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

In the Matter of the Accusation and Petition to Revoke Probation

Against:

DEL SUR PHARMACY, A CALIFORNIA CORPORATION, dba

FAIRBANKS PHARMACY,

Pharmacy Permit No. PHY 55594;

and

BERNARD J. GRAMLICH,

Pharmacist License No. RPH 53112,

Respondents.

Agency Case No. 7732

OAH No. 2024090015

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 16, 2025.

It is so ORDERED on June 16, 2025.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
E-mail: Amie.Flynn@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation and Petition to Revoke Probation Against: **DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY** **16089 San Dieguito Road # H102** **P.O. Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacy Permit No. PHY 55594,** **and** **BERNARD J. GRAMLICH** **PO Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	Case No. 7732 OAH No. 2024090015 **STIPULATED SURRENDER OF LICENSE AND ORDER AS TO BERNARD J. GRAMLICH ONLY**

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Amie J. Flynn, Deputy Attorney General.

2. Bernard J. Gramlich (Respondent Gramlich) is represented in this proceeding by attorney Edward Idell whose address is: 355 South Grand Ave., Ste. 1750, Los Angeles, California 90071-1562.

3. On or about September 26, 2001, the Board issued Pharmacist License Number RPH 53112 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation and Petition to Revoke Probation No. 7732 and will expire on August 31, 2025, unless renewed.

JURISDICTION

4. Accusation and Petition to Revoke Probation No. 7732 was filed before the Board and the Accusation and Petition to Revoke Probation and all other statutorily required documents were properly served on Respondent on June 12, 2024. Respondent timely filed his Notice of Defense contesting the Accusation and Petition to Revoke Probation. On February 28, 2025, First Amended Accusation and Petition to Revoke Probation were properly served on Respondent and its counsel. A copy of the First Amended Accusation and Petition to Revoke Probation is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation and Petition to Revoke Probation No. 7732. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation and Petition to Revoke Probation; the right to confront and cross-examine the witnesses against him; the right to present

evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

8. Respondent understands and agrees that the charges and allegations in First Amended Accusation and Petition to Revoke Probation Number 7732, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

9. For the purpose of resolving the First Amended Accusation and Petition to Revoke Probation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation and Petition to Revoke Probation and Respondent hereby gives up his right to contest those charges.

10. Respondent understands that by signing this stipulation, he enables the Board to issue an order accepting the surrender of his Pharmacist License Number RPH 53112 and he agrees to be bound by the Board's imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

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

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

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

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

ORDER

IT IS HEREBY ORDERED that Pharmacist License Number RPH 53112 issued to Respondent Gramlich is surrendered and accepted by the Board.

The surrender of respondent's license and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the Board. Respondent understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be treated as if their license was revoked.

Respondent may only seek a new or reinstated license from the Board by way of a petition for reinstatement. Respondent shall petition for reinstatement of a revoked license.

Respondent further stipulates that should he apply for any license from the Board on or after the effective date of this decision, the investigation and prosecution costs in the amount of $59,474.23, shall be paid, jointly and severally with Respondent Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy, to the Board prior to issuance of the new license.

Respondent may not reapply for any license from the Board for three (3) years from the effective date of this decision. Respondent stipulates that should he apply for any license from the Board on or after the effective date of this decision, all allegations set forth in First Amended

Accusation and Petition to Revoke Probation Number 7732 shall be deemed to be true, correct and admitted by respondent when the Board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board. Respondent is required to report this surrender as disciplinary action.

ACCEPTANCE

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

DATED: _____

_____
BERNARD J. GRAMLICH
Respondent

I have read and fully discussed with Respondent Bernard J. Gramlich the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____

_____
EDWARD IDELL, ESQ.
Attorney for Respondent

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Accusation and Petition to Revoke Probation Number 7732 shall be deemed to be true, correct and admitted by respondent when the Board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board. Respondent is required to report this surrender as disciplinary action.

ACCEPTANCE

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

DATED: 5-7-25

BERNARD J. GRAMLICH
Respondent

I have read and fully discussed with Respondent Bernard J. Gramlich the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 5-14-25

EDWARD IDELL, ESQ.
Attorney for Respondent

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ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

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

DATED: May 15, 2025

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

Amie J. Flynn

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation and Petition to Revoke Probation No. 7732

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation and Petition to Revoke Probation Against: **DEL SUR PHARMACY, A CALIFORNIA CORPORATION,** **DBA FAIRBANKS PHARMACY** **16089 San Dieguito Road # H102** **P. O. Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacy Permit No. PHY 55594,** **and** **BERNARD J. GRAMLICH** **PO Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	Case No. 7732 OAH No. 2024090015 **FIRST AMENDED ACCUSATION AND PETITION TO REVOKE PROBATION**

PARTIES

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

2. On May 25, 2017, the Board issued Pharmacy Permit Number PHY 55594 to Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy (Respondent Pharmacy). Bernard J. Gramlich, 50% shareholder, is and has been Chief Executive Officer, President, Secretary and Treasurer/Chief Financial Officer of Respondent Pharmacy since May 25, 2017. Charles Adam Covello, 50% shareholder, is and has been Vice-President of Respondent Pharmacy since May 1, 2017. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2025, unless renewed.

3. On September 26, 2001, the Board issued Pharmacist License Number RPH 53112 to Bernard J. Gramlich (Respondent Gramlich). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2025, unless renewed. Respondent Gramlich is and has been the Pharmacist-in-Charge of Respondent Pharmacy since May 25, 2017.

4. In a disciplinary action entitled "*In the Matter of the Accusation Against Del Sur Pharmacy and Bernard J. Gramlich,"* Case No. 7183, the Board issued Decisions and Orders effective February 8, 2023, in which Respondent Pharmacy's Pharmacy Permit and Respondent Gramlich's Pharmacist License were revoked. However, the revocations were stayed and both Respondent Pharmacy's Pharmacy Permit and Respondent Gramlich's Pharmacist License were placed on probation for five (5) years with certain terms and conditions. A copy of those Decisions and Orders are attached as Exhibit A and are incorporated by reference.

JURISDICTION PROVISIONS

5. This First Amended Accusation and Petition to Revoke Probation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

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

7. Section 4300, subdivision (a), of the Code states:

Every license issued may be suspended or revoked.

8. Section 4300.1 of the Code states:

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

9. Section 4307 of the Code states, in pertinent part:

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

(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.

…

STATUTORY PROVISIONS

10. Section 651 of the Code states:

(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.

…

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, "as low as," "and up," "lowest prices," or words or phrases of similar import. Any advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5)(A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(B) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

…

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

…

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

…

(16) A statement, or statements, providing public health information encouraging preventive or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of health services or commodities. A board or committee shall not, by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

(j) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

…

11. Section 4022 of the Code states:

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

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

….

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

12. Section 4023.5 of the Code states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

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13. Section 4059 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.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

…

14. Section 4070 of the Code states:

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval

of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

15. Section 4076 of the Code states, in pertinent part:

(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

…

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

…

16. Section 4077 of the Code states, in pertinent part:

(a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

17. Section 4078 of the Code states, in pertinent part:

(a)(1) No person shall place a false or misleading label on a prescription.

…

18. Section 4081 of the Code states:

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

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the

pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

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

….

19. Section 4113 of the Code states, in pertinent part:

…

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

…

20. Section 4116, of the Code states, in pertinent part:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

…

21. Section 4126.8 of the Code states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

22. Section 4127.1 of the Code states:

(a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

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(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

…

23. Section 4169 of the Code states, in pertinent part:

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

…

(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 of 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.

…

24. Section 4301 of the Code states, in pertinent part:

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

...

(j) The violation of any of the statutes of this state, of 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...

…

25. Section 4306.5 of the Code states:

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.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

…

26. Section 4341 of the Code states:

Notwithstanding any other provision of law, prescription drugs or devices may be advertised if the advertisement conforms with the requirements of Section 651.

27. Section 4342 of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

…

28. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

29. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

30. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

31. Health and Safety Code section 111300 states:

It is unlawful for any person to adulterate any drug or device.

32. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

33. Health and Safety Code section 111335 states:

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

34. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

35. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

36. Health and Safety Code section 111550 states:

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).

(3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (l) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

REGULATORY PROVISIONS

37. California Code of Regulations (CCR), title 16, (Regulations) section 1707.2 states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all settings:

(1) upon request;

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;

(3) whenever the prescription drug has not previously been dispensed to a patient; or

(4) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

…

38. Regulations section 1735 states:

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

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

(2) Altering the strength of a drug

(3) Combining components or active ingredients

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

…

39. Regulations section 1735.2 states, in pertinent part:

…

(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

…

(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.

…

40. Regulations section 1735.3 states, in pertinent part:

(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.

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(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.

41. Regulations section 1735.4 states:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) - (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy -- Dispose of Properly” or “Hazardous -- Dispose of Properly.”

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42. Regulations section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

43. Regulations section 1735.6 states:

…

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

…

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) (A) For sterile compounding, each BSC or CACI shall be externally exhausted.

(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

…

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44. Regulations section 1735.8 states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

45. Regulations section 1751.1 states:

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

(1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Biannual video of smoke studies in all ISO Class 5 certified spaces.

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(6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) 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 created. 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).

46. Regulations section 1751.6 states, in pertinent part:

…

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

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(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

47. Regulations section 1773 states:

(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:

(1) Obey all laws and regulations substantially related to the practice of Pharmacy;

…

48. Regulations section 1774 states:

(a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:

(1) Obey all laws and regulations substantially related to the practice of pharmacy;

…

UNITED STATES PHARMACOPOEIA

49. The United States Pharmacopeia (USP) is a nonprofit organization that sets standards for medicines, food ingredients, and dietary supplements. The USP standards include tests to ensure the quality, potency, and purity of products. USP Chapter 795 provides minimum guidelines for compounding non-sterile compounded preparations (CNSP) and USP Chapter 800 defines the guidelines for compounding hazardous drug (HD) preparations under sterile or nonsterile conditions. HD is any drug identified by the National Institute for Occupational Safety and Health (NIOSH) as hazardous or potentially hazardous on the basis of at least one of the following criteria: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity.

50. USP Chapter 795 defines components used in compounding as active pharmaceutical ingredient (API) under the following conditions:

• Must comply with the criteria in the USP–NF monograph, if one exists;

• Must have a certificate of analysis (COA) that includes specifications (a document that verifies a product's quality, safety, purity and compliance with regulations, e.g., compendial

requirements for quality) and test results for the component that show the API meets expected quality;

• In the United States, must be manufactured by an FDA-registered facility;

• Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction.

All components other than APIs:

• Should be accompanied by a COA that verifies that the component meets the criteria in the USP–NF monograph, if one exists, and any additional specifications for the component

• In the United States, should be manufactured by an FDA-registered facility (If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select a component that is suitable for the intended use)

• Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction.

51. USP Chapters require a master formula record (MFR) and a compounding record (CR) for every unique compounded product. USP Chapter 795 defines MFR record as, "A detailed record of procedures that describes how the CNSP is to be prepared…CNSPs are prepared according to the MFR, and the details of each preparation are documented on a compounding record. Any changes or alterations to the MFR must be approved and documented according to the facility's SOP [Standard Operating Procedure]."

52. Per USP 795, a MFR must include at least the following information:

• Name, strength or activity, and dosage form of the CNSP,

• Identification and amounts of all components; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility),

• Container closure system(s),

• Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps,

• Physical description of the final CNSP,

• Beyond-use date (BUD) and storage requirements,

• Reference source to support the assigned BUD,

• If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s),

• Labeling requirements (e.g., shake well),

• Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results,

• Any other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature).

53. A CR documents the compounding of each CNSP. A CR must be created for all CNSPs. Each CR must be reviewed for completeness before the CNSP is released. The name or other unique identifier of the person completing the review and the date of the review must be documented on the CR. The CR must permit traceability of all components in the case of a recall or known quality issue. The MFR can be used as the basis for preparing the CR. For example, a duplicate can be made of the MFR with blank fields for recording the information necessary to complete the CR. USP 795 lists the minimum information that must be included in a CR:

• Name, strength or activity, and dosage form of the CNSP

• Date—or date and time—of preparation of the CNSP

• Assigned internal identification number (e.g., prescription, order, or lot number)

• A method to identify the individuals involved in the compounding process and individuals verifying the final CNSP

• Name, vendor or manufacturer, lot number, and expiration date of each component

• Weight or measurement of each component

• Total quantity of the CNSP compounded

• Assigned beyond-use date (BUD) and storage requirements

• If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)

• Physical description of the final CNSP

• Results of quality control procedures (e.g., pH testing and visual inspection)

• MFR reference for the CNSP.

54. USP Chapter 795 defines BUD for different preparations as follows:

Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms		
Nonpreserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms		
Oral Liquids (nonaqueous	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms	180	Controlled room temperature or refrigerator

55. USP chapter 795 section 6.2.2 states that upon receipt of a component (API) the compounder must, at a minimum, document receipt date, quantity received, supplier name, lot number, and expiration date. If the component lacks vendor expiration date, the date of receipt by the compounding facility must be clearly and indelibly marked on each packaging system and must not be used by the compounding facility after 3 years from the date of receipt.

56. USP chapter 795 section 7.2 requires that a compounding record (CR) documents the compounding of each CNSP. A CR must be created for all CNSPs. Each CR must be reviewed for completeness before the CNSP is released. The name or other unique identifier of the person completing the review and the date of the review must be documented on the CR. The CR must permit traceability of all components in the case of a recall or known quality issue. The MFR can be used as the basis for preparing the CR. For example, a duplicate can be made of the MFR with blank fields for recording the information necessary to complete the CR.

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57. USP chapter 795 section 12, defines Quality Assurance (QA) as a system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards and Quality Control (QC) as the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CNSP.

58. USP Chapter 800, section 5.2, requires storage of HD API in an area separate from non-HD in a manner to prevent contamination and personnel exposure. The HDs must be stored in an externally ventilated, negative pressure room with at least 12 air changes per hour (ACPH).

COST RECOVERY FOR FIRST AMENDED ACCUSATION

59. 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.

DEFINITIONS AND GLOSSARY

60. Semaglutide is an FDA approved antidiabetic medication used for the treatment of type 2 diabetes and an anti-obesity medication used for long-term weight management. It is a dangerous drug pursuant to Business and Professions Code section 4022.

61. Semaglutide with L-Carnitine is a non-sterile to sterile compounded medication used as an anti-obesity medication used for long-term weight management with a metabolism booster. It is a dangerous drug pursuant to Business and Professions Code section 4022.

62. Antineoplastics are medicines used to treat cancer and other diseases. It is a general name for drugs that stop tumor cells from growing and dividing.

63. 5-Fluorouracil (5FU) (antineoplastic agent) is a cytotoxic chemotherapy medication used to treat cancer (colorectal, oesophageal, stomach, cancer, breast, and cervical) by intravenous injection. When 5FU is used on the skin, 5FU is used to treat skin cancer and certain types of skin conditions that could become cancer. 5FU is an antineoplastic drug and must be compounded and handled under USP 800 and is classified as a hazardous drug. It is a dangerous drug pursuant to Business and Professions Code section 4022.

64. Xeomin (incobotulinumtoxinA), is an FDA approved acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment or improvement of: chronic sialorrhea in patients 2 years of age and older, upper limb spasticity in adults, upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy, cervical dystonia in adults, blepharospasm in adults, temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity in adults. It is a dangerous drug pursuant to Business and Professions Code section 4022.

65. Botox Cosmetic (onabotulinumtoxinA) is an FDA approved acetylcholine release inhibitor and a neuromuscular blocking agent indicated in adult patients for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity, moderate to severe lateral canthal lines associated with orbicularis oculi activity, moderate to severe forehead lines associated with frontalis muscle activity. It is a dangerous drug pursuant to Business and Professions Code section 4022.

66. Cyanocobalamin is an FDA approved synthetic compound of vitamin B12 used to treat vitamin deficiencies. It is a dangerous drug pursuant to Business and Professions Code section 4022.

67. Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body.

68. Beyond-use date (BUD): The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.

69. Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.

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70. Compounded non-sterile preparations (CNSP): preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.

71. Compounding record (CR): Documents the compounding of each CNSP.

72. FDA: US Food and Drug Administration.

73. Hazardous drug (HD): any drug identified by the National Institute for Occupational Safety and Health (NIOSH) as hazardous or potentially hazardous on the basis of at least one of the following criteria: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity.

74. Master formulation record (MFR): A detailed record of procedures that describes how the CNSP is to be prepared.

75. Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

76. Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.

77. Standard Operating Procedure (SOP).

INTRODUCTION

78. This case involves allegations of various pharmacy compounding violations by Respondents resulting initially from two separate investigations and three subsequent inspections which resulted in additional violations. Despite never being licensed as a sterile compounding pharmacy, Respondent Gramlich conducted sterile compounding from at least December 23, 2019, through August 16, 2023, and failed to review the compounding policies and procedures annually. Of note, the last review was in 2017. The first investigation involved Respondent Gramlich compounding non-sterile to sterile injectable drug preparations of Semaglutide with L-Carnitine Injection for use in the "medspa" located within Respondent pharmacy and owned by Respondent Gramlich. The second investigation involved Respondents' non-sterile compounding practices. Probation compliance inspections uncovered additional law violations by Respondent

Pharmacy and Respondent Gramlich.

79. Pharmacy compounding is when a licensed pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs of an individual patient.

80. Typically, pharmacies compound in order to meet the unique needs of an individual patient (either human or animal) when a Food and Drug Administration (FDA) approved commercially available drug does not meet those needs. This may consist of creating entirely new drugs by mixing them from bulk chemicals or it may consist of simply altering an existing "finished drug" by removing or altering an ingredient (such as a dye or other inactive ingredient to which a particular patient is sensitive or allergic). Compounded drug products may include topical creams intended for use on the skin, eye drops, pills or tablets intended for oral ingestion, or injectable products that may be intended for injection via subcutaneous, intramuscular (IM), or intravenous (IV) methods. Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.]. Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by section 503A of the FDCA [21 U.S.C. § 353a].

81. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

82. There is a great risk to consumers if poor compounding practices are used. Poor compounding practices can result in serious drug quality problems, including contaminants in the drug, such as heavy metals, toxins, and bacterial growth. Additionally, poor compounding practices can lead to the creation of a drug that contains too much or too little active ingredient. This can lead to serious patient injury and death.[1] Unnecessary use of compounded drugs

[1] An example of the dangerousness of poor compounding practices that led to patient injury was the infamous New England Compounding Center (NECC) tragedy. In 2012, NECC, a compounding pharmacy in Massachusetts shipped nationwide (to at least 20 states, including California), compounded sterile injectable steroids that were contaminated with a fungus. The (continued…)

needlessly exposes patients to potentially serious health risks.

