**604787**	**120**	**San Ysidro Pharmacy Inc**	**10**	
08/22/2011	1178450	160	The Medicine Shoppe	14	6
09/16/2011	**606551**	**120**	**San Ysidro Pharmacy Inc**	**10**	
09/19/2011	1180096	150	The Medicine Shoppe	13	7
10/14/2011	**608214**	**120**	**San Ysidro Pharmacy Inc**	**10**	
10/17/2011	791700	150	L M Caldwell Pharmacist	12	7
11/11/2011	**609846**	**120**	**San Ysidro Pharmacy Inc**	**15**	
11/14/2011	793104	150	L M Caldwell Pharmacist	19	12
11/15/2011	793216	90	L M Caldwell Pharmacist	30	18
GRAND TOTAL		**2300**			

(7) Oxycodone Dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 2267 tablets of **oxycodone** 30 mg prescribed by Dr. Diaz. A total of 17 prescriptions were dispensed to AM.

San Ysidro Pharmacy dispensed 8 of the 17 prescriptions and 967 of the 2267 tablets, as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Actual Days Supply	Days Early
01/05/2011	324788	180	L M Caldwell Pharmacist	15		
01/07/2011	778578	180	L M Caldwell Pharmacist	30		12
04/28/2011	**598197**	**150**	**San Ysidro Pharmacy Inc**	**30**	7	
05/26/2011	**600038**	**120**	**San Ysidro Pharmacy Inc.**	**30**	**15**	
06/23/2011	**601762**	**120**	**San Ysidro Pharmacy Inc**	**30**		
06/27/2011	1175072	120	The Medicine Shoppe	15		11
07/21/2011	**603248**	**120**	**San Ysidro Pharmacy Inc**	**30**		
07/25/2011	1176648	120	The Medicine Shoppe	30		11
08/18/2011	**604788**	**120**	**San Ysidro Pharmacy Inc**	**10**		**6**
08/22/2011	1178449	160	The Medicine Shoppe	14		6
09/16/2011	**606552**	**120**	**San Ysidro Pharmacy Inc**	**10**		
09/19/2011	1180095	150	The Medicine Shoppe	13		7
10/14/2011	**608213**	**120**	**San Ysidro Pharmacy Inc**	**10**		
10/17/2011	791701	150	L M Caldwell Pharmacist	12		12
11/11/2011	**609848**	**97**	**San Ysidro Pharmacy Inc**	**15**		
11/14/2011	793105	150	L M Caldwell Pharmacist	19		9
11/15/2011	793218	90	L M Caldwell Pharmacist	30		18
GRAND TOTAL		**2267**				

(8) Methadone dispensed to AM

Between January 1, 2011 and November 15, 2011, AM received 1320 tablets of methadone 10 mg prescribed by Dr. Diaz. A total of 8 prescriptions were dispensed to AM. San Ysidro Pharmacy dispensed 6 of the 8 prescriptions and 980 of the 1320 tablets, as shown below:

Date Filled	RX#	Qty	Pharmacy Name	EDS	Days Early
04/28/2011	**598195**	**120**	**San Ysidro Pharmacy Inc**	**30**	
05/26/2011	**600042**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
06/23/2011	**601764**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
07/21/2011	**603247**	**180**	**San Ysidro Pharmacy Inc**	**30**	**2**
08/18/2011	**604785**	**160**	**San Ysidro Pharmacy Inc**	**25**	**2**
09/16/2011	**606550**	**160**	**San Ysidro Pharmacy Inc**	**26**	
10/24/2011	792078	160	L M Caldwell Pharmacist	30	
11/14/2011	793126	180	L M Caldwell Pharmacist	30	9
GRAND TOTAL		**1320**			

(9) **AM - Corresponding Responsibility Analysis**

(a) Respondents failed to meet their corresponding responsibility to assure legitimacy of prescriptions dispensed to AM, in that they ignored and/or failed to appropriately respond to numerous warning signs or red flags:

(i) AM was young – 27 years old
(ii) AM received duplicate therapy from multiple pharmacies for narcotics intended for severe pain - methadone, oxycodone, and hydroporphone
(iii) AM received repetitive combinations of narcotics
(iv) AM's diagnosis was chronic back pain – non specific diagnosis
(v) AM's primary method of payment was cash

(b) Respondents additionally failed to access the CURES reporting system, which would have shown that AM was using multiple pharmacies and insufficiently questioned prescriptions from Dr. Diaz.

I. ANALYSIS OF PRESCRIPTION RECORDS - PATIENT SM

(1) Patient SM filled prescriptions at San Ysidro Pharmacy on five occasions from March 30 through June 11, 2009 prior to his death on September 20,2009.

(2) SM was a laborer, with a history of on the job accidents who had been diagnosed with chronic cervical spine and lower back pain. On March 30, 2009, Respondents dispensed prescriptions for hydromorphone 8 mg (11 day supply) and corisoprodol 350 mg (30 day supply)

to SM. Thereafter he only filled prescriptions for fentanyl troches (a compound medication) on four occasions:

(a) Prescription N552798(April 3, 2009) - 6 day supply
(b) Prescription N553545(April 16, 2009) - 15 day supply
(c) Prescription N555220 (May 15, 2009) - 5 day supply
(d) Prescription N556921(June 11, 2009) - 30 day supply

(3) Fentanyl 1600 mcg troche was a medication compounded for SM by San Ysidro Pharmacy. A troche is a lozenge that is dissolved in the mouth, typically for severe breakthrough pain in patients already taking a narcotic analgesic. The starting dose is 200 mcg for each pain episode. This may be repeated after waiting 15 minutes between doses, maximum of 4 units per day.