83. FDA approved drugs are extensively reviewed by the FDA for safety, effectiveness, and quality during the approval process. This approval process is extensively relied upon by consumers and health professionals in the United States. Compounded drugs are not FDA approved. This means that the FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients. (https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.) Unfortunately, compounded drug preparations are sometimes misleadingly marketed as having met the standards for FDA approval when they have not actually done so, as in this case. While the FDA oversees drug manufacturing, it does not license pharmacies or pharmacists, nor control when or how their licenses permit compounding. The states issue these licenses and have primary jurisdiction. The states also set compounding standards that complement FDA standards for compounding as a form of drug manufacturing.

84. California law authorizes the Board to treat violations of federal statutes regulating controlled substances and dangerous drugs, as well as federal laws and regulations governing pharmacy practice, as grounds for discipline. (Bus. & Prof. Code, § 4301, subds. (j), (o).)

85. California law allows all licensed pharmacists to compound *non-sterile* drug products in licensed pharmacies. (e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.) All compounding must be consistent with standards in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.)

86. The United States Pharmacopeia (USP) is a nonprofit organization that sets standards for medicines, food ingredients, and dietary supplements. The USP standards include tests to ensure the quality, potency, and purity of products. USP Chapter 795 provides minimum guidelines for compounding non-sterile compounded preparations (CNSP) and USP Chapter 800

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preparations led to an outbreak of resistant spinal meningitis killing over 100 people in 9 states (with approximately another 793 people confirmed sick). [See FDA Press Release: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following]

defines the guidelines for compounding hazardous drug (HD) preparations under sterile or nonsterile conditions. HD is any drug identified by the National Institute for Occupational Safety and Health (NIOSH) as hazardous or potentially hazardous on the basis of at least one of the following criteria: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity.

87. The Pharmacy Law also contains additional standards that supplement the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq*., 4128 *et seq*., 4129 *et seq*., Cal. Code Regs., tit. 16, §§ 1735 *et seq*., 1751 *et seq*.)

88. An additional specialty license is required before any licensed pharmacy is allowed to compound sterile drug products (Bus. & Prof. Code, § 4127 et seq.) and particular regulatory requirements apply to preparation, maintenance, and distribution of sterile drug products. (Cal. Code Regs., tit. 16, § 1751 et seq.; see also Cal. Code Regs., tit. 16, § 1735 et seq.) Each sterile compounding pharmacy must be inspected prior to each annual renewal of a sterile compounding license to ensure compliance with all compounding and sterile compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) One of the highest risk types of compounding is compounding sterile injectable drug products. Any drug product that is intended to be injected into the body is required to be sterile because the preparation is delivered directly into a sterile area of the body, thus increasing the chances of infection or other negative outcomes. All of this demonstrates the attention and resources devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug products.

89. In this case, Respondent Gramlich engaged in unlawful compounding of a drug preparation intended for sterile administration, namely Semaglutide with L-Carnitine Injection. Semaglutide with L-Carnitine Injection is a non-sterile to sterile injectable drug preparation which is commonly prescribed for weight loss. Respondent Gramlich compounded this sterile preparation without an understanding of, or meeting the minimum practice standards in USP chapter 797, Pharmaceutical compounding - sterile preparations, as required. Respondents also advertised on social media a weight loss program which included the compounded Semaglutide

with L-Carnitine Injection, and claimed this compound was FDA-approved for weight loss. Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs.

90. The second inspection involved Respondents' non-sterile compounding practices, including but not limited to, the unsafe handling of hazardous drugs (HDs), such as fluorouracil (5FU), a lack of and poor record keeping, improper storage of drugs, offering for sale adulterated and misbranded drugs, incorrect assignment of beyond use date (BUD), incorrectly labeling compounded preparations, failure to follow the pharmacy's own policies and procedures, and, failure to maintain a current inventory of dangerous drugs.

91. The Board's probation compliance inspections uncovered additional law violations by Respondents, including but not limited to, compounding sterile products without being licensed to do so, failing to store hazardous drugs separate from non-hazardous drugs, selling pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law of Division 104 of the Health and Safety Code, offering for sale misbranded drugs, failing to maintain accurate compounding records, failing to maintain master formula records, incorrectly assigning BUD, failing to correctly label compounded preparations, failing to ensure compounding quality control and assurance, and offering for sale adulterated drugs.

FACTUAL ALLEGATIONS

92. Respondent Gramlich owns and operates a pharmacy in Rancho Santa Fe, California. Effective February 8, 2023, Respondent Pharmacy and Respondent Gramlich were placed on five years' probation for 1) failure to transmit cures data as required, 2) unprofessional conduct – violating state laws and regulations governing pharmacy, 3) erroneous or uncertain prescriptions, 4) unauthorized furnishing of dangerous drugs, 5) failure to review drug therapy and patient medication record, 6) failure to provide consultation, 7) dispensing of prescription label with the wrong prescriber, and, 8) failure of the pharmacist to adhere to approved protocol.

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93. The Accusation in the matter leading to Respondents' probation arose from events that occurred from 2018 through 2019. The stipulated settlement whereby Respondents agreed to probation was entered into on November 5, 2022. The first inspection giving rise to the Accusation and the Petition to Revoke Probation was completed May 17, 2023. The second inspection was completed on August 16, 2023. Therefore, the first two investigations in the Accusation and Petition to Revoke Probation were not completed until after the stipulated settlement was executed and under consideration by the Board, and none of the charges could have been brought in that proceeding.

94. On June 4, 2024, Board Inspectors S.S. and S.F. conducted a probation compliance inspection of the pharmacy.

95. On July 18, 2024, Board Inspectors S.S. and S.F. performed a follow-up inspection of the June 4, 2024, inspection and conducted a probation compliance inspection of the pharmacy.

96. On September 3, 2024, Board Inspector S.F. conducted a joint inspection of the pharmacy with Drug Enforcement Agency (DEA) agents.

May 17, 2023, Inspection

97. On or about April 12, 2023, the Board received an online complaint from consumer Q.V. regarding Respondent Pharmacy's lack of consultation for her husband's new medication.

98. On May 17, 2023, Board Inspector K.S. conducted an inspection of the pharmacy and noted business signage outside the pharmacy on the front door which read, "Fairbanks Pharmacy and Med Spa." Respondent Gramlich was present and assisted the Board Inspector throughout the duration of the Board Inspector's visit. The Board Inspector also noted that an establishment license was issued for this same address by the Board of Barbering and Cosmetology for Fairbanks Day Spa (Day Spa), with license number A313l68. This license was placed in public view adjacent to the pharmacy permit.

99. When asked about the licensed Day Spa, Respondent Gramlich stated he was the co-owner. The Board Inspector asked why he had signage indicating it was a "Med Spa" when it was licensed as a Day Spa, and Respondent stated that it "was operated under the authority of a Medical Director." There was a locked door separating the "Med Spa/Day Spa" from the

pharmacy area where dangerous drugs and records were kept. When the Board Inspector inspected the pharmacy area, she noted prescriptions labelled "Fairbanks Med Spa." The Board Inspector also noted that inside the pharmacy dispensing area, in the rear was a walled off area designated for non-sterile compounding, with a door that led into a stocking area, then a separate door that led into a single compounding room. Respondent Gramlich stated he compounded both hazardous (hormones) and non-hazardous products. There was one negative pressure and external vented compounding hood.[2] Respondent Gramlich explained that he alternates days he compounds non-hazardous and hazardous non-sterile compounds. Respondent Gramlich stated he did not compound any antineoplastic products, but did consider those drugs currently listed in the National Institute for Occupational Safety and Health, 2016 (NIOSH) tables 2 and 3 as hazardous. (https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.)[3] Drugs are classified as hazardous if they possess characteristics such as genotoxicity, organ toxicity, teratogenicity or development toxicity, reproductive toxicity and carcinogenicity.

100. The compounding room and the compounding hood were last certified by TSS on November 7, 2022.

101. Inside the pharmacy freezer, the Board Inspector saw used sterile water for injection and ten vials labeled as: "Semaglutide/L Carnitine 2.6mg-100mg Coastal Wellness, Fairbanks Med Spa." Records showed Respondents ordered the ingredients for the compounding of the Semaglutide with L-Carnitine 2.6mg/100mg injections. Respondent Gramlich stated that the compounded sterile preparations (CSP) belonged to Dr. R.C. and not the Respondents, however no records of sales for the ingredients were provided to support this claim. Respondents had no knowledge of the FDA's requirements of compounding with Semaglutide, however, Respondents had advertised the CSP as having been "FDA approved."

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[2] A pharmacy compounding hood is a device used to mix compounds. It includes containment ventilated enclosures (CVEs) such as powder hoods, biological safety cabinets, and compounding aseptic containment isolators.

[3] The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) updated its list of hazardous drugs in 2016 to include 34 drugs which were compiled from lists of information from four institutions that generate lists of hazardous drugs for their respective institutions.

102. The Board Inspector requested the following which were not available for review - records relating to analytical testing of compounded products as part of the pharmacy quality reviews and current Basic Life Support certification.

August 16, 2023, Inspection

103. On August 16, 2023, Board Supervising Inspector C.A., along with Board Inspector K.S., conducted an inspection at Respondent Pharmacy due to Respondents' probation status and as a follow up to the May 17, 2023, inspection.

104. During the inspection, in response to why the containment ventilated enclosure (CVE) was off, Respondent Gramlich stated that he did not believe it needed to run all the time, in contrast to Respondent Pharmacy's Standard Operating Procedures (SOPs) which required the CVE to run continually.

105. During the inspection, it was noted that Respondent Pharmacy's SOP for hazardous drugs was not being followed; the SOP for nonsterile compounding area were not being followed, and Respondents were not compliant with United States Pharmacopeia chapter on non-sterile compounding, USP 795, (e.g. garb as described is not worn, the powder containment hood was turned off, etc.); the SOP for nonsterile hazardous drug compounding area was not being followed; the retest date for the TSS certification reports was May 8, 2023, but no documentation of the room or equipment re-certification was available; the lot number recorded on the compounding logs do not correlate to the log used in the compounding logs received on inspection; the data to support the sustained release, "SR," was not provided; the dispensing labels for prescriptions did not show the lot number dispensed, the date compounded and each had a "discard" date of one year from the fill date; an open vial of Xeomin was found in the pharmacy's refrigerator and 4 boxes of BOTOX Cosmetic (onabotulinumtoxinA) were found in the pharmacy's freezer; an open vial of Cyanocobalamin 1000mcg/ml 10ml was located in the consultation room, an open vial was located on the counter, and a box of Cyanocobalamin was located in the cupboard of the consultation room.

106. Board Inspector K.S. issued an Inspection Report dated August 16, 2023, to Respondent Gramlich requesting documentation relating to Respondents' compounding activities.

Board Inspector K.S. also issued an Official Receipt, Number 390276, documenting items received from Respondents during the August 16, 2023, inspection.

107. On October 26, 2023, Respondents provided documentation to the Board. Board Supervising Inspector C.A. reviewed and analyzed Respondents' compounding records. The investigation revealed that Respondent Pharmacy and Respondent Gramlich were in violation of multiple pharmacy laws and regulations.

108. From August 16, 2023, to October 26, 2023, Respondents provided additional documentation and clarifications to the Board's Inspectors.

June 4, 2024, Inspection

109. During the June 4, 2024, probation compliance inspection of the pharmacy, Respondent Gramlich stated to Board Inspector S.S. that the HDs were stored separately in a cabinet in the compounding room. Upon inspection, however, it was discovered that the HDs were comingled with non-HD products. The cabinets contained HD APIs such as anastrozole, finasteride, testosterone, tretinoin, and compounded estriol 10%, as well as non-HD APIs such as salicylic acid, phenylephrine, hydroquinone, fluocinolone, minoxidil, trazodone, and compounded T4 and T3 preparations. Respondent Gramlich stated that he presumed they were all HD products.

110. Board Inspectors S.S. and S.F. inspected the API containers stored on the shelves and cabinets of the compounding room and saw several containers that did not bear a manufacturer expiration date and did not have the pharmacy's receipt date. A few containers had their label discolored from white to yellowish-tan and lacked expiration dates. In addition, several compounding components on the active inventory shelves were found to be expired. A few of the liquid bottles had syringes attached to them which appeared dirty and stained. Respondent Gramlich acknowledged that he kept the syringes on the bottles to reuse them for measuring.

111. Board Inspectors S.S. and S.F. also noticed a container with a PCCA manufacturer label which was crossed off with a marker and the following words were written on the container: "Hypromellose USP Medisca 3223-01 197163 2/25". The actual PCCA label on the container read, "PCCA Methocel E4M Premium CR (Hypromellose USP)." When the Board Inspectors

questioned Respondent Gramlich about this, he stated he transferred Hypromellose from its original Medisca container to PCCA's container because the original container was too large to handle for compounding. He explained he often transferred components from larger to smaller containers for ease of handling and use.

112. Board Inspector S.S noted that the following products did not bear an expiration date: PCCA Mequinol Lot# C197617; PCCA Mandelic Acid (DL) Lot# C190499; and PCCA Resorcinol USP Lot# C182551; it was not clear when the pharmacy received these products, and there was no beyond use date marked on the products.

113. Board Inspectors S.S. and S.F. also noted vials of Sterile Water for Injection on the shelves, which are normally used in compounding sterile products. Respondent Fairbanks Pharmacy is not equipped to conduct sterile compounding.

114. RX 63651 for MI was observed at the will-call area, ready to be dispensed, with an incorrect beyond use date (BUD). The BUD on the label was May 29, 2025, whereas it should have been 180 days or less from the compounded date of May 29, 2024. The maximum BUD on this preparation should have been November 29, 2024.

115. Board Inspector S.F. inspected the refrigerator and freezer contents. In the freezer, there was a disposable coffee cup which had three vials of frozen product inside.

• Two of the vials were labeled with the following:

"Tirzepatide 16.6 mg/ml Levocarnitine 100mg/ml 10ml. Lot: 52824SR2 EXP: F= 11/24 T= 30 days Keep Refrigerated Made by: Coastal Wellness"

• The third vial was labeled with the following:

"Tirzepatide 16.6mg/ml Levocarnitine 100mg/ml 10ml Lot: 240429SR1 EXP: F=10/24 T= 30 days Keep Refrigerated Made by: Coastal Wellness".

There were no seals on any of the vials. When the Board Inspectors inquired about the vials, Respondent Gramlich stated that they belonged to Dr. R.C. who had asked him to store them at his pharmacy. The Board Inspectors then asked whether he had any information about these compounded vials, to which he responded that he did not. Respondent Gramlich stated he did not have any acquisition records and did not know where they were compounded. Respondent

Gramlich apparently tried to contact Dr. R.C. during the inspection, but did not receive a response.

116. On June 5, 2024, Respondent Gramlich emailed Board Inspector S.S. a copy of what he called "invoice from Dr. Cohen" with the following information:

"Coastal Wellness INVOICE
[R.C.] M.D.
11230 Sorrento Valley RD Suite 120
San Diego, CA 92121
Phone: 858-345-1055 INVOICE:
Fax: 858-345-4828 DATE: 05/28/21

To:
Fairbanks Day Spa FOR:
16089 San Dieguito Rd Consultation Services
Rancho Santa Fe, Ca 92067
San Francisco, CA 78910
Description: Tirzepatide 16.6mg/L-Carnitine 100mg, Quantity 3

Note: Please store bottles in freezer.

Thank you for your business!"

Board Inspector S.S. noted Fairbanks Day Spa's address also had "San Francisco, CA 78910" and the invoice was dated "05/28/21." Tirzepatide was approved by the FDA for the treatment of diabetes in May 2022 and for weight loss on November 8, 2023. Prior to May 2022, it was not available on the market.

117. Board Inspector S.F. also noted a packet marked with the following information: StarWest Botanicals, Item #209345-51, Gotu Kola Herb Powder Organic, Centella Asiatica, Origin: India, Processed, packaged and quality tested in California, USA. Respondent Gramlich stated he did not have any acquisition record or Certificate of Analysis (COA) for this product. He stated a customer had personally purchased it and brought it the pharmacy to be used as a component in the patient's compounded preparation. However, Respondent Gramlich could not provide any master formula record or compounding record for this product. He claimed he had not used it. (Gotu Kola is claimed to be effective for minor burns, psoriasis, reducing stretch marks/scars, improvement of circulations, and boosting of cognitive function.)

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118. USP chapters require a master formula record (MFR) and a compounding record (CR) for every unique compounded product. Board Inspectors S.S. and S.F. reviewed several MFR and CR records. Respondent Gramlich stated he used a number of references for obtaining MFRs.

119. Respondent Gramlich was inconsistent with using accurate MFRs. The Board Inspectors reviewed CRs, which all lacked the name of vendor or manufacturer of the components. Respondent Gramlich stated he assumed that the NDC number of the API was sufficient. The CRs also lacked accurate final quantity, accurate BUD expressed in MM/DD/YY, physical description of final CNSP, quality review documentation, and reference to MFRs.

120. Board Inspector S.F. picked a CNSP from the will-call area and asked Respondent Gramlich to provide the MFR and CR for that specific product. The order was for 45gm of Ivermectin 1% cream. Respondent Gramlich provided MFR from PCCA (Professional Compounding Centers of America) for Ivermectin 1%/ Ketotifen 0.05% cream 100gm (with expiration date of 35 days) and stated that he used this formula to compound the Ivermectin cream. The Board Inspectors explained to Respondent Gramlich that this Ivermectin needed to have its own specific MFR. Respondent Gramlich had indicated on the CR that he made 47.7gm of Ivermectin cream on May 29, 2024, with a BUD date of June 2024. However, the label showed the expiration date as "Exp: 5/29/2025." Respondent Gramlich stated the database automatically printed each label with a one year expiration date from the processing date, and he forgot to change the date on the label. The Board Inspectors explained that the expiration dates are determined by manufacturers and that BUDs are determined by the compounding pharmacist according to the established MFR. Respondent Gramlich stated he was too busy doing everything and forgot to correct the dates.

July 18, 2024, Inspection

121. On July 18, 2024, Board Inspectors S.S. and S.F. performed a follow-up inspection of the June 4, 2024, inspection and conducted a probation compliance inspection of the pharmacy.

122. Upon spot-checking a few CRs, the Board Inspectors noted that PIC Gramlich had started documenting the lot numbers and expiration dates of the ingredients. However, they still

lacked all of the required documentation such as the name of the manufacturers. Respondent Gramlich stated he was trying to complete them as he compounded, but he had a lot to do and did not have time to do it all. Inspector S.F. again explained to Respondent Gramlich the USP Chapter 795 and Board's requirements for MFR and CR.

123. The inspection confirmed from the June 4, 2024, inspection that compounding records continued to have multiple deficiencies by Respondents in maintaining accurate compounding records.

124. The inspection confirmed from the June 4, 2024, inspection that Respondents continued to compound preparations without first preparing a written Master Formula Records.

125. Rx 60845 for R.J. was observed at the will-call area, ready to be dispensed, with an incorrect beyond use date (BUD). The BUD on the label was July 17, 2025, whereas it should have been 180 days or less from the compounded date of July 17, 2024. The maximum BUD on this preparation should have been January 17, 2025.

126. The inspection revealed that Respondents lacked compounding quality assurance and control. Respondent Gramlich had compounded progesterone 50mg SR capsules on July 21, 2023, and sent them to ARL Bio Pharma (ARL) for analytical evaluations. The results of the analytical evaluations showed that the capsules tested out of the acceptable +/- 10% allowable variability from the intended strength. This issue was reported in previous investigations. The lab had conducted an out-of-specification investigation and confirmed the results. Respondent Gramlich did not provide any further explanation or corrections to the Board.

127. The inspections revealed that Respondent Pharmacy was not compliant with the term of probation, "Obey All Laws." Specifically on June 4, 2024 and July 18, 2024, Board Inspectors S.S. and S.F. determined that that Respondent Pharmacy violated BPC section 4126.8/USP 800 section 5.2, BPC section 4342(a)/BPC section 4301(o)/HSC section 111440, BPC section 4169(a)(2)/Regulations section 1735.2/USP 795 section 6.2.2, Regulations section 1735.3(a)/USP 795 section 7.2, Regulations section 1735.2(e)-(i)/USP 795, BPC section 4126.8/BPC section 4077(a), USP 795 section 12/Regulations section 1735.8(a) and (d), BPC

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section 4169(a)(2)/HSC sections 111255, 111295, 111300, as described and set forth above in violation of Regulations section 1774(a)(1).

128. The inspections revealed that Respondent Gramlich was not compliant with the term of probation, "Obey All Laws." Specifically on June 4, 2024 and July 18, 2024, Board Inspectors S.S. and S.F. determined that Respondent Gramlich violated BPC section 4126.8/USP 800 section 5.2, BPC section 4342(a)/BPC section 4301(o)/HSC section 111440, BPC section 4169(a)(2)/Regulations section 1735.2/USP 795 section 6.2.2, Regulations section 1735.3(a)/USP 795 section 7.2, Regulations section 1735.2(e)-(i)/USP 795, BPC section 4126.8/BPC section 4077(a), USP 795 section 12/Regulations section 1735.8(a) and (d), BPC section 4169(a)(2)/HSC sections 111255, 111295, 111300, and Regulations section 1774(a) as described and set forth above in violation of Regulations section 1773(a)(1).

September 3, 2024, Inspection

129. On September 3, 2024, Board Inspector S.F. returned to Respondent Pharmacy for a joint inspection with the Drug Enforcement Agency. They were met and assisted by Respondent Gramlich. During the course of that inspection, Inspector S.F. discovered three glass vials contained in a plastic bubble bag in Respondent Pharmacy's freezer, without any evidence that this product was compounded in the required environment and no recordkeeping of any sort, including acquisition records, was available for the compounded product. The three glass bottles had a pre-printed label that had the following: "Sterile Empty Vial 10ml." They each also had the following written by hand: "SemA 41524 (illegible) 10/24."

130. Board Inspector S.F. noted that the three glass vials were inappropriately labeled.

Causes for Discipline Relating to May 17, 2023, Inspection

FIRST CAUSE FOR DISCIPLINE

(Adulterated Preparations)

131. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, a Code section 4113, subdivision (c), in that Respondents violated Code section 4169, subdivision (a)(2), and Health and Safety Code sections 111250, 111255, 111295, 111300,

and 111550, by manufacturing (compounding), holding or offering for sale adulterated drugs as set forth more fully above in paragraphs 97 through 102. The circumstances are that Respondents compounded ten vials of a sterile compounded product from non-sterile ingredients, without supporting evidence that the product was compounded in the required environment and without appropriate recordkeeping of the compounded product which were only labeled Semaglutide/L Carnitine 2.6mg/100mg Coastal Wellness Fairbanks Med Spa.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Compounding Quality Assurance)

132. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.8, subdivision (c), as set forth more fully above in paragraphs 97 through 102, by routinely making and dispensing compounded prescriptions between December 23, 2019 and August 16, 2023, when the compounded product was not sent for qualitative and quantitative analysis until May 18, 2023.

THIRD CAUSE FOR DISCIPLINE

(Misbranded Drugs)

133. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in that Respondents violated Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330, 111335, 111440, 111445, and 111550, as set forth more fully above in paragraphs 97 through 102, by misbranding drugs. The circumstances are that Respondents compounded ten vials of a sterile compounded product from non-sterile ingredients, which were misbranded in that the vials were inappropriately labelled only as Semaglutide with L-Carnitine 2.6mg/100mg Coastal Wellness Fairbanks Med Spa.

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FOURTH CAUSE FOR DISCIPLINE

(Prevent Sales of Preparations or Drugs Lacking Quality of Strength; Penalties for Knowing or Willful Violation of Regulations Governing Those Sales)

134. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, and Code section 4113, in that Respondents violated Health and Safety Code sections 111330, 111440, 111445, and 111550, as set forth more fully above in paragraphs 97 through 102, when it purchased, labeled (misbranded), held and offered for sale: Semaglutide with L-Carnitine 2.6mg/100mg Coastal Wellness Fairbanks Med Spa.

FIFTH CAUSE FOR DISCIPLINE

(Advertisement of Prescription Drugs)

135. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in that Respondents violated Code sections 4341 and 651(a)(b)(1), as set forth more fully above in paragraphs 97 through 102, by advertising on social media a weight loss program of Semaglutide with L-Carnitine Injection which claimed it was FDA-approved for weight loss. Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs.

SIXTH CAUSE FOR DISCIPLINE

(Compounding Policies and Procedures)

136. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Section 4301, subdivision (o), for violating regulations governing the practice of pharmacy, and Section 4113, subdivision (c), for failing to ensure compliance with all laws, in that Respondents violated Regulations section 1735.5, subdivision (b), as set forth more fully above in paragraphs 97 through 102, by failing to annually review compounding policies and procedures. Specifically, Respondent compounded prescriptions routinely from December 23, 2019, through August 16, 2023; however, as of the inspection on May 17, 2023, the most recent documented review of the compounding policies and procedures was performed on August 13, 2017.

SEVENTH CAUSE FOR DISCIPLINE

(Labeling of Compounded Drug Preparations)

137. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.4, subdivision (a), as set forth more fully above in paragraphs 97 through 102, and as follows: ten vials of a non-sterile to sterile injectable product discovered labelled only as Semaglutide/LCarnitine 2.6mg/100mg Coastal Wellness Fairbanks Med Spa.

EIGHTH CAUSE FOR DISCIPLINE

(Sterile Compounding Recordkeeping Requirements)

138. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in that Respondents violated Code section 4070, subdivision (c), and Regulations sections 1751.1 subdivisions (a)(11), (b) and (c), 1735.2, and 1735.3, as set forth more fully above in paragraphs 97 through 102, and as follows: Respondent Gramlich compounded ten vials of a non-sterile to sterile injectable preparations, Semaglutide/LCarnitine 2.6mg/100mg, Coastal Wellness, Fairbanks Med Spa. These ten vials were found in the pharmacy freezer. Respondents produced invoice records (#43561 dated March 21, 2023, and #40898 dated January 12, 2023) for the active pharmaceutical ingredient (API) semaglutide sodium salt which identified the purchaser as Fairbanks Pharmacy; however, no documentation of a master formula, compounding log, records of end-product evaluation testing/results or lot number were available.

NINTH CAUSE FOR DISCIPLINE

(Training of Sterile Compounding Staff)

139. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1751.6, subdivisions (b) and (c), as set forth more fully above in paragraphs 97 through 102, and as follows: ten vials of a compound non-

sterile to sterile injectable Semaglutide with Carnitine 2.6mg/100mg were found in the pharmacy during an inspection. Respondent Gramlich stated he compounded the sterile products from a non-sterile active pharmaceutical ingredient (API). However, Respondent Gramlich could not produce training records demonstrating competence in the safe handling and compounding of sterile drug preparations during the inspection on May 17, 2023, and again when asked on August 16, 2023.

TENTH CAUSE FOR DISCIPLINE

(Violation of Requirements for Labeling Prescription Container)

140. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in that Respondents violated Code sections 4076, subdivision (a)(6), and 4078, subdivision (a)(1), by not following requirements for labeling prescription containers as set forth more fully above in paragraphs 97 through 102. Specifically, Respondents dispensed dangerous drugs in containers prior to May 8, 2023, and through August 16, 2023, with prescription labels naming the pharmacy as Fairbanks Pharmacy & Med Spa. The licensed name of the pharmacy permit is Fairbanks Pharmacy, and there was no DBA (doing business as) filed as Fairbanks Pharmacy & Med Spa.

ELEVENTH CAUSE FOR DISCIPLINE

(Acts or Omissions by Pharmacist: Unprofessional Conduct as to Respondent Gramlich Only)

141. Respondent Gramlich is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, in that Respondent Gramlich violated Code section 4306.5, subdivisions (a) and (b), and Regulations sections 1735.2, 1735.4, 1735.5, subdivision (b), 1751.1 subdivisions (a), (b) and (c), and, 1751.6 subdivisions (b) and (c), as set forth more fully above in paragraphs 97 through 102, and as follows: Respondent Gramlich participated in the acquisition, compounding and offering for sale of a non-sterile to sterile compounded product which was not properly labeled and was not compounded in compliance with the minimum

practice standard in the United States Pharmacopeia chapter on sterile compounding, USP 797, and did not conform with labeling or recordkeeping requirements. Additionally, Respondent Gramlich advertised on social media a weight loss program of Semaglutide with L-Carnitine Injection which claimed it was FDA-approved for weight loss. Compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs.

Causes for Discipline Relating to August 16, 2023, Investigation

TWELFTH CAUSE FOR DISCIPLINE

(Incorrectly Assigned Beyond Use Date, Assignment of a Date or Date and Time)

142. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated California Code of Regulations, title 16, section 1735.2 (i), as set forth more fully above in paragraphs 103 through 108, by incorrectly assigning beyond use dates, assignment of a date or date and time. Specifically, Respondents failed to give a date or time beyond which the compounded drug preparation should not be used, stored, transported, or administered on the following non-sterile compounded drug preparations:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount
2/1/23	None	2423bg1	147738	Estradiol 1.5mg cap	180 days (no date)	90
1/18/23	None	21423bg3	147372	Sertraline 200mg susp	30 days (no date)	150
1/31/23	None	2223bg4	147709	DHEA 7-Keto 10mg caps	180 days (no date)	30
1/30/23	389	2223bg3	147664	Estradiol 1mg/ml cream	30 days (no date)	30
1/23/23	424	12023bg10	146612	Progesterone 75 mg SR Cap	None	30
1/30/23	none	2223bg1	147665	DHEA 10mg SR Capsules	180 days (no date)	30
1/30/23	None	2223bg2	147662	Progesterone 100mg SR	180 days (no date)	30
2/1/23	20	2223bg7	147745	T4 38mcg/T3 9MCG SR cap	180 days (no date)	270
2/1/23	None	2423bg3	147719	T4 150mcg T3 10mcg SR V-Cap	180 days (no date)	45
1/30/23	280	2223bg6	143033	Metronidazole 100mg/ml	30 days (no date)	120
2/1/23	none	2223bg8	147716	Progesterone 100mg SR cap	180 days (no date)	30
2/2/23	99	2923bg3	147775	Progesterone 150mg SR Cap	180 days (no date)	90
2/1/23	None	2223bg5	147735	E2-E3 80/20 5mg/ml	30 days (no date)	30
2/4/23 (compounded date)	526	2423bg2 2423bg1	None	Estradiol 1.5mg SR Cap	180 days (no date)	Unknown
2/4/23	None	2923bg2	147813	Progesterone 100mg SR caps	180 days (no date)	90
2/6/23	None	2923bg2	147816	Progesterone 100mg SR caps	180 days (no date)	90
2/6/23	None	2723bg8	147856	Fluorouracil 2%/SA 17% cream	30 days (no date)	30
2/6/23	None	2723bg11	145350	T4 25mcg/T3 15MCG SR cap	180 days (no date)	90
2/6/23	None	2723bg12	145080	DHEA 10mg SR cap	180 days (no date)	60
Not on log possible 2/7/23	None	2723bg5	None on log Dispensing show 147719	T4 150mcg/T3 3MCG SR V-CAP	180 days (no date)	None on log Likely 100
2/7/23	None	2723bg5	146437	Boric Acid 600mg vag caps	180 days (no date)	24
2/8/23	99	2923bg3	147164	Progesterone 150mg SR Caps	180 days (no date)	30
2/8/23	None possibly 2923bg2	Not requested	147911	Progesterone 100mg SR Caps	180 days (no date)	90

2/8/23	none possibly 2923bg7	Not requested	146847	E2 0.5mg E3 2mg crm	30 days (no date)	30
2/9/23	11	2923bg9	147927	Testosterone 2% cream	30 days (no date)	30
2/9/23	204	2923bg6	144135	Estriol 2mg/gm Vag cream	30 days (no date)	30
2/10/23	204	21523bg2	144839	Estriol 2mg/gm Vag cream	30 days (no date)	30
2/9/23	none	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90days (no date)	90
2/9/23	298	21323bg4	142081	T4 15mcg/T3 3mcg cap	180 days (no date)	90
2/9/23	None	2923bg1	147932	T4 25mcg/ml Sol	30 days (no date)	32
2/9/23	151	21023bg4	147953	Dilt 2%/LID 1.5%/ Crm	30 days (no date)	30
2/10/23	183	21023bg3	147975	Testosterone 20mg/gm cream	30 days (no date)	30
2/10/23	295	21523bg1	144818	Naltrexone 4.5mg/ml	30days	90
2/10/23	204	21523bg2	144839	Estriol 2mg/gm vag cram	30 days (no date)	30
2/10/23	None	21323bg1	145665	T4 19mcg/T3 4.5mcg cap	180 days (no date)	90
2/10/23	None	21023bg1	147970	Omeprazole 10mg/ml Susp	30 days (no date)	15
2/11/23	None	21423bg2	146421	Estradiol 2mg test 0.75mg/mg cream	30 days (no date)	60
2/13/23	101	21323bg2	147258	DHEA 5mg SR Cap	180 days (no date)	30
2/2/23	None	21323bg3	148003	Ivermectin 18mg caps	180 days (no date)	30
2/13/23	250	21423bg7	146000	DHEA 2mg/gm cream	30 days (no date)	30
2/13/23	None	21323bg5	145398	T4 65mcg SR Caps	180 days (no date)	100
2/13/23	None possibly 21323bg6	Not requested	147998	E3/E2/E1 1-2mg Pro200 test 0.2mg Cap	180 days (no date)	30
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90 days (no date)	90
2/14/23	None	21723bg61	148045	Denamarin 90mg Vet LIQ	30 days (no date)	30
2/14/23	None	21623bg4	148035	Anastrozole 0.5mg cap	180 days (no date)	12
2/14/23	None	21523bg1	146040	Testosterone 1% cream	180 days (no date)	90
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	60 days (no date)	30
2/15/23	389	21623bg1	143951	Estradiol 1mg/gm cream	30 days (no date)	30
2/15/23	None	21523bg3	148074	Nystatin 50K NS	30 days (no date)	30
2/15/23	171	21623bg6	148080	Naltrexone 0.5mg cap	180 days (no date)	7
2/15/23	199	21623bg3	146753	Testosterone 0.1% cream	30 days (no date)	30
2/15/23	241	21623bg7	148077	Naltrexone 2mg cap	180 days (no date)	7
2/16/23	None	21623bg8	148105	T4 140mcg/T3 10mcg SR V-Cap	180 days (no date)	30
2/16/23	None	21623bg5	148104	DIM 100mg Diindolylmethane	None	200
2/16/23	None	22023bg5	147425	Progesterone 100mg SR Caps	180 days (no date)	30
2/16/23	533	22023bg1	143899	Testosterone 5% Chry 2.5%	30 days (no date)	30
2/16/23	101	21623bg7	148106	DHEA 5mg SR Cap	180 days (no date)	30
2/17/23	None	22023bg4	148147	Progesterone 200mg SR Caps	180 days (no date)	30
2/18/23	None	22023bg5	146948	Progesterone 100mg SR Caps	180 days (no date)	30
2/20/23	120	22023bg2	148165	Testosterone 3mg/gm cream	30 days (no date)	30
2/20/23	None	22323bg2	148180	Progesterone 110mg SR caps	180 days (no date)	30
2/20/23	None	22323bg3	148181	E3/E4 2mg Caps	180 days (no date)	30
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30 days (no date)	30
2/21/23	None	22323bg5	148186	Hydroquinone 8% emol Cream	30 days (no date)	30
2/23/23	None	22423bg5	148275	E2/E3 5M p 150M T 10m DHEA2.5	30 days (no date)	60
2/23/23	None	22323bg7	148263	Pantoprazole 20mg/ml susp	30 days (no date)	20
2/24/23	19 Possibly 22723bg1	Note: "Only made one"	146494	BEN/LID/TET20/6/4% gel	30 days (no date)	200
2/24/23	19 Possibly 22723bg3	22723bg1	146495	BEN/LID/TET20/6/4% gel	180 days (no date)	500
2/25/23	104	22723bg5	145548	Testosterone 50mg/gm cream	30 days (no date)	60
2/27/23	457	22723bg4	145911	E2-E3 2.5mg/gm cream	30 days (no date)	30
2/28/2	None	22823bg1	148370	Omeprazole 10mg/ml Susp	30 days (no date)	42
2/28/23	None	22823bg2	148369	Lamotrigine 100mg/ml Susp	30 days (no date)	30

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THIRTEENTH CAUSE FOR DISCIPLINE

(Incorrectly Assigned Beyond Use Date, Shortest Expiration Date or Beyond Use Date of Any Ingredient)

143. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.2 (i), subdivision (1)(A), as set forth more fully above in paragraphs 103 through 108, by incorrectly assigning beyond use dates, shortest expiration date or beyond use date of any ingredient. Specifically, Respondents assigned beyond use dates which exceeded the beyond use date of ingredients in the compounded drug preparation on at least the following 21 compounded drug preparations:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount	Notes
1/30/23	389	2223bg3	147664	Estradiol 1mg/ml cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/1/23	None	2223bg5	147735	E2-E3 80/20 5mg/ml	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/8/23	none possibly 2923bg7	Not requested	146847	E2 0.5mg E3 2mg crm	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/9/23	11	2923bg9	147927	Testosterone 2% cream	30 days (no date)	30	Testosterone exp 2/28/23 Hydrogel exp 6/9/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm Vag cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/9/23	none	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90days (no date)	90	Simethicone lot C192317: exp 3/10/22
2/10/23	183	21023bg3	147975	Testosterone 20mg/gm cream	30 days (no date)	30	Testosterone exp 2/28/23 Simethicone lot C192317: exp 3/10/22 Hydrogel exp 6/9/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm vag cram	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/11/23	None	21423bg2	146421	Estradiol 2mg test 0.75mg/mg cream	30 days (no date)	60	Testosterone exp 2/28/23
2/13/23	250	21423bg7	146000	DHEA 2mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/13/23	None possibly 21323bg6	Not requested	147998	E3/E2/E1 1-2mg Pro200 test 0.2mg Cap	180 days (no date)	30	Testosterone exp 2/28/23
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90 days (no date)	90	Testosterone exp 2/28/23 Hydrogel expired 6/9/22
2/14/23	None	21523bg1	146040	Testosterone 1% cream	180 days (no date)	90	Testosterone exp 2/28/23 Simethicone lot C192317: exp 3/10/22 Hydrogel expired 6/9/22
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	60 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	389	21623bg1	143951	Estradiol 1mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	199	21623bg3	146753	Testosterone 0.1% cream	30 days (no date)	30	Testosterone exp 2/28/23 Simethicone lot C192317 exp 3/10/22 Hydrogel lot 8581501 6/9/22
2/16/23	533	22023bg1	143899	Testosterone 5% Chry 2.5%	30 days (no date)	30	Testosterone exp 2/28/23 Simethicone lot C192317: exp 3/10/22

							Hydrogel exp 6/9/22
2/20/23	120	22023bg2	148165	Testosterone 3mg/gm cream	30 days (no date)	30	Testosterone exp 2/28/23 Hydrogel exp 6/9/22
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30 days (no date)	30	Testosterone exp 2/28/23 Atrevis hydrogel lot 8581501 exp 6/9/22
2/23/23	None	22423bg5	148275	E2/E3 5M p 150M T 10m DHEA2.5	30 days (no date)	60	Testosterone exp 2/28/23
2/25/23	104	22723bg5	145548	Testosterone 50mg/gm cream	30 days (no date)	60	Testosterone exp 2/28/23 Atrevis hydrogel lot 8581501 exp 6/9/22

FOURTEENTH CAUSE FOR DISCIPLINE

(Incorrectly Assigned Beyond Use Date, Water-Containing Oral Formulations)

144. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.2, subdivision (i), (1)(E), as set forth more fully above in paragraphs 103 through 108, by incorrectly assigning beyond use date for water-containing oral formulations. Specifically, Respondents assigned a beyond use date which was greater than 14 days without documentation showing any of the required factors were analyzed to extend the beyond use date, on at least the following water-containing oral formulations:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount
1/30/23	280	2223bg6	143033	Metronidazole 100mg/ml	30 days (no date)	120
2/10/23	295	21523bg1	144818	Naltrexone 4.5mg/ml	30days (no date)	90
2/10/23	None	21023bg1	147970	Omeprazole 10mg/ml Susp	30 days (no date)	15
2/14/23	None	21723bg61	148045	Denamarin 90mg Vet LIQ	30 days (no date)	30
2/15/23	None	21523bg3	148074	Nystatin 50K NS	30 days (no date)	30
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30 days (no date)	30
2/23/23	None	22323bg7	148263	Pantoprazole 20mg/ml susp	30 days (no date)	20
2/28/2	None	22823bg1	148370	Omeprazole 10mg/ml Susp	30 days (no date)	42
2/28/23	None	22823bg2	148369	Lamotrigine 100mg/ml Susp	30 days (no date)	30
6/30/23	None	7323bg8	150324	Denamarin 90 Vet Liq	8/23	30
6/28/23	None	7323bg7	150612	Sertraline 250mg/5ml susp	8/23	200
7/3/23	None	7323bg8	148696	Nystatin 50K NS	8/23	30
7/17/23	None	71723bg10	151817	Sertraline 250mg/5ml susp	8/23	200
7/25/23	None	72723bg5	150882	Pantoprazole 20mg/ml Susp	8/23	30
7/27/23	259	72723bg9	152086	Budesonide 1mg/ml susp	8/23	60

FIFTEENTH CAUSE FOR DISCIPLINE

(Incorrectly Assigned Beyond Use Date, Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations)

145. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.2, subsection (i), subdivisions (1)(F)

and (G), as set forth more fully above in paragraphs 103 through 108, by incorrectly assigning beyond use date for water-containing topical/dermal and mucosal liquid and semisolid formulations. Specifically, Respondents assigned a beyond use date which was greater than 30 days without documentation showing that any of the required factors were analyzed to extend the beyond use date on at least the following 34 compounded preparations with water-containing topical/dermal and mucosal liquid and semisolid formulations:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount
2/9/23	none	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90 days (no date)	90
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90 days (no date)	90
2/14/23	None	21523bg1	146040	Testosterone 1% cream	180 days (no date)	90
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	60 days (no date)	30
6/29/23	9235	7323bg4	149216	DHEA 100mg/ml Cream	8/23	30
6/29/23	183	7323bg2	147975	Testosterone 20mg/gm cream	8/23	30
7/3/23	None	7323bg5	148689	E3-E4 80/20 2.5mg/gm cream	8/23	30
7/5/23	None	7523bg3	149295	Estradiol 2mg test 0.75mg/gm Cream	8/23	60
7/5/23	None	7523bg4	150776	E2/ E3 2.5 test 5mg/g	8/23	30
7/3/23	None	7523bg5	151565	E2 1.25/E3 1.25mg/gm	8/23	30
7/3/23	389	7623bg3	151566	Estradiol 1mg/mg cream	8/23	30
7/3/23	None	7623bg7	151618	E2 1.25/E3 1.25mg/gm	8/23	30
7/5/23	204	7623bg6	151619	Estradiol 2mg/mg cream	8/23	30
7/3/23	16	7623bg1	150178	Test 20%/pentox 5% cream	8/24	30
7/5/23	119	7623bg2	150766	E2 1.25/E3 1.25mg/gm	8/24	30
7/5/23	None	7623bg4	148503	E3-E2 90/20 2.5mg/gm cream	8/23	30
7/10/23	204	71723bg5	144135	Estradiol 2mg/mg cream	8/23	30
7/17/23	None	71723bg4	151822	E2 0.85/E3 0.2mg/0.15ml	1/23	30
7/17/23	None	71923bg1	150255	Testosterone 5mg/gm cream	8/23	30
7/17/23	None	71923bg2	150068	E2 6.25/prog 175mg cream	8/23	30
7/19/23	None	72023bg3	151917	Test 30mg E2/E3 4 Prog 200mg	8/23	30
7/19/23	None	72023bg4	151909	Testosterone 200mg/gm	8/23	90
7/19/23	None	72123bg1	151916	Tranexamic Acid 4.5% cream	8/23	30
7/17/23	None	71723bg3	145902	E2 0.5/ E3 2.25/prog 100.ml	8/23	40
7/21/23	None	72523bg4	150711	E2/E3/test 0.5/2/1mg/gm	8/23	30
7/24/23	None	Not requested	147926	E2 1.2mg E3 4.8mg Crm	8/23	90
7/22/23	565	72523bg5	148996	E2/E3 1.25ng/gm 80/20 cream	8/23	30
7/26/23	87	72623bg2	152049	Testosterone 0.5% cream	8/23	30
7/26/23	None	72623bg3	152051	HQ-12% KOJIC6% VIT-C 5% cream	8/23	30
7/27/23	None	72723bg1	147735	E2-E3 80/20 5mg/ml cream	8/23	30
7/31/23	None Possibly 73123bg4	Not requested	150204	E3/E2 1.25/0.15gm 80/20 CRM	8/23	9
7/27/23	None Possibly 73123bg3	Not requested	147859	E3/E2 80/20 CRM	8/23	30
7/27/23	None Possibly 73123bg5	Not requested	152099	E2/E3 5mg Pro 100mg GM	8/23	30
7/28/23	204	Not requested	144839	Estriol 2mg/gm Vag CRM	8/25	30

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Compounding Records)

146. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.3 subdivisions (a)(2), (E), (F), (H), (I),

and (J), as set forth more fully above in paragraphs 103 through 108, as follows: Respondents failed to maintain complete compounding records on at least the following 128 compounded preparations:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	amount	Missing information	Violations
2/1/23	None	2423bg1	147738	Estradiol 1.5mg cap	90	Lot/exp Estradiol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/18/23	None	21423bg3	147372	Sertraline 200mg susp	150	Lot sertraline, stevia, mango, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/31/23	None	2223bg4	147709	DHEA 7-Keto 10mg caps	30	Lot/exp Keto-7 DHEA, Cellulose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/30/23	389	2223bg3	147664	Estradiol 1mg/ml cream	30	Lot/exp: Simethicone (PCCA) Propylene Glycol, VersaPro cream Exp: estradiol 10% triturate lot 478 Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/23/23	424	12023bg10	146612	Progesterone 75 mg SR Cap	30	Lot/exp: lactose, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(D) 1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/30/23	none	2223bg1	147665	DHEA 10mg SR Capsules	30	Lot/exp: DHEA Micro Cellulose, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/30/23	None	2223bg2	147662	Progesterone 100mg SR	30	Lot/exp, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/1/23	20	2223bg7	147745	T4 38mcg/T3 9MCG SR cap	270	Exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/1/23	None	2423bg3	147719	T4 150mcg T3 10mcg SR V-Cap	45	exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
1/30/23	280	2223bg6	143033	Metronidazole 100mg/ml	120	Lot/exp: metronidazole, fixed oil Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

2/1/23	none	2223bg8	147716	Progesterone 100mg SR cap	30	Lot/exp, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/2/23	99	2923bg3	147775	Progesterone 150mg SR Cap	90	Lot/exp, Hypromellose USP Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/1/23	None	2223bg5	147735	E2-E3 80/20 5mg/ml	30	Exp/manufacture: Estriol 10 % trituration (lot 478), Estradiol 10% trituration (lot 478) Lot/exp. Propylene gylcol, Simethicone, VersaPro cream Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/4/23 (compound ed date)	526	2423bg2 2423bg1	None on log 147738	Estradiol 1.5mg SR Cap	Unknown	Lot/exp, Methocel E4M, Estradiol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(I) 1735.3(a)(2)(J)
2/4/23	None	2934bg2 Corrected to 2923bg2	147813	Progesterone 100mg SR caps	90	Lot/exp, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/6/23	None	2923bg2	147816	Progesterone 100mg SR caps	90	Lot/exp, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/6/23	None	2723bg8	147856	Fluorouracil 2%/SA 17% cream	30	Lot/exp, 5FU, salicylic Acid, Propylene Glycol, Versa ProCream base Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/6/23	None	2723bg11	145350	T4 25mcg/T3 15MCG SR cap	90	Exp; Levothyroxine 1:1000 (T4)(lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506), Hypromellose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/6/23	None	2723bg12	145080	DHEA 10mg SR cap	60	Lot/exp: DHEA, Cellulose, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
Not on log possible 2/7/23	None	2723bg5	None on log Dispensing show 147719	T4 150mcg/T3 3MCG SR V-CAP	None on log Likely 100	Exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506), Hypromellose, E4M Quality reviews/post compounding process Same Lot number 2723bg5	1735.3(a)(2)(B) 1735.3(a)(2)(F) 1735.3(a)(2)(G) 1735.3(a)(2)(H) 1735.3(a)(2)(I) 1735.3(a)(2)(J)
2/7/23	None	2723bg5	146437	Boric Acid 600mg vag caps	24	Exp: boric acid	1735.3(a)(2)(F) 1735.3(a)(2)(G)

						Quality reviews/post compounding process Same Lot number 2723bg5	1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/8/23	99	2923bg3	147164	Progesterone 150mg SR Caps	30	Lot/exp: Hypromellose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/8/23	None possibly 2923bg2	Not requested	147911	Progesterone 100mg SR Caps	90	Lot/exp: Hypromellose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/8/23	none possibly 2923bg7	Not requested	146847	E2 0.5mg E3 2mg crm	30	Exp/manufacture: Estriol 10% trituration (lot 478), Estradiol 10% trituration (lot 478) Lot/exp. Propylene glycol, Simethicone, VersaPro cream Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/9/23	11	2923bg9	147927	Testosterone 2% cream	30	Lot/exp. Testosterone (Medisca), PEG, Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/9/23	204	2923bg6	144135	Estriol 2mg/gm Vag cream	30	Exp/manufacture: Estriol 10% trituration (lot 478) Lot/exp: PEG, simethicone, Cream base	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	204	21523bg2	144839	Estriol 2mg/gm Vag cream	30	Exp/manufacture: Estriol 10 % trituration (lot 478) Lot/exp: PEG, simethicone, Cream base	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/9/23	none	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90	Exp/manufacture: Estriol 10 % trituration, Estradiol 10% trituration Lot/exp. PEG, Simethicone, VersaPro cream Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/9/23	298	21323bg4	142081	T4 15mcg/T3 3mcg cap	90	Exp; Levothyroxine 1:1000 (T4)(lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506), Hypromellose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/9/23	None	2923bg1	147932	T4 25mcg/ml Sol	32	Exp/manufacture: Levothyroxine Lot/exp: glycerin, water Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

2/9/23	151	21023bg4	147953	Dilt 2%/LID 1.5%/ Crm	30	Lot/exp: diltiazem, Exp/manufacture/exp: base Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	183	21023bg3	147975	Testosterone 20mg/gm cream	30	Lot/exp. Testosterone, PEG, simethicone, Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	295	21523bg1	144818	Naltrexone 4.5mg/ml	90	Lot/exp. Naltrexone, stevia, water Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	204	21523bg2	144839	Estriol 2mg/gm vag cram	30	Exp/manufacture: Estriol 10% (lot 478) Lot/exp. Propylene glycol, Simethicone, Versapro cream Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	None	21323bg1	145665	T4 19mcg/T3 4.5mcg cap	90	Exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506), Hypromellose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/10/23	None	21023bg1	147970	Omeprazole 10mg/ml Susp	15	Lot/exp: stevia, glycerin, omeprazole, grilled chicken Exp/manufacture: Sodium hydroxide 10% lot 471 Sodium bicarb 9% lot 470	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/11/23	None	21423bg2	146421	Estradiol 2mg test 0.75mg/mg cream	60	Exp/manufacture: Estradiol 10 % (lot 478) Lot/exp: Testosterone, Gycerin, Versabase	1735.3(a)(2)(F) 1735.3(a)(2)(H)
2/13/23	101	21323bg2	147258	DHEA 5mg SR Cap	30	Lot/exp: DHEA, Cellulose NF, Hypromellouse USP Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/2/23	None	21323bg3	148003	Ivermectin 18mg caps	30	Lot/exp: ivermectin PCCA Loxoral Base exp 7/11/24	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/13/23	250	21423bg7	146000	DHEA 2mg/gm cream	30	Lot/exp: DHEA, PEG, Base, simethicone Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/13/23	None	21323bg5	145398	T4 65mcg SR Caps	100	Exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Methocel E4M, cellulose,	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

						Quality reviews/post compounding process	
2/13/23	None possibly 21323bg6	Not requested	147998	E3/E2/E1 1-2mg Pro200 test 0.2mg Cap	30	Exp/manufacture: Estradiol, estriol, estrone, testosterone	1735.3(a)(2)(F) 1735.3(a)(2)(H)
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90	Lot/exp. Testosterone, glycerin Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/14/23	None	21723bg61	148045	Denamarin 90mg Vet LIQ	30	Lot/exp/manufacture: Denamarin Advance, grilled chicken Lot/exp: suspend all Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/14/23	None	21623bg4	148035	Anastrozole 0.5mg cap	12	Lot/exp/manufacture: anastrozole 2%/micro Lot/exp: microcrystalline Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/14/23	None	21523bg1	146040	Testosterone 1% cream	90	Lot/exp. Testosterone, PEG, Simethicone Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	30	Exp/manufacture: Estradiol 10 % (lot 478) Lot/exp. Simethicone, propylene glycol, versabase Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/15/23	389	21623bg1	143951	Estradiol 1mg/gm cream	30	Exp/manufacture: Estradiol 10% (lot 478) Lot/exp. Simethicone, Propylene Glycol, versabase Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/15/23	None	21523bg3	148074	Nystatin 50K NS	30	Lot/exp: Polysorbate, mucolox, water	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/15/23	171	21623bg6	148080	Naltrexone 0.5mg cap	7	Lot/exp. Naltrexone, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/15/23	199	21623bg3	146753	Testosterone 0.1% cream	30	manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/15/23	241	21623bg7	148077	Naltrexone 2mg cap	7	Lot/exp. Naltrexone, lactose	1735.3(a)(2)(F) 1735.3(a)(2)(H)