(a) Prescription number N555220 was issued with directions of one troche every 4-6 hours as needed for pain. This was a significant increase in dosage compared to two prior prescriptions (one troche every 12-24 hours) dispensed to SM. No documentation indicated the original prescriptions document was clarified with the physician.

(4) On July 1, 2009, SM initiated detox treatment, and was discharged on July 9, 2009 to a rehabilitation program. His prescription history shows he filled multiple prescriptions at other pharmacies on the day he was transferred to the rehabilitation program and in the days prior to his death.

CAUSES FOR DISCIPLINE

FIRST CAUSE FOR DISCIPLINE

(Unlawful Manufacture and Sale of Misbranded Drugs – Domperidone)

27. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, sub-divisions (j) and (o), in conjunction section 4169, sub–division (a)(3) and Health and Safety Code sections 111335 and 111400 due to their compounding of at least 4 batches of the unapproved drug domperidone, and their dispensing to two patients approximately 840 10 mg capsules of the unapproved drug domperidone between April 15 and August 25, 2015.

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SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Sale of Misbranded Drugs - Domperidome)

28. Respondents are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with section 4169, subdivision (a)(3) and Health and Safety Code sections 111335 and 111375, subdivision (c) due to their dispensing to two patients approximately 840 10 mg capsules of the unapproved drug domperidone (compounded by Respondents) between April 15 and August 25, 2015, without adequate warning or notification to consumers that such products were FDA unapproved and potentially dangerous.

THIRD CAUSE FOR DISCIPLINE

(Failure to Implement Electronic Monitoring of Schedule II Prescriptions)

29. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations, section 1715.5 (a) (which mandates specific information be reported for each Schedule II prescription dispensed) in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 Schedule II controlled substance prescriptions dispensed to **Patient AM.**

FOURTH CAUSE FOR DISCIPLINE

(Failure to Timely Comply with Department of Justice Reporting Requirements)

30. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Health and Safety code section 11165(d) (requiring the dispensing pharmacy to report specific information about certain controlled substance transactions within seven days), in that on dates approximately between April 28, 2011 and August 8, 2011, Respondents failed to report to the Department of Justice at least 13 controlled substance prescriptions dispensed to **Patient AM.**

FIFTH CAUSE FOR DISCIPLINE

(Failure to Assume Corresponding Responsibility)

31. Respondents are subject to discipline pursuant to Code section 4300 for

unprofessional conduct as defined in section 4301, subdivision (d), (j) and (o), in conjunction with Health and Safety Code section 11153(a) in that on dates approximately between April 28, 2011 and November 11, 2011, based on evidence reviewed by Board Inspectors, Respondents failed to meet their corresponding responsibility to assure legitimacy prescriptions, in that Respondents ignored and/or failed to appropriately respond to numerous warning signs or red flags that should put a reasonable and prudent dispensing pharmacist on notice that prescriptions for **Patient AM** may not have been legitimate, including but not limited to the patients age in relation to the combination of medications prescribed, the appropriateness of the therapy, the duplicate medications the patient received, the repetitive combination of medications, and the payment method of cash.

SIXTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

32. Respondents are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with title 16, California Code of Regulations section 1761(a) in that on May 15, 2009, Respondent dispensed prescription C555220, written by Dr. Diaz for **Patient SM** for fentanyl troche, without contacting the prescriber for clarification, despite instructions for dosage which exceeded the recommended maximum dose for this medication

DISCIPLINARY CONSIDERATIONS

33. To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

A. **Prior Citation** (Respondent San Ysidro Pharmacy, Inc.) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 2012 56574** was issued to Respondent Pharmacy for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,125.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Offense	Amount of Fine

1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	None
2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date . . .	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

B. **Prior Citation** (Respondent Raymond Steve Hoyt) - On or about January 17, 2014, Administrative Citation/Assessment of Fine No. **CI 201359523** was issued to Respondent Hoyt for violating Codes and Regulations as set forth below, resulting in the issuance of a $1,625.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	**Offense**	**Amount of Fine**
1. CA Code of Regulations (CCR), title 16, § 1716	Variation from prescription	$500.
2. Business and Professions Code § 4070	Reduction of Oral or Electronic Prescription to writing	$500
3 CCR, title 16, § 1735.2, subdivision (h)	Every compounded drug product shall be given an expiration date	$250
4. CCR, title 16, § 1735.2, subdivision (a)	Training of Compounding Staff	$375

OTHER MATTERS

3. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, San Ysidro Pharmacy, Inc.shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if it is revoked.

4. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 46711 issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, while Raymond Steve Hoyt has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, he shall be prohibited from serving as a

manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 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 Permit License Number PHY 46711, issued to San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President);

2. Revoking or suspending Pharmacist License Number RPH 39935, issued to Raymond Steve Hoyt;

3. Prohibiting Respondent San Ysidro Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc.is revoked;

4. Prohibiting Respondent Raymond Steve Hoyt from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46711 is placed on probation or until Pharmacy Permit Number PHY 46711 is reinstated if Pharmacy Permit Number 46711 issued to San Ysidro Pharmacy, Inc.,is revoked;

5. Ordering San Ysidro Pharmacy, Inc., dba San Ysidro Pharmacy, Raymond Steve Hoyt (President) and Raymond Steve Hoyt, as an individual licensee, 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;

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

DATED: 9/12/17

Virginia Herold

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

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