						Quality reviews/post compounding process	1735.3(a)(2)(J)
2/16/23	None	21623bg8	148105	T4 140mcg/T3 10mcg SR V-Cap	30	Exp; Levothyroxine 1:1000 (T4) (lot 523), Lot/exp: Cellulose, Liothyronine 1:100 (T3) (lot 506), Hypromellose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/16/23	None	21623bg5	148104	DIM 100mg Diindolylmethane	200	Diindolylmethane exp 6/22/23 Quality reviews/post compounding process	1735.3(a)(2)(B) 1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/16/23	None	22023bg5	147425	Progesterone 100mg SR Caps	30	Lot/exp: Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/16/23	533	22023bg1	143899	Testosterone 5% Chry 2.5%	30	Lot/exp: testosterone, Chrysin, simethicone, propylene Glycol, Lot/exp/manufacture: hydrogel	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/16/23	101	21623bg7	148106	DHEA 5mg SR Cap	30	Lot/exp: DHEA, Cellulose, Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/17/23	None	22023bg4	148147	Progesterone 200mg SR Caps	30	Lot/exp Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/18/23	None	22023bg5	146948	Progesterone 100mg SR Caps	30	Lot/exp Methocel E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/20/23	120	22023bg2	148165	Testosterone 3mg/gm cream	30	Lot/exp: testosterone, glycerin, Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/20/23	None	22323bg2	148180	Progesterone 110mg SR caps	30	Lot/exp E4M Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/20/23	None	22323bg3	148181	E3/E4 2mg Caps	30	Lot/exp: estriol, estradiol Methocel E4M, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30	manufacture: Atrevis hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/21/23	None	22323bg5	148186	Hydroquinone 8% emol Cream	30	Lot/exp: hydroquinone, Lot/exp/manufacture: BHT, propylene	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

						glycol, emollient cream, Quality reviews/post compounding process	
2/23/23	None	22423bg5	148275	E2/E3 5M p 150M T 10m DHEA2.5	60	Exp/manufacture: Estradiol 10% (lot 478) estriol 10% (lot 478), testosterone Lot/exp. Simethicone, PEG, versabase	1735.3(a)(2)(F) 1735.3(a)(2)(H)
2/23/23	None	22323bg7	148263	Pantoprazole 20mg/ml susp	20	Lot/exp: susp vehicle, water, pantoprazole Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/24/23	19 Possibly 22723bg1	Note:"Only made one"	146494	BEN/LID/TET20/6/4 % gel	200	Exp: tetracaine, Lot/exp: propylene glycol, tween 80 Lot/exp/manufacture: BHT gran, Lidoderm	1735.3(a)(2)(F) 1735.3(a)(2)(H)
2/24/23	19 Possibly 22723bg3	22723bg1	146495	BEN/LID/TET20/6/4 % gel	500	Exp: tetracaine, Lot/exp: PEG, poloazmer 407, lidocaine, tween 80 Lot/exp/manufacture: Lidoderm	1735.3(a)(2)(F) 1735.3(a)(2)(H) .
2/25/23	104	22723bg5	145548	Testosterone 50mg/gm cream	60	Lot/exp: Testosterone, glycerin Lot/exp/manufacture: hydrogel Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/27/23	457	22723bg4	145911	E2-E3 2.5mg/gm cream	30	Exp/manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: reagent, versapro Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/28/2	None	22823bg1	148370	Omeprazole 10mg/ml Susp	42	Lot/exp: stevia, glycerin, omeprazole, grilled chicken Exp/manufacture: Sodium hydroxide 10% lot 471 Sodium bicarb 9% lot 470 Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
2/28/23	None	22823bg2	148369	Lamotrigine 100mg/ml Susp	30	Lot/exp: lamotrigine, suspendall Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/29/23	9235	7323bg4	149216	DHEA 100mg/ml Cream	30	Lot/exp: DHEA, PEG Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/29/23	None	7323bg15	148691	DHEA 10mg SR capsules	30	Lot/exp: DHEA, cellulose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

6/29/23	None	72023bg1	150474	Oxytocin 10U SL tab	50	Manufacture: oxytocin (lot 208), tablet triturate (lot 538) exp 8/23	1735.3(a)(2)(F) 1735.3(a)(2)(H)
6/29/23	183	7323bg2	147975	Testosterone 20mg/gm cream	30	Lot/exp: Propylene Glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/30/23	None	7323bg8	150324	Denamarin 90 Vet Liq	30	Lot/exp: supend all Lot/exp/manufacture: bacon flavor	1735.2(i)(1)(E) 1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	None	7323bg5	148689	E3-E4 80/20 2.5mg/gm cream	30	Exp/manufacture: Estradiol 10% (lot 478) estriol 10% (lot 478), Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/28/23	None	7323bg7	150612	Sertraline 250mg/5ml susp	200	Lot/exp: sertraline, stevia, mango, suspendall Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	None	7323bg8	148696	Nystatin 50K NS	30	Lot/exp: polysorbate, water	1735.3(a)(2)(F) 1735.3(a)(2)(H)
6/21/23	None	7323bg8	143455	Tooth paste fluoride 1.1%	30	Manufacture/ lot /Exp: Carboxy 3% (6092) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/30/23	None	7323bg9	148181	E3/E2 2mg caps	30	Lot/exp: Estriol, Estradiol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/1/23	101	7323bg16	147299	DHEA 5mg SR caps	30	Lot/exp: DHEA, Cellulose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	332	7323bg17	150603	Liothyronine 10mcg SR caps	30	Manufacture: Liothyronine1:1000 (T3) (lot 506), microcrystalline Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/29/23	224	7323bg18	151515	DHEA 25mg SR caps	30	Lot/exp: DHEA, Cellulose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
6/29/23	None	7323bg19	149684	Methylene blue 100mg caps	30	Lot/exp: methylene blue, lactose, Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	None	7523bg1	148868	T4 140mcg T3 10mcg SR V-CAP	100	manufacture: Liothyronine1:1000 (T3) (lot 506), microcrystalline Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/5/23	None	7523bg3	149295	Estradiol 2mg test 0.75mg/gm Cream	60	manufacture: estradiol 10% trituration (lot 478), glycerin	1735.3(a)(2)(F) 1735.3(a)(2)(H)

7/5/23	None	7523bg4	150776	E2/ E3 2.5 test 5mg/g	30	manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	None	7523bg5	151565	E2 1.25/E3 1.25mg/gm	30	manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	389	7623bg3	151566	Estradiol 1mg/mg cream	30	manufacture: estradiol 10% (lot 478), Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	None	7623bg7	151618	E2 1.25/E3 1.25mg/gm	30	manufacture: estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/5/23	204	7623bg6	151619	Estradiol 2mg/mg cream	30	manufacture: estradiol 10% (lot 478), Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/3/23	16	7623bg1	150178	Test 20%/pentox 5% cream	30	Quality reviews/post compounding process	1735.2(i)(1)(A) 1735.3(a)(2)(J)
7/5/23	119	7623bg2	150766	E2 1.25/E3 1.25mg/gm	30	manufacture: estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/5/23	None	7623bg4	148503	E3-E2 90/20 2.5mg/gm cream	30	manufacture/exp: estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/5/23	None	7623bg5	150967	DHEA 10gm SR cap	30	Lot/exp: DHEA, cellulose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/10/23	204	71723bg5	144135	Estradiol 2mg/mg cream	30	manufacture: estradiol 10% (lot 478),	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

						Lot/exp: propylene glycol Quality reviews/post compounding process	
7/17/23	None	71723bg4	151822	E2 0.85/E3 0.2mg/0.15ml	30	manufacture: estradiol 10% (lot 478), estriol 10% (lot 478) Lot: propylene glycol, base Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/17/23	None	71723bg10	151817	Sertraline 250mg/5ml susp	200	Lot/exp: sertraline, stevia, mango, suspendall Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/7/23	None	7723bg6	149487	T4 19mcg/T3 4.5mcg Cap	90	Manufacture: Liothyronine1:1000 (T3) (lot 506), microcrystalline Quality reviews/post compounding process	1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/17/23	None	71923bg1	150255	Testosterone 5mg/gm cream	30	Lot/exp: glycerin Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/17/23	None	71923bg2	150068	E2 6.25/prog 175mg cream	30	Manufacture/exp: Estradiol 10% (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/19/23	None	72023bg3	151917	Test 30mg E2/E3 4 Prog 200mg	30	Manufacture/exp: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/19/23	None	72023bg4	151909	Testosterone 200mg/gm	90	Lot/exp: glycerin Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/19/23	None	72123bg1	151916	Tranexamic Acid 4.5% cream	30	Lot/exp: PCCA lipoderm Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/17/23	None	71723bg3	145902	E2 0.5/ E3 2.25/prog 100.ml	40	Manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Lot/exp: propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/12/23	None	71223bg8	151030	E3E2E1-2mg pro 200 test 0.5mg	30	Lot/exp: estriol, estradiol, estrone, testosterone (spectrum) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

7/14/23	None	72523bg1	149399	Sermorelin 600mcg Trit	90	Quality reviews/post compounding process	1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/21/23	None	72523bg4	150711	E2/E3/test 0.5/2/1mg/gm	30	Manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/24/23	None	Not requested	147926	E2 1.2mg E3 4.8mg Crm	90	Manufacture: Estradiol 10% (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/22/23	565	72523bg5	148996	E2/E3 1.25ng/gm 80/20 cream	30	Manufacture: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/26/23	87	72623bg2	152049	Testosterone 0.5% cream	30	Lot/exp: Propylene glycol Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/26/23	None	72623bg3	152051	HQ-12% KOJIC6% VIT-C 5% cream	30	Lot/exp: Glycerin Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/27/23	None	72723bg1	147735	E2-E3 80/20 5mg/ml cream	30	Manufacture: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/25/23	None	72723bg5	150882	Pantoprazole 20mg/ml Susp	30	Lot/exp: water Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/27/23	259	72723bg9	152086	Budesonide 1mg/ml susp	60	Lot/exp: budesonide Quality reviews/post compounding process	1735.2(i)(1)(E) 1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/27/23	None	73123bg1	150474	Oxytocin 10U SL tab	50	Manufacture: oxytocin 1U/mann trit (lot 208), tablet triturate (lot 538)	1735.3(a)(2)(F) 1735.3(a)(2)(H)
7/31/23	None	73123bg2	150020	T4/T3 38mcg/9mcg ODT tabs	100	Manufacture: Liothyronine1:1000 (T3) lot 506, Exp: Liothyronine1:1000 (T3) lot 506, levothyroxine 1:1000 (T4) (lot 523) Lot/exp: Lactose, sucrose Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/31/23	None 73123bg4	Not requested	150204	E3/E2 1.25/0.15gm 80/20 CRM	9	Manufacture: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

7/27/23	None Possibly 73123bg3	Not requested	147859	E3/E2 80/20 CRM	30	Manufacture: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/27/23	None Possibly 73123bg5	Not requested	152099	E2/E3 5mg Pro 100mg GM	30	Manufacture: Estradiol 10 % (lot 478), estriol 10% (lot 478) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/28/23	204	Not requested	144839	Estriol 2mg/gm Vag CRM	30	Manufacture: Estradiol 10 % (lot 478), Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/28/23	None	Not requested	149939	T4 25mcg/T3 15mcg SR Cap	90	Manufacture/Exp: Liothyronine1:1000 (T3) lot 506, Exp: levothyroxine 1:1000 (T4) (lot 523) Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)
7/27/23	525	Nothing provided	None	Progesterone	100	Quality reviews/post compounding process	1735.3(a)(2)(J)
2/7/23	None	Nothing provided	None	Boric acid 600mg Vag caps	100	Quality reviews/post compounding process	1735.3(a)(2)(J)
8/18/23	None Possible 81623bg8	Never made it	151030	E2E2E1-2mg Pro 200 TEST 0.5mg	30	Lot/exp: estriol, estradiol, estrone, testosterone (spectrum), Quality reviews/post compounding process	1735.3(a)(2)(F) 1735.3(a)(2)(H) 1735.3(a)(2)(J)

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Correctly Label Compounded Preparations)

147. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.4, subdivisions (a)(4), (5) and (6) as set forth more fully above in paragraphs 103 through 108, by incorrectly labeling compounded preparations. Specifically, Respondents incorrectly labeled 21 compounded preparations which lacked at least the beyond use date for the drug preparation, the date compounded, and the lot number or pharmacy reference number, as follows:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount	notes
8/12/23	None	2723bg5	146437	Boric Acid 600mg	Stock bottle 180 days (~9/7/23)	24	label discard 8/13/24 No lot number, no date compounded. Filled Rx found in will call 8/16/23
1/30/23	none	2223bg1	147665	DHEA 10mg SR Capsules	180 days (no date)	30	label discard: 1/30/24 no lot number, no date compounded

2/1/23	20	2223bg7	147745	T4 38mcg/T3 9MCG SR cap	180 days (no date)	270	label discard 2/1/24 o lot number, no date compounded
2/1/23	None	2423bg3	147719	T4 150mcg T3 10mcg SR V-Cap	180 days (no date)	45	label discard 9/17/24 No lot number, no date compounded.
2/1/23	none	2223bg8	147716	Progesterone 100mg SR cap	180 days (no date)	30	label discard 2/1/24 no lot number, no date compounded
2/2/23	99	2923bg3	147775	Progesterone 150mg SR Cap	180 days (no date)	90	label discard 2/2/24 no lot number no date compounded
2/4/23	None	2934bg2 Corrected to 2923bg2	147813	Progesterone 100mg SR caps	180 days (no date)	90	label discard 9/25/24 no lot number no compounded date
2/6/23	None	2923bg2	147816	Progesterone 100mg SR caps	180 days (no date)	90	no lot number no compounded date
2/6/23	None	2723bg12	145080	DHEA 10mg SR cap	180 days (no date)	60	label discard 2/6/24 no lot number no compounded date
Not on log possible 2/7/23	None	2723bg5	None on log Dispensing show 147719	T4 150mcg/T3 3MCG SR V-CAP	180 days (no date)	None on log Likely 100	label discard on 9/17/24 no lot number no compounded date
2/8/23	99	2923bg3	147164	Progesterone 150mg SR Caps	180 days (no date)	30	label discard 2/8/24 no lot number no compounded date
2/2/23	None	21323bg3	148003	Ivermectin 18mg caps	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
2/16/23	None	21623bg8	148105	T4 140mcg/T3 10mcg SR V-Cap	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
2/16/23	101	21623bg7	148106	DHEA 5mg SR Cap	180 days (no date)	30	label discard 2/16/24 no lot number no compounded date
2/18/23	None	22023bg5	146948	Progesterone 100mg SR Caps	180 days (no date)	30	label discard 2/18/24 no lot number no compounded date
2/20/23	None	22323bg2	148180	Progesterone 110mg SR caps	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
7/1/23	101	7323bg16	147299	DHEA 5mg SR caps	1/24	30	label discard 6/30/24 no lot number no compounded date
6/29/23	224	7323bg18	151515	DHEA 25mg SR caps	1/24	30	label discard 6/28/24 no lot number no compounded date
7/3/23	16	7623bg1	150178	Test 20%/pentox 5% cream	8/24	30	label discard 7/2/24 no lot number no compounded date
7/27/23	None	73123bg1	150474	Oxytocin 10U SL tab	8/23	50	label discard 9/17/24 no lot number no compounded date

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Follow Policies and Procedures)

148. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in that Respondents violated Regulations section 1735.5, subdivision (a), as set forth more fully above in paragraphs 103 through 108, when Respondents failed to follow their own policies and procedures. Specifically, Respondents failed to follow at least the following policies and procedures:

1) SOP 3.15 (Hazardous Drug Inventory) implemented on June 6, 2023, by Respondent Gramlich and not followed when:

a. Hazardous drugs (HD) and non-HD drugs were not stored separately; and,

b. Appropriate Personal Protection Equipment (PPE) was not available to be worn.

2) SOP 1.30 Nonsterile compounding area, implemented on August 13, 2017, reviewed on June 6, 2023, by Respondent Gramlich and not followed:

a. On August 16, 2023, when the nonsterile compounding area was not clean and organized to prevent mix-up or cross-contamination;
b. On August 16, 2023, when the powder containment hood was off;
c. On August 16, 2023, when powders were found in the trash can in the compounding area;
d. On August 16, 2023, when a half-compounded preparation dated August 15 and August 11 were left in the off containment ventilated enclosure (CVE);
e. On August 16, 2023, when the compounding room and containment ventilated enclosure (CVE) were not cleaned but showed compounding was taking place;
f. On August 16, 2023, when the compounding equipment was not clean, well-maintained and used for its intended purpose; and,
g. When compounding and storage of HD's occurred in the non-sterile, non-HD compounding and/or storage area(s).

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Written Documentation Regarding Appropriate Cleaning of Facilities and Equipment to Prevent Cross-Contamination with Non-Hazardous Drugs)

149. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in combination with Regulations section 1735.6, subdivision (d), as set forth more fully above in paragraphs 103 through 108, by failing to maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. Specifically, Respondents failed to recognize they were compounding with an antineoplastic agent, 5-fluorouracil (5FU), and other non-antineoplastic hazardous drugs in the same compounding room and within same containment ventilated enclosures without proper documentation of cleaning.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Compound Hazardous Drugs in an Appropriate Environment)

150. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, and Code section 4113, subdivision (c), in combination with Regulations section 1735.6, subdivision (e), as set forth more fully above

in paragraphs 103 through 108, by failing to compound hazardous drugs in an appropriate environment. Specifically, Respondents failed to recertify their compounding environment when the retest date was May 8, 2023. Respondent Pharmacy continued to compound with an antineoplastic agent, 5-fluorouracil (5FU), and other non-antineoplastic hazardous drugs in the same compounding room and within the same containment ventilated enclosure without knowing the environment met the requirements after the certification expired.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Incomplete Sales Records)

151. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in combination with Code section 4059, subdivision (a), as set forth more fully above in paragraphs 103 through 108, by maintaining incomplete sales records. The circumstances are as follows: Respondents failed to correctly give the names and addresses of the supplier and the buyer, as noted in invoices for Xeomin (incobotulinumtoxinA), on or about January 26, 2023, February 21, 2023, February 23, 2023, March 6, 2023, March 23, 2023, April 11, 2023, April 26, 2023, May 13, 2023, May 18, 2023, June 19, 2023, June 29, 2023, July 20, 2023, and August 3, 2023, and BOTOX Cosmetic (onabotulinumtoxinA), on or about August 13, 2023 and August 13, 2023.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Keep a Current Inventory)

152. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs, and Code section 4113, subdivision (c), in combination with Code section 4081, subdivision (a), and Regulations section 1718, as set forth more fully above in paragraphs 103 through 108 by failing to keep a current inventory. Specifically, Respondents failed to have a current inventory for at least the following:

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1. On August 16, 2023, when Xeomin (incobotulinumtoxinA) was found in the pharmacy inventory, but records show this was sold on or about April 11, 2023, to R.G.

2. On August 16, 2023, when Cyanocobalamin 1000mcg/ml vials were found in the consultation room and a box in the cupboard; Respondent Gramlich stated they belonged to Dr. R.C. but were still within the licensed pharmacy premises.

3. Disposition records for simethicone lot C192317 from March 10, 2022, to October 12, 2023, testosterone USP micronized lot 173118 from February 28, 2023, to March 12, 2023, and PCCA Atrevis Hydrogel lot 8581501 from June 9, 2022 to March 12, 2023 were requested but Respondent Gramlich failed to provide records.

4. Furnishing records for HydraFacial, C.H., GlacialRx, ZO Skin Health, West Coast Laser, M.M., A.C., Coastal Regenerative Orthopedics & Wellness Center, A.N., or J.J. Respondent Gramlich admitted to not keeping furnishing records in an October 26, 2023, statement.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Adulterated Drugs)

153. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, in that Respondents violated Code section 4169, subdivision (a)(2), and Health and Safety Code sections 111250, 111255, 111295, 111300, and 111550, by manufacturing (compounding), holding or offering for sale at least the following adulterated drugs:

1) On August 16, 2023, when an open vial of cyanocobalamin 1000mcg/ml was found in the "patient consultation" room. This product is only to be used for 28 days once opened, and the open vial did not contain the date when it was opened.

2) On August 16, 2023, when an open vial of Xeomin (incobotulinumtoxinA) was found in the pharmacy's refrigerator. This product is only to be used on one patient and within 24 hours after dilution. Respondent Gramlich stated that he did not know when this vial was diluted, and the vial was not dated.

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3) When at least the following 17 compounded preparations were compounded with an already expired component as follows:

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount	Notes
1/30/23	389	2223bg3	147664	Estradiol 1mg/ml cream	30 days (no date)	30	Simethicone lot C192317: Exp 3/10/22
2/1/23	None	2223bg5	147735	E2-E3 80/20 5mg/ml	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/8/23	none possibly 2923bg7	Not requested	146847	E2 0.5mg E3 2mg crm	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm Vag cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/9/23	None	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90days (no date)	90	Simethicone lot C192317: exp 3/10/22
2/10/23	183	21023bg3	147975	Testosterone 20mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22 Hydrogel exp 6/9/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm vag cram	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/13/23	250	21423bg7	146000	DHEA 2mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90 days (no date)	90	Hydrogel exp 6/9/22
2/14/23	None	21523bg1	146040	Testosterone 1% cream	180 days (no date)	90	Simethicone lot C192317: exp 3/10/22 Hydrogel exp 6/9/22
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	60 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	389	21623bg1	143951	Estradiol 1mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	199	21623bg3	146753	Testosterone 0.1% cream	30 days (no date)	30	simethicone lot C192317 exp 3/10/22 Hydrogel lot 8581501 6/9/22
2/16/23	533	22023bg1	143899	Testosterone 5% Chry 2.5%	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22 Hydrogel exp 6/9/22
2/20/23	120	22023bg2	148165	Testosterone 3mg/gm cream	30 days (no date)	30	Hydrogel exp 6/9/22
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30 days (no date)	30	Atrevis hydrogel lot 8581501 exp 6/9/22
2/25/23	104	22723bg5	145548	Testosterone 50mg/gm cream	30 days (no date)	60	Atrevis hydrogel lot 8581501 exp 6/9/22

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

154. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, in that Respondents violated Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330, 111335, 111440, 111445 and 111550, when Respondents held, offered for sale, and/or transferred at least the following misbranded drugs:

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1. Misbranded as they were labeled with "SR" for sustained release or slow release when the FDA had not approved this labeling claim, as required.

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount
1/23/23	424	12023bg10	146612	Progesterone 75 mg SR Cap	None	30
1/30/23	None	2223bg1	147665	DHEA 10mg SR Capsules	180 days (no date)	30
1/30/23	None	2223bg2	147662	Progesterone 100mg SR	180 days (no date)	30
2/1/23	20	2223bg7	147745	T4 38mcg/T3 9MCG SR cap	180 days (no date)	270
2/1/23	None	2423bg3	147719	T4 150mcg T3 10mcg SR V-Cap	180 days (no date)	45
2/1/23	None	2223bg8	147716	Progesterone 100mg SR cap	180 days (no date)	30
2/2/23	99	2923bg3	147775	Progesterone 150mg SR Cap	180 days (no date)	90
2/4/23 (compounded date)	526	2423bg2 2423bg1	None on log 147738	Estradiol 1.5mg SR Cap	180 days (no date)	Unknown
2/4/23	None	2934bg2 Corrected to 2923bg2	147813	Progesterone 100mg SR caps	180 days (no date)	90
2/6/23	None	2923bg2	147816	Progesterone 100mg SR caps	180 days (no date)	90
2/6/23	None	2723bg11	145350	T4 25mcg/T3 15MCG SR cap	180 days (no date)	90
2/6/23	None	2723bg12	145080	DHEA 10mg SR cap	180 days (no date)	60
Not on log possible 2/7/23	None	2723bg5	None on log Dispensing show 147719	T4 150mcg/T3 3MCG SR V-CAP	180 days (no date)	None on log Likely 100
2/8/23	99	2923bg3	147164	Progesterone 150mg SR Caps	180 days (no date)	30
2/8/23	None possibly 2923bg2	Not requested	147911	Progesterone 100mg SR Caps	180 days (no date)	90
2/13/23	101	21323bg2	147258	DHEA 5mg SR Cap	180 days (no date)	30
2/13/23	None	21323bg5	145398	T4 65mcg SR Caps	180 days (no date)	100
2/16/23	None	21623bg8	148105	T4 140mcg/T3 10mcg SR V-Cap	180 days (no date)	30
2/16/23	None	22023bg5	147425	Progesterone 100mg SR Caps	180 days (no date)	30
2/16/23	101	21623bg7	148106	DHEA 5mg SR Cap	180 days (no date)	30
2/17/23	None	22023bg4	148147	Progesterone 200mg SR Caps	180 days (no date)	30
2/18/23	None	22023bg5	146948	Progesterone 100mg SR Caps	180 days (no date)	30
2/20/23	None	22323bg2	148180	Progesterone 110mg SR caps	180 days (no date)	30
6/29/23	None	7323bg15	148691	DHEA 10mg SR capsules	1/24	30
7/1/23	101	7323bg16	147299	DHEA 5mg SR caps	1/24	30
7/3/23	332	7323bg17	150603	Liothyronine 10mcg SR caps	1/24	30
6/29/23	224	7323bg18	151515	DHEA 25mg SR caps	1/24	30
7/3/23	None	7523bg1	148868	T4 140mcg T3 10mcg SR V-CAP	1/24	100
7/5/23	None	7623bg5	150967	DHEA 10gm SR cap	1/24	30

2. Misbranded as they were labeled with a beyond use date (BUD) which was false and misleading because the compounding components expired before the assigned BUD of the preparation.

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount	notes
1/30/23	389	2223bg3	147664	Estradiol 1mg/ml cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/1/23	None	2223bg5	147735	E2-E3 80/20 5mg/ml	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/8/23	none possibly 2923bg7	Not requested	146847	E2 0.5mg E3 2mg crm	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/9/23	11	2923bg9	147927	Testosterone 2% cream	30 days (no date)	30	Testosterone expired on 2/28/23 Hydrogel exp 6/9/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm Vag cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/9/23	none	2923bg8	147926	E2 1.2mg E3 4.8mg cream	90days (no date)	90	Simethicone lot C192317: exp 3/10/22
2/10/23	183	21023bg3	147975	Testosterone 20mg/gm cream	30 days (no date)	30	Testosterone expired on 2/28/23 Simethicone lot C192317: exp 3/10/22

							Hydrogel exp 6/9/22
2/10/23	204	21523bg2	144839	Estriol 2mg/gm vag cram	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/11/23	None	21423bg2	146421	Estradiol 2mg test 0.75mg/mg cream	30 days (no date)	60	Testosterone expired on 2/28/23
2/13/23	250	21423bg7	146000	DHEA 2mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/13/23	None possibly 21323bg6	Not requested	147998	E3/E2/E1 1-2mg Pro200 test 0.2mg Cap	180 days (no date)	30	Testosterone expired on 2/28/23
2/13/23	None	21423bg1	145404	Testosterone 10mg/gm cream	90 days (no date)	90	Testosterone expired 2/28/23 Hydrogel expired 6/9/22
2/14/23	None	21523bg1	146040	Testosterone 1% cream	180 days (no date)	90	Testosterone expired on 2/28/23 Simethicone lot C192317: exp 3/10/22 Hydrogel expired 6/9/22
2/14/23	66	21623bg2	143743	Estradiol 2mg/gm cream	60 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	389	21623bg1	143951	Estradiol 1mg/gm cream	30 days (no date)	30	Simethicone lot C192317: exp 3/10/22
2/15/23	199	21623bg3	146753	Testosterone 0.1% cream	30 days (no date)	30	Testosterone Micronized usp Lot 1731184 EXP 2/28/23 Simethicone lot C192317 exp 3/10/22 Hydrogel lot 8581501 6/9/22
2/16/23	533	22023bg1	143899	Testosterone 5% Chry 2.5%	30 days (no date)	30	Testosterone expired on 2/28/23 Simethicone lot C192317: exp 3/10/22 Hydrogel exp 6/9/22
2/20/23	120	22023bg2	148165	Testosterone 3mg/gm cream	30 days (no date)	30	Testosterone expired on 2/28/23 Hydrogel exp 6/9/22
2/21/23	199	22323bg4	148190	Testosterone 0.1%/gm cream	30 days (no date)	30	Testosterone lot 173118H exp 2/28/23 Atrevis hydrogel lot 8581501 exp 6/9/22
2/23/23	None	22423bg5	148275	E2/E3 5M p 150M T 10m DHEA2.5	30 days (no date)	60	Testosterone expired on 2/28/23
2/25/23	104	22723bg5	145548	Testosterone 50mg/gm cream	30 days (no date)	60	Testosterone lot 173118H exp 2/28/23 Atrevis hydrogel lot 8581501 exp 6/9/22

3. Misbranded because the patients' label showed a discard by date which was one year from the date the label was printed but was not the beyond used date of the preparations.

Rx or label date	Lot number per log	Lot number per PIC	Rx number	Drug	BUD	amount	notes
8/12/23	None	2723bg5	146437	Boric Acid 600mg	Stock bottle 180 days (~9/7/23)	24	label discard 8/13/24 No lot number, no date compounded. Rx found in will call 8/16/23
1/30/23	none	2223bg1	147665	DHEA 10mg SR Capsules	180 days (no date)	30	label discard: 1/30/24 no lot number, no date compounded
2/1/23	20	2223bg7	147745	T4 38mcg/T3 9MCG SR cap	180 days (no date)	270	label discard 2/1/24 no lot number, no date compounded
2/1/23	None	2423bg3	147719	T4 150mcg T3 10mcg SR V-Cap	180 days (no date)	45	label discard 9/17/24 No lot number, no date compounded.
2/1/23	none	2223bg8	147716	Progesterone 100mg SR cap	180 days (no date)	30	label discard 2/1/24 no lot number, no date compounded

2/2/23	99	2923bg3	147775	Progesterone 150mg SR Cap	180 days (no date)	90	label discard 2/2/24 no lot number no date compounded
2/4/23	None	2934bg2 Corrected to 2923bg2	147813	Progesterone 100mg SR caps	180 days (no date)	90	label discard 9/25/24 no lot number no compounded date
2/6/23	None	2923bg2	147816	Progesterone 100mg SR caps	180 days (no date)	90	label discard 2/1/24 no lot number no compounded date
2/6/23	None	2723bg12	145080	DHEA 10mg SR cap	180 days (no date)	60	label discard 2/6/24 no lot number no compounded date
Not on log possible 2/7/23	None	2723bg5	None on log Dispensing show 147719	T4 150mcg/T3 3MCG SR V-CAP	180 days (no date)	None on log Likely 100	label discard on 9/17/24 no lot number no compounded date
2/8/23	99	2923bg3	147164	Progesterone 150mg SR Caps	180 days (no date)	30	label discard 2/8/24 no lot number no compounded date
2/2/23	None	21323bg3	148003	Ivermectin 18mg caps	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
2/16/23	None	21623bg8	148105	T4 140mcg/T3 10mcg SR V-Cap	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
2/16/23	101	21623bg7	148106	DHEA 5mg SR Cap	180 days (no date)	30	label discard 2/16/24 no lot number no compounded date
2/18/23	None	22023bg5	146948	Progesterone 100mg SR Caps	180 days (no date)	30	label discard 2/18/24 no lot number no compounded date
2/20/23	None	22323bg2	148180	Progesterone 110mg SR caps	180 days (no date)	30	label discard 9/17/24 no lot number no compounded date
7/1/23	101	7323bg16	147299	DHEA 5mg SR caps	1/24	30	label discard 6/30/24 no lot number no compounded date
6/29/23	224	7323bg18	151515	DHEA 25mg SR caps	1/24	30	label discard 6/28/24 no lot number no compounded date
7/3/23	16	7623bg1	150178	Test 20%/pentox 5% cream	8/24	30	label discard 7/2/24 no lot number no compounded date
7/27/23	None	73123bg1	150474	Oxytocin 10U SL tab	8/23	50	label discard 9/17/24 no lot number no compounded date

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Respondent Gramlich's Education, Training, or Experience as a Pharmacist as to Respondent Gramlich Only)

155. Respondent Gramlich is subject to disciplinary action under Code section 4306.5, subdivision (a), in that Respondent Gramlich inappropriately exercised his education, training, or experience as a pharmacist when he allowed each of the following to occur:

a. He used expired components in his compounded preparations;

b. He failed to maintain a current inventory of dangerous drugs;

c. He informed Board Inspectors on August 16, 2023, that if he cleaned the compounding room and waited two hours, he could compound non-Hazardous Drugs after compounding Hazardous Drugs in the same room in the same containment ventilated enclosure;

d. He failed to understand that he was compounding using an antineoplastic agent, 5-fluorouracil (5FU);

e. He cross-contaminated compounded preparations because he failed to ensure proper cleaning and decontamination of antineoplastic agent, 5-fluorouracil (5FU);

f. He failed to label his compounded preparations correctly;

g. He failed to maintain compliant compounding records; and,

h. He failed to assign compliant beyond use dates to his compounded preparations.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement His Best Professional Judgment as to Respondent Gramlich Only)

156. Respondent Gramlich is subject to disciplinary action under Code section 4306.5, subdivision (b), in that Respondent Gramlich failed to exercise or implement his best professional judgment when he allowed each of the following to occur:

a. He used expired components in his compounded preparations;

b. He failed to maintain a complete inventory of dangerous drugs;

c. He informed Board Inspectors on August 16, 2023, that if he cleaned the compounding room and waited 2 hours, he could compound non-HD after compounding HD in the same room in the same containment ventilated enclosure;

d. He failed to understand he was compounding using an antineoplastic agent, 5-fluorouracil (5FU);

e. He cross-contaminated compounded preparations because he failed to ensure proper cleaning and decontamination of antineoplastic agent, 5-fluorouracil (5FU);

f. He failed to label his compounded preparations correctly;

g. He failed to maintain compliant compounding records; and,

h. He failed to assign compliant beyond use dates to his compounded preparations.

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Causes for Discipline Relating to June 4, and July 18, 2024, Inspections

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Store Hazardous Drugs and Active Ingredients Separate from Non-Hazardous Drugs)

157. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, in that Respondents violated Code section 4126.8 and USP Chapter 800 section 5.2, by comingling HD and non-HD compounding components. The storage cabinets contained HD APIs such as anastrozole, finasteride, testosterone, tretinoin, compounded estriol 10% and non-HD APIs such as salicylic acid, phenylephrine, hydroquinone, fluocinolone, minoxidil, trazodone, and compounded T4 and T3 preparations, as set forth more fully in paragraphs 109 through 128.

TWENTY-EIGHTH CAUSE FOR DISCIPLINE

(Improper Storage of Expired Drugs in Compounding Room)

158. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for failing to follow regulations governing the practice of pharmacy and regulating dangerous drugs, in conjunction with Health & Safety Code section 111295, in that a number of expired raw ingredients were stored in the compounding room, as set forth more fully in paragraphs 109 through 128.

TWENTY-NINTH CAUSE FOR DISCIPLINE

(Prohibited Acts)

159. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, in conjunction with Code section 4169(a)(2), and Regulations section 1735.2, and USP Chapter 795 section 6.2.2, in that the following products did not bear an expiration date: PCCA Mequinol Lot# C197617; PCCA Mandelic Acid (DL) Lot# C190499; PCCA Resorcinol USP Lot# C182551, and it was not clear when the pharmacy received these

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Products, and there was no beyond use date marked on the products, as set forth more fully in paragraphs 109 through 128.

THIRTIETH CAUSE FOR DISCIPLINE

(Failure to Obtain a Sterile Compounding Permit)

160. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and Code section 4113, subdivision (c), in that Respondents violated Code section 4127.1, by compounding sterile drugs without a sterile compounding permit, as set forth more fully in paragraphs 97 through 130.

THIRTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Accurate Compounding Records)

161. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Regulations section 1735.3(a) and USP Chapter 795 section 7.2, in that a review of compounding records indicated multiple deficiencies in maintaining accurate compounding records, as set forth more fully above in paragraphs 109 through 128. Some examples are as follows:

June 4, 2024, Inspection:

Compound Name	Rx No., Patient Name	Date Rx processed (noted as Date filled on CR)	Date Made	Made by:	Assigned BUD	Information Missing on the CR:
Progesterone 150mg Caps	62324-0 AM	4/8/24	4/9/24	PIC Gramlich	8/2024	Complete compounding instructions, MFC name of the components, Accurate BUD, Accurate final Qty, Physical description of final CNSP, Reference to MFR, Quality reviews
C-Liothyronine: Liothyronine Sodium%, Microcrystalline Cellulose%		3/27/24	4/4/24	PIC Gramlich	10/2024	Complete compounding instructions, MFC name of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Quality reviews
C-Levothyroxine: Levothyroxine Sodium%,		3/27/24	4/4/24	PIC Gramlich	10/2024?	Complete compounding instructions, MFC of the components, Accurate

Microcrystalline Cellulose%						BUD, Physical description of final CNSP, Reference to MFR, Quality reviews
DHEA 5mg Caps	0-0 WB	4/15/24	4/17/24	PIC Gramlich	10/2024	Complete compounding instructions, MFC of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
DEHA 5mg Caps	60620-1 DB	3/26/24	3/26/24	PIC Gramlich	8/2024	Complete compounding instructions, MFC of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
Naltrexone 4.5mg Cap	60941-1 CW	4/22/24	4/23/24	PIC Gramlich	10/2024	Complete compounding instructions, MFC of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
Naltrexone 1.5mg Cap	60753-0 EG	2/15/24	4/17/24	PIC Gramlich	10/2024	Complete compounding instructions, MFC of the components, Accurate BUD, physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
E2/E3 2mg Cap	60828-1 MK	3/28/24	3/28/24	PIC Gramlich	8/2024	Complete compounding instructions, MFC of the components, Accurate BUD, physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
Ivermectin 1% Cream	0-0 ML	5/29/24	5/29/24	PIC Gramlich	6/2024	Complete compounding instructions, MFC of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
E2/E3/TEST 4mg/5mg/Gm Cream	61427-0 RC	3/6/24	3/8/24	PIC Gramlich	4/2024	Complete compounding instructions, MFC of the components, Accurate

						BUD, Physical description of final CNSP, Reference to MFR, Accurate final quantity, Quality reviews
C-Estradiol (Estradiol %, Microcrystalline Cellulose %)		4/22/24	4/24/24	PIC Gramlich	10/2024	Complete compounding instructions, MFC of the components, Accurate BUD, Physical description of final CNSP, Reference to MFR, Quality reviews

July 18, 2024, Follow Up Inspection:

Compound Name	**Rx No., Patient Name**	**Date Rx processed (noted as Date filled on CR)**	**Date Made**	**Made by:**	**Assigned BUD**	**Information Missing on the CR:**
Progesterone 150mg Capsule	62434-1, RB	7/2/24	7/15/24	PIC Gramlich	01/15/25	Complete compounding instructions, MFC of the components, Accurate final quantity, Reference to MF, Quality reviews
Minoxidil 0.5mg Capsule	61338-2, AW	7/15/24	7/15/24	PIC Gramlich	01/15/25	Complete compounding instructions, MFC name of the components, Accurate final Qty, Reference to MFR, Quality reviews
Methylene Blue 7mg Capsule	63653-1, BF	7/10/24	7/15/24	PIC Gramlich	01/15/25	Complete compounding instructions, MFC name of the components, Accurate final quantity, Reference to MF, Quality reviews
E2/E3/Prog 0.5/2.25/100mg cream	60845-4, JJ	7/17/24	7/18/24	PIC Gramlich	08/18/24	Compounding instructions, MFC name of the components, Accurate final quantity, Reference to MF, Quality reviews, Physical descriptions of the final CNSP, Storage requirements

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Some additional examples showing deficiencies in maintaining accurate compounding records are as follows:

Compound Name	Date Rx processed (noted as Date Filled on CR)	Date Made	BUD	Made by	Formula	Information / Records Missing
Anastrozole 0.5mg Cap	3/4/24	3/5/24	5/2024	PIC Gramlich	C-anastrozole powder 0.1, Microcrystalline cellulose powder 0.94, Caps #1 BL/WH #4	No MFR, Used 2 anastrozole 1mg tablets, No MFC for the tablets, Inaccurate CR, No MFC/ Lot #/ Expiration date for cellulose, No compounding instructions; No Quality assurance (QA); No Quality control (QC); No storage instructions; No container information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	3/27/24	3/27/24	8/2024	PIC Gramlich	C-anastrozole powder 0.5, Microcrystalline cellulose powder 4.7, Caps #1 BL/WH #20	No MFR, Used 10 anastrozole 1mg tablets, Inaccurate CR, No MFC for the tablets, No compounding instructions;

						No QA/ QC/ storage/ or container information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	4/8/24	4/9/24	8/2024	PIC Gramlich	C-anastrozole powder 0.1, Microcrystalline cellulose powder 0.94, Caps #1 BL/WH #4	No MFR, Used ? (#) anastrozole 1mg tablets, Inaccurate CR, No MFC/ lot # /expiration date for the tablets, No compounding instructions; No QA/ QC/ storage or container information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	5/2/24	5/6/24	8/2024	PIC Gramlich	C-anastrozole powder 0.1, Microcrystalline cellulose powder 0.94, Caps #1 BL/WH #4	No MFR, Used 2 anastrozole 1mg tablets, Inaccurate CR, No compounding instructions/ QA/ QC/ storage or container information, No final quantity, No accurate BUD

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THIRTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formula Records)

162. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Regulations section 1735.2(a) and USP Chapter 795 section 7.1, in that preparations were compounded without first preparing a written Master Formula Record, as set forth more fully in paragraphs 109 through 128. Specifically, the following preparations were compounded without first preparing a MFR:

Compound Name	Date Rx processed (noted as Date Filled on CR)	Date Made	BUD	Made by	Formula Used	Information / Records Missing
Anastrozole 0.5mg Cap	3/4/24	3/5/24	5/2024	PIC Gramlich	C-anastrozole powder 0.1; Microcrystalline cellulose powder 0.94; Caps #1 BL/WH #4	No MFR, Used 2 anastrozole 1mg tablets without MFR for the tablets, No MFC/ Lot #/ Expiration date for cellulose, No compounding instructions; Quality assurance (QA)/ No Quality control (QC), No storage or container information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	3/27/24	3/27/24	8/2024	PIC Gramlich	C-anastrozole powder 0.5; Microcrystalline cellulose powder 4.7; Caps #1 BL/WH #20	No MFR, Used 10 anastrozole 1mg tablets without any MFR, No MFC for the tablets, No compounding instructions, No QA/ QC/ storage or container

						information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	4/8/24	4/9/24	8/2024	PIC Gramlich	C-anastrozole powder 0.1; Microcrystalline cellulose powder 0.94; Caps #1 BL/WH #4	No MFR, Used ? anastrozole 1mg tablets without any MFR, No MFC/ lot #/ expiration date for the tablets, No compounding instructions, No QA/ QC/ storage or container information, No final quantity, No accurate BUD
Anastrozole 0.5mg Cap	5/2/24	5/6/24	8/2024	PIC Gramlich	C-anastrozole powder 0.1, Microcrystalline cellulose powder 0.94, Caps #1 BL/WH #4	No MFR, Used 2 anastrozole 1mg tablets, Inaccurate CR, No compounding instructions, No QA/ QC/ storage or container information, No final quantity, No accurate BUD

Some additional examples with the RX Number and Patient Name are as follows:

Compound Name	**Rx No., Patient Name**	**Date Rx processed (noted as Date filled on CR)**	**Date Made**	**Made by:**	**Assigned BUD**	**Information /Records Missing**
Ivermectin 1% Cream	0-0 ML	5/29/24	5/29/24	PIC Gramlich	6/2024 on CR, on label at will-call area (ready to dispense): 5/29/25	No MFR. PIC Used MF for Ivermectin 1%/Ketotifen 0.05% cream

E2/E3/TEST 4mg/5mg/Gm Cream	61427-0 RC	3/6/24	3/8/24	PIC Gramlich	4/2024	No MFR. Used Estriol/Estradiol [50/50% 0.25-2.5 mg/gm/ testosterone 0.25mg/gm to 10mg/gm topical cream MF. Also used simethicone liquid for compounding but there is no simethicone listed in this MF.

THIRTY-THIRD CAUSE FOR DISCIPLINE

(Incorrectly Assigned Beyond Use Dates (BUD))

163. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, in that Respondents violated Code section 4126.8, in conjunction with Regulations section 1735.2(i) and USP Chapter 795, section 10.3, BUD Definition, in that Respondents incorrectly assigned beyond use dates (BUD), as set forth more fully in paragraphs 109 through 128. Specifically, the following compounded preparations failed to establish the appropriate beyond use date in which they should no longer be used, stored, transported, or administered:

Compound Name	Rx No., Patient Name	Date Rx processed (noted as Date filled on CR)	Date Made	Made by:	Assigned BUD
C-Liothyronine: Liothyronine Sodium%, Microcrystalline Cellulose%		3/27/24	4/4/24	PIC Gramlich	10/2024 (No exact date, i.e. 10/4/24))
C-Levothyroxine: Levothyroxine Sodium%, Microcrystalline Cellulose%		3/27/24	4/4/24	PIC Gramlich	10/2024 (No exact date)
DHEA 5mg Caps	0-0 WB	4/15/24	4/17/24	PIC Gramlich	10/2024 (No exact date)
Naltrexone 4.5mg Cap	60941-1 CW	4/22/24	4/23/24	PIC Gramlich	10/2024 (No exact date)
Naltrexone 1.5mg Cap	60753-0 EG	2/15/24	4/17/24	PIC Gramlich	10/2024 (No exact date)
Ivermectin 1% Cream	0-0 ML	5/29/24	5/29/24	PIC Gramlich	6/2024 on CR (No exact date), On the label at will-

					call (ready to dispense): 5/29/25 Correct BUD?: No MF
C-Estradiol (Estradiol %, Microcrystalline Cellulose %)		4/22/24	4/24/24	PIC Gramlich	10/2024 (No exact date)
Progesterone 150mg Cap	62324-0 AM	4/8/24	4/9/24	PIC Gramlich	8/24 (No exact date)
DHEA 5mg Cap	60620-1	3/26/24	3/26/24	PIC Gramlich	8/24 (No exact date)
E2/E3 2mg Caps	60828-1	3/28/24	3/28/24	PIC Gramlich	8/14 (no exact date)
E2/E3/Test 4mg/5mg/Gm cream	61427-0 RC	3/6/24	3/8/24	PIC Gramlich	4/24 (No exact date)

THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Correctly Label Compounded Preparations)

164. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and in violation of Code section 4077(a), in conjunction with Regulations section 1735.4(a), in that the inspection revealed that Respondents incorrectly assigned beyond use dates (BUDs) for Rx 63651 for MI and Rx 60845 for R.J. which were observed at the will-call area, ready to be dispensed, as set forth more fully in paragraphs 114 and 125.

THIRTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Compounding Quality Assurance)

165. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), violating regulations governing the practice of pharmacy, in that Respondents violated Regulations section 1735.8, subdivision (a), and (d) and USP Chapter 795 Section 12, as set forth more fully above in paragraph 126. Specifically on July 21, 2023, Respondent Pharmacy had four capsules of progesterone 50mg SR tested for potency. The results were reported at 114.3%, 115.5%, 114.7% and 114.8%, all of which far exceeded the intended potency of these compounds. Moreover, on July 23, 2024, Respondent Pharmacy had three capsules of progesterone 100mg SR tested for potency. The results were reported as 112.9%, 97.5% and

5.9%. Two out of three far exceeded the intended potency of these compounds.

THIRTY-SIXTH CAUSE FOR DISCIPLINE

(Adulterated Dangerous Drugs)

166. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and in violation of Code section 4169(a)(2), in conjunction with Health & Safety Code sections 111255, 111295, and 111300, in that Respondents had no evidence that three glass vials of a sterile compounded product, labelled as Tirzepatide 16.6 mg/ml Levocarnitine 100 mg/ml, located in Respondent Pharmacy were compounded in the required environment nor was there any sort of recordkeeping associated with these compounded preparations, which were adulterated dangerous drugs, as set forth more fully in paragraphs 115 and 116.

Causes for Discipline Relating to September 3, 2024, Inspection

THIRTY-SEVENTH CAUSE FOR DISCIPLINE

(Adulterated Dangerous Drugs)

167. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and in violation of Code section 4169(a)(2), in conjunction with Health & Safety Code sections 111255, 111295, and 111300, in that Respondents had no evidence on how the products in three glass vials contained in a plastic bubble bag in Respondent Pharmacy's freezer were compounded, and there were no acquisition records for the products as set forth more fully in paragraph 129.

THIRTY-EIGHTH CAUSE FOR DISCIPLINE

(Misbranded Dangerous Drugs)

168. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing the practice of pharmacy and regulating dangerous drugs, and in violation of Code section 4169(a)(3), in conjunction with Health & Safety Code sections 111330, 111335, 111440, and 111445, in that the three glass vials

contained in a plastic bubble bag in Respondent Pharmacy's freezer were inappropriately labeled, as set forth more fully in paragraph 130.

FIRST AMENDED PETITION TO REVOKE PROBATION

169. This First Amended Petition to Revoke Probation is brought before the Board under Probation Term and Condition Number 1, Obey All Laws, in the *Decision and Order In the Matter of the Accusation Against Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; and Charles Adam Covello, Officer, Case No. 7183,* and Probation Term and Condition Number 1, Obey All Laws, in the *Decision and Order In the Matter of the Accusation Against Bernard J. Gramlich, Case No. 7183.* That term and condition in both Disciplinary Orders specifically states:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

170. Grounds exist for revoking the probation and reimposing the order of revocation of Pharmacy Permit Number PHY 55594 issued to Respondent Pharmacy and Pharmacist License Number RPH 53112 issued to Respondent Gramlich. The Board's Disciplinary Orders referenced in paragraph 169, above, also contain Probation Term and Condition 15, as to Respondent Pharmacy, and Term and Condition 14, as to Respondent Gramlich, which provides as follows:

///

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

FIRST CAUSE TO REVOKE PROBATION

(Obey All Laws and Regulations Related to Pharmacy)

171. At all times after the effective date of Respondents' probation, Condition 1 stated:

Respondent shall obey all state and federal laws and regulations.

172. Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy's and Respondent Bernard J. Gramlich's probation are subject to revocation because Respondents failed to comply with Probation Condition 1, as set forth in paragraphs 97 through 130, above, incorporated herein by reference.

173. Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy's probation is subject to revocation because Respondent Pharmacy failed to comply with Regulations section 1774, as set forth more fully in paragraphs 97 through 130, above.

174. Respondent Bernard J. Gramlich's probation is subject to revocation because Respondent Gramlich failed to comply with Regulations section 1773, as set forth more fully in paragraphs 97 through 130, above.

175. The June 4 and July 18, 2024, inspections revealed that Respondent Pharmacy was not compliant with the term of probation, "Obey All Laws." Specifically on June 4, 2024, and July 18, 2024, Board Inspectors S.S. and S.F. determined that Respondent Pharmacy violated BPC 4126.8/USP 800 section 5.2, BPC 4342(a)/BPC 4301(o)/HSC 111440, BPC 4169(a)(2)/

Regulations section 1735.2/USP 795 Section 6.2.2, Regulations section 1735.3(a)/USP 795 Section 7.2, Regulations section 1735.2(e)-(i)/USP 795, BPC 4126.8/BPC 4077(a), USP 795 Section 12/Regulations section 1735.8(a) and (d), BPC 4169(a)(2)/HSC 111255, 111295, and 111300, and Regulations section 1774(a) as described and set forth above in violation of Regulations section 1774(a)(1).

176. Respondent Bernard J. Gramlich's probation is subject to revocation because Respondent Gramlich violated BPC 4126.8/USP 800 Section 5.2, BPC 4342(a)/BPC 4301(o)/HSC 111440, BPC 4169(a)(2)/Regulations section 1735.2/USP 795 section 6.2.2, Regulations section 1735.3(a)/USP 795 section 7.2, Regulations section 1735.2(e)-(i)/USP 795, BPC 4126.8/BPC 4077(a), USP 795 Section 12/ Regulations section 1735.8(a) and (d), BPC 4169(a)(2)/HSC 111255, 111295, and 111300, and Regulations section 1774(a)(1) as described and set forth above in violation of Regulations section 1773(a)(1), as set forth more fully in paragraph 175 above.

177. The September 3, 2024, inspection revealed that Respondent Pharmacy was not compliant with the term of probation, "Obey All Laws." Specifically on September 3, 2024, Board Inspector S.F. determined that that Respondent Pharmacy violated BPC section 4169(a)(2)/HSC 111255, 111295, and 111300 and BPC section 4169(a)(3)/HSC sections 111335, 111330, 111440, and 111445 as described and set forth above in violation of Regulations section 1774(a)(1).

178. Respondent Bernard J. Gramlich's probation is subject to revocation because Respondent Gramlich violated BPC section 4169(a)(2)/HSC sections 111255, 111295, and 111300 and BPC section 4169(a)(3)/HSC sections 111335, 111330, 111440, and 111445 as described and set forth above in violation of Regulations section 1773(a)(1), as set forth more fully in paragraph 177 above.

SECOND CAUSE TO REVOKE PROBATION

(Violation of Probation)

179. At all times after the effective date of Respondents' probation, Condition 15, as to Respondent Pharmacy, and Condition 14, as to Respondent Gramlich, stated:

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

180. Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy's and Respondent Bernard J. Gramlich's probation are subject to revocation because Respondent Pharmacy failed to comply with Probation Condition 15 and Respondent Gramlich failed to comply with Probation Condition 14, as set forth more fully in paragraphs 97 through 178, above.

DISCIPLINE CONSIDERATIONS AS TO RESPONDENT PHARMACY

181. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on August 10, 2021, in case number CI 2020 90752, the Board issued a Letter of Admonishment to Respondent Pharmacy, pursuant to Code section 4005 and 4315, et seq., for failure to comply with the laws and regulations that govern the practice of pharmacy in California. Specifically, Respondent Pharmacy violated Regulations section 1716 for filling four prescriptions which varied from the order written by the prescriber, and Code section 4063 for filling five prescriptions which were not authorized by the prescriber. That decision is now final.

DISCIPLINE CONSIDERATIONS AS TO RESPONDENT GRAMLICH

182. To determine the degree of discipline, if any, to be imposed on Respondent Gramlich, Complainant alleges that on August 10, 2021, in case number CI 2020 92246, the Board issued a Letter of Admonishment to Respondent Gramlich, pursuant to Code section 4005 and 4315, et seq., for failure to comply with the laws and regulations that govern the practice of pharmacy in

California. Specifically, Respondent Pharmacy violated Regulations section 1716 for filling four prescriptions which varied from the order written by the prescriber, and Code section 4063 for filling five prescriptions which were not authorized by the prescriber. That decision is now final.

OTHER MATTERS

183. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit is placed on probation or until the Pharmacy Permit is reinstated if it is revoked.

184. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy, while Bernard J. Gramlich has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were 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 the Pharmacy Permit is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked.

185. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 53112 issued to Bernard J. Gramlich, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this First Amended Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 7183 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY 55594 issued to Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy;

2. Revoking or suspending Pharmacy Permit No. PHY 55594, issued to Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy;

3. Prohibiting Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55594 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;

4. Revoking the probation that was granted by the Board of Pharmacy in Case No. 7183 and imposing the disciplinary order that was stayed thereby revoking Pharmacist License No. RPH 53112 issued to Bernard J. Gramlich;

5. Revoking or suspending Pharmacist License No. RPH 53112 issued to Bernard J. Gramlich;

6. Prohibiting Bernard J. Gramlich from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55594 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;

7. Prohibiting Bernard J. Gramlich from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 53112 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy and Bernard J. Gramlich to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 2/27/2025

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2025.02.27 12:41:16 -08'00'

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

SD2024800179/84375976.docx

Exhibit A

Decisions and Orders

Board of Pharmacy Case No. 7183

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

In the Matter of the Accusation Against:

DEL SUR PHARMACY, A CALIFORNIA CORPORATION, dba FAIRBANKS PHARMACY;
BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO;
CHARLES ADAM COVELLO, OFFICER,
Original Pharmacy Permit No. PHY 55594;

and

BERNARD GRAMLICH,
Pharmacist License No. RPH 53112,

Respondents.

Agency Case No. 7183

OAH No. 2022030854

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on February 8, 2023.

It is so ORDERED on January 9, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against: **DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY; BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO; CHARLES ADAM COVELLO, OFFICER** **16089 San Dieguito Road # H102** **P. O. Box 9227** **Rancho Santa Fe, CA 92067** **Original Permit No. PHY 55594,** **and** **BERNARD GRAMLICH** **PO Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	Case No. 7183 OAH No. 2022030854 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY; BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO; CHARLES ADAM COVELLO, OFFICER ONLY**

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Amie J. Flynn, Deputy Attorney General.

2. Respondent Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; and Charles Adam Covello, Officer (Respondent) is represented in this proceeding by attorney Edward Idell, Esq., whose address is: 355 South Grand Avenue, Suite 1750, Los Angeles, California 90071.

3. On or about May 25, 2017, the Board issued Original Permit No. PHY 55594 to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; and Charles Adam Covello, Officer (Respondent). The Original Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7183, and will expire on May 1, 2023, unless renewed.

JURISDICTION

4. Accusation No. 7183 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on January 12, 2022. Respondent timely filed its Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7183 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7183. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

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

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

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 7183.

10. Respondent agrees that its Original Permit is subject to discipline and it agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

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

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

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Permit No. PHY 55594 issued to Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; and Charles Adam Covello, Officer is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5 years) on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Respondent's compliance with the terms and conditions of its probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the board its costs of investigation and prosecution in the amount of $24,049.75. Respondent shall be jointly and severally liable for costs with Respondent Bernard Gramlich.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

6. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Original Permit with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Original Permit shall be considered a violation of probation.

If Respondent's Original Permit expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent wish to discontinue business, Respondent may tender the Original Permit to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

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9. **Sale or Discontinuance of Business**

During the period of probation, should Respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to Respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

10. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

11. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws

and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

12. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a pharmacy in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent is informed otherwise in writing by the board or its designee. If Respondent is not open and engaged in its ordinary business as a pharmacy for a minimum of 120 hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours Respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which Respondent will resume business as required.

Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which Respondent is open and engaged in its ordinary business as a pharmacy in California for a minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

13. **Consultant Review of Pharmacy Operations**

Respondent shall retain, at its own expense, an independent consultant who shall review the operations of the facility, during the period of probation, on a monthly basis for compliance of the facility with state and federal laws and regulations governing the practice of pharmacy, and compliance by Respondent. The consultant shall provide the board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the board with reports documenting the inspection. The reports shall be provided directly to the board, and receive confirmation of receipt from the board, prior to providing to the Respondent. Should the

board determine that the consultant is not appropriately assessing the operations of Respondent, or providing the appropriate written reports, the board shall require Respondent to obtain a different consultant through the same process outlined above, by submitting a new name of an expert within sixty (60) days of Respondent being notified of the need for a new consultant. During the period of probation, the board shall retain discretion to reduce the frequency of the consultant's review.

Respondent shall submit the name of the proposed consultant for approval within thirty (30) days of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board to serve in this position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to Respondent related to the causes for discipline in Case No. 7183. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

14. **No New Ownership or Management of Licensed Premises**

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

15. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied

or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Edward Idell, Esq. I understand the stipulation and the effect it will have on my Original Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY; BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO; CHARLES ADAM COVELLO, OFFICER
Respondent

I have read and fully discussed with Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; Charles Adam Covello, Officer the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

EDWARD IDELL, ESQ.
Attorney for Respondent

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Edward Idell, Esq. I understand the stipulation and the effect it will have on my Original Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11-5-22

DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY; BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO; CHARLES ADAM COVELLO, OFFICER
Respondent

I have read and fully discussed with Respondent Del Sur Pharmacy, A California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; Charles Adam Covello, Officer the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11-5-22

EDWARD IDELL, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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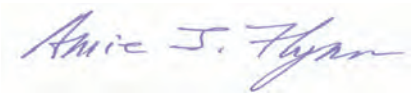
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: November 7, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General



AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7183

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against:	Case No. 7183
DEL SUR PHARMACY, A CALIFORNIA CORPORATION, **DBA FAIRBANKS PHARMACY** **BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO** **CHARLES ADAM COVELLO, OFFICER** **16089 San Dieguito Road # H102** **P. O. Box 9227** **Rancho Santa Fe, CA 92067** **Original Permit No. PHY 55594,** **and** **BERNARD GRAMLICH** **P O Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	**ACCUSATION**

PARTIES

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

2. On or about May 25, 2017, the Board issued Original Permit Number PHY 55594 to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy (Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2022, unless renewed.

3. On or about May 25, 2017, the Board issued Original Permit Number PHY 55594 to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy (Respondent Pharmacy). Bernard J. Gramlich, 50% shareholder, is and has been Chief Executive Officer, President, Secretary and Treasurer/Chief Financial Officer since May 25, 2017. Charles Adam Covello, 50% shareholder, is and has been Vice-President since May 1, 2017.

4. On or about September 26, 2001, the Board issued Pharmacist License Number RPH 53112 to Bernard Gramlich (Respondent Gramlich). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2023, unless renewed. Bernard Gramlich is and has been the Pharmacist-in-Charge of Respondent Pharmacy since May 25, 2017.

JURISDICTION

5. Business and Professions Code (Code) section 4300 states, 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.
>
> …
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The

action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. Code section 4300.1 states:

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

STATUTORY AND REGULATORY PROVISIONS

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

8. Section 4035 of the Code states:

> "Person" includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

9. Code section 4052.2 states, in pertinent part:

> (a) Notwithstanding any other 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, licensed correctional clinic, 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 correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):
>
> . . .
>
> (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 correctional clinic, as defined in Section 4187, 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.

10. Code section 4059, states, in pertinent part:

(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.

….

11. Code section 4076 states, in pertinent part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

. . .

12. Section 4113 of the Code states in relevant part:

…

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

….

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13. Code section 4301 states in pertinent part:

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

. . .

(j) The violation of any of the statutes of this state, of 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.

. . .

14. Section 4307 of the Code states:

(a) 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 of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, 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.

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

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

15. Section 4210 of the Code states:

(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.

16. Health and Safety (H&S) Code section 11165 states, in pertinent part:

. . .

(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

(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 date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a 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) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, 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) Prescribing date of the prescription.

(10) Date of dispensing of the prescription.

. . .

17. California Code of Regulations (CCR), title 16, section 1707.2, subdivision (b)(1)(A), states that a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting which the patient or agent is present whenever the prescription drug has not been dispensed to a patient.

18. CCR, title 16, section 1707.3 states that prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

19. CCR, title 16, section 1761, subdivision (a), states that 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.

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DEFINITIONS

20. **Selective Serotonin Reuptake Inhibitors (SSRIs)** are a type of antidepressant that work by increasing levels of serotonin within the brain. Serotonin is a neurotransmitter that is often referred to as the "feel good hormone." SSRIs are typically used for the treatment of major depressive disorder, anxiety disorders, and other psychological conditions. Escitalopram and Fluoxetine are both SSRIs.

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B & PC 4022	CONTROLLED SUBSTANCE PER H & SC	INDICATIONS FOR USE
Lexapro	Escitalopram	Yes	No	SSRI antidepressant, anxiolytic
Prozac	Fluoxetine	Yes	No	SSRI antidepressant, anxiolytic
Zestril	Lisinopril	Yes	No	Hypertension

COST RECOVERY

21. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

22. Respondent Fairbanks Pharmacy is a pharmacy located in Rancho Santa Fe, California. During the relevant time, Respondent Gramlich was employed at Fairbanks Pharmacy as the Pharmacist-In-Charge.

Fluoxetine 20 mg and Escitalopram 10 mg Dispensed to Patient TG

23. TG is a patient who had Down Syndrome and resided at a senior living facility in the San Diego area. The facility required all residents to use the services of Respondent Pharmacy during the spring of 2018. Due to this agreement, Respondent Pharmacy would routinely fill and deliver prescriptions to patients at the facility.

24. On June 10, 2018, the Board received a complaint alleging that on May 3, 2018, Respondent Fairbanks Pharmacy dispensed two SSRIs, fluoxetine and escitalopram, together in the same bubble pill pack (also called a blister pack), to TG. The medication list from the facility did not show the date and physician who issued the prescription, the quantity to dispense, or initials of the pharmacist who received the approval for the prescription. Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions.

25. Respondent Gramlich failed to review TG's prescription profile when the prescription for escitalopram 10 mg and fluoxetine 20 mg were filled on or about June 2, 2018. TG's prescription for 20 mg of fluoxetine was discontinued by Dr. Y on December 20, 2017. TG's prescription for 10 mg of escitalopram was supposed to replace the previous fluoxetine prescription. Had Respondent Gramlich reviewed TG's prescription profile, he would have discovered that prescriptions for 20 mg of fluoxetine were filled on May 3, 2018 and May 22, 2018 based on prescriptions issued by Dr. H. Respondent Gramlich should have questioned the prescriptions for two different SSRIs by two doctors. Instead, Respondent Gramlich filled TG's fluoxetine prescription in addition to escitalopram, even though the medications were duplicative and prescribed by two different physicians.

26. Respondent Gramlich did not caution TG about the potential risks of taking two SSRIs at once. Because of the combination of these two drugs, which TG took for two months, TG suffered from stomach cramps and headaches and became irritable, anxious, angry and confused. When questioned about why both SSRIs were dispensed to TG, Respondent Gramlich responded that the pharmacy did not have the prescribing doctor's name at the time both medications were ordered by the facility. However, this statement was false because the name of the prescribing physicians was printed on top of the bubble pill pack.

27. On or about March 25, 2018, Dr. H prescribed 10 mg escitalopram to TG, which was subsequently dispensed at a different pharmacy on March 29, 2018. On or about May 25, 2018, this prescription was transferred to Respondent Fairbanks Pharmacy. On June 22, 2018, Dr. H called in an additional prescription for 20 mg escitalopram, which was processed on June 28, 2018 by Respondent Fairbanks Pharmacy.

28. The prescribing doctor, Dr. H, intended for the prescription for 10 mg escitalopram to be discontinued when TG received the prescription for 20 mg escitalopram, but the prescription was ambiguous. Respondent Gramlich failed to clarify this ambiguity with Dr. H, or to notify TG to stop taking the 10 mg escitalopram that was dispensed on June 22, 2018. Consequently, TG took 30 mg of escitalopram instead of the intended dose of 20 mg.

Other Prescriptions Dispensed to TB

29. Respondent Pharmacy filled several other prescriptions for TG. On or about April 30, 2018, Respondent Fairbanks Pharmacy filled prescriptions for clotrimazole cream; 20 mg of fluoxetine; 100 mg of allopurinol; 5 mg of lisinopril; and 20 mg of simvastatin. On or about May 3, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5 mg of lisinopril. On or about May 17, 2018, Respondent Fairbanks Pharmacy filled a prescription for 100 mg of allopurinol. On or about June 5, 2018, Respondent Fairbanks Pharmacy filled a prescription for 20 mg of simvastatin. For each of these prescriptions, Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions. Additionally, for each of the prescriptions that were filled on April 30, 2018, the medication list from the facility did not have annotations which showed the date and physician who issued the prescription, the quantity to dispense, or the initials of pharmacist who received the approval for the prescription, as required. Additionally, Respondent Gramlich failed to request the prescriptions from the physician.

Other Prescriptions Dispensed

30. On or about February 28, 2019, the Board conducted an inspection of Respondent Fairbanks Pharmacy. Following the Board's inspection, the Board investigator reviewed a CURES Report of the prescriptions prescribed between June 30, 2017 and December 30, 2018. The review of CURES showed that most of the prescriptions were for the administration of vaccines. However, the following prescriptions, which were not for vaccines, were processed, filled, and dispensed with Respondent Gramlich identified as the prescriber:

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Patient	Drug	Rx #	Initial Fill	Refill	Refill
MS	Bi-est 80/20 5mg/ml	100702	11/3/2017	1/29/2018	6/27/2018
KD	Dextroamphetamine 10 mg	100948	12/4/2017		
CS	Gentamicin 0.03% ophthalmic drops	103870	6/19/2018		
HL	Amlodipine-denazepril 5/20 mg	103581	6/25/2018		
HL	Omeprazole 20 mg	103582	6/25/2018		
CA	Cyanocobalamin 1,000 mcg	100376	9/28/2017		

31. On or about November 3, 2017, Respondent Fairbanks Pharmacy filled a prescription for 30 mg of Bi-Est 80/20. The prescription was prescribed by Dr. G for patient MS. However, the prescription was processed under the name of Respondent Gramlich instead of the actual prescriber.

32. On or about December 1, 2017, Respondent Fairbanks Pharmacy filled a prescription for 10 mg of dextroamphetamine. The prescription was prescribed by Dr. M for patient KD. However, the prescription was processed under the name of Respondent Gramlich instead of the actual prescriber.

33. On or about June 19, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5 ml of gentamicin 0.3% ophthalmic drops for patient CS. Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions.

34. On or about May 31, 2018, Respondent Fairbanks Pharmacy filled prescriptions for 5/20 mg of benazepril, as well as 20 mg of omeprazole, for Patient HL. The prescription was processed under the name of Respondent Gramlich instead of the actual prescriber, and Respondent Gramlich failed to confirm the identity of HL's current physician. On or about June 25, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5/20 mg of benazepril. This prescription was prescribed by Dr. M for patient HL. For each of these prescriptions, the medication list from the facility did not have annotations which showed the date and physician who approved the prescription, the quantity to dispense, and the initials of pharmacist who received the approval for the prescription, as required.

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Qualifications of Respondent Gramlich

35. On or about September 28, 2017, Respondent Gramlich prescribed and administered 1000 mcg of Vitamin B-12 to a patient, pursuant to Respondent Fairbanks Pharmacy's Collaborative Practice Agreement, which provides in part that a pharmacist "[u]nder protocol and professional judgment may perform the injection."

36. During its investigation, the Board determined that Respondent Gramlich did not complete a clinical residency training, and was unable to provide proof that he previously worked as a paramedic. Respondent Gramlich also stated that he did not pursue a postgraduate residency program, but instead received clinical experience in direct patient care training. The doctor who provided clinical training, Dr. L, is a naturopathic doctor, not a physician.

37. Pursuant to Code section 4210, subdivision (a)(2)(C), clinical training can only be provided by a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system. Consequently, the training received by Respondent Gramlich from Dr. L was not valid, and did not qualify Respondent Gramlich for the issuance of an Advance Practice Pharmacist license.

FIRST CAUSE FOR DISCIPLINE

(Failure to Transmit CURES Data as Required)

38. Respondents are subject to discipline under Health & Safety Code section 11165, subdivision (d), and Code section 4113, in that they failed to submit CURES data of controlled substance prescriptions filed at Fairbanks Pharmacy within the required reporting parameter. The circumstances are as follows:

39. On March 4, 2019, the Board obtained a CURES report from May 25, 2017 to March 4, 2019, which showed that a total of 998 prescriptions for controlled substances were transmitted. The CURES report of Respondent Pharmacy for the controlled substances dispensed from January 1, 2018 to December 31, 2018, were reported to the Department of Justice after the Board's inspection on December 7, 2018, and not within the required reporting parameter.

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SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating State Laws and Regulations Governing Pharmacy)

40. Respondents are subject to discipline under Code section 4301, subdivisions (j) and (o), in conjunction with Code sections 4052.2(a), 4059(a), 4076(a)(4), and 4210(a)(2)(C); Health & Safety Code section 11165(d); and, CCR, title 16, sections 1707.2, 1707.3 and 1761(a); in that Respondent Gramlich acted with unprofessional conduct, in that he violated state laws and regulations governing pharmacy when he prescribed prescriptions in an unauthorized manner, as set forth in paragraphs 22 through 34, above.

THIRD CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

41. Respondents are subject to discipline under Code sections 4301, subdivision (o), and CCR, title 16, section 1761, subdivision (a), in that Respondent Gramlich dispensed multiple prescriptions which contained omissions and ambiguity, and failed to clarify ambiguities on multiple prescriptions, as set forth in paragraphs 22 through 34, above.

FOURTH CAUSE FOR DISCIPLINE

(Unauthorized Furnishing of Dangerous Drugs)

42. Respondents are subject to discipline under Code sections 4301, subdivision (j) and (o), and 4059, subdivision (a), in that Respondent Gramlich dispensed numerous prescriptions when he was not authorized to do so, as set forth in paragraphs 22 through 34, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Review Drug Therapy and Patient Medication Record)

43. Respondents are subject to discipline under Code sections 4301, subdivision (o), and CCR, sections 1707.2 and 1707.3, in that Respondent Gramlich failed to review patient TG's Prescription Profile before delivering prescription drugs resulting in the dispensing of discontinued medications, as set forth in paragraphs 22 through 34, above.

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SIXTH CAUSE FOR DISCIPLINE

(Failure to Provide Consultation)

44. Respondents are subject to discipline under Code section 4301, subdivision (o), and CCR, section 1707.2, subdivision (b)(1)(A), in that Respondent Gramlich failed to provide consultation to patient TG on June 22, 2018, which resulted in TG taking both escitalopram and fluoxetine, as set forth in paragraphs 22 through 34, above.

SEVENTH CAUSE FOR DISCIPLINE

(Dispensing of Prescription Label with the Wrong Prescriber)

45. Respondents are subject to discipline under Code section 4301, subdivision (o), and 4076, subdivision (a)(4), in that Respondent Gramlich dispensed prescriptions with labels bearing the wrong prescriber on two separate occasions, as set forth in paragraphs 31 through 32, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure of the Pharmacist to Adhere to Approved Protocol)

46. Respondents are subject to discipline under Code sections 4301, subdivision (o), and 4052.2, subdivision (a), in that Pharmacist Gramlich prescribed and administered Vitamin B-12 shots under a Collaborative Practice Agreement that was inadequate for the following reasons, as set forth below and in paragraphs 35 through 37, above:

a. The Collaborative Practice Agreement did not indicate the requirement that the supervising physician or primary physician be notified in writing within 24 hours of any initiation, change, adjustment, or discontinuation of therapy.

b. The Collaborative Practice Agreement did not indicate the requirement that the procedures to be performed by the pharmacist is related to a condition for which the patient has been seen by a physician.

c. Respondent Gramlich completed his training in providing clinical services to patients under the supervision of Dr. L, who is a naturopathic doctor.

d. Respondent Gramlich has not completed a clinical residency training or other program which demonstrated clinical experience in direct patient care delivery. Therefore, he was not qualified to administer vitamin B-12 injections.

OTHER MATTERS

75. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

76. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, and Respondent Gramlich, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 55594 was revoked, suspended, or placed on probation, Respondent Gramlich shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

77. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, and Charles Adam Covello, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 55594 was revoked, suspended, or placed on probation, Charles Adam Covello shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

78. Pursuant to Section 4307, if Pharmacist License Number RPH 53112 issued to Bernard J. Gramlich is suspended or revoked, Respondent Gramlich shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

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PRAYER

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

1. Revoking or suspending Original Permit Number PHY 55594, issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 53112, issued to Bernard Gramlich;

3. Ordering Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy and Bernard Gramlich 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;

4. Ordering that Respondent Bernard Gramlich is prohibited from serving as an officer, director, associate, partner, manager, qualifying individual or member of the personnel of record of a licensee pursuant to Code section 4307;

5. Ordering that Respondent Charles Adam Covello is prohibited from serving as an officer, director, associate, partner, manager, qualifying individual or member of the personnel of record of a licensee pursuant to Code section 4307; and,

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

DATED: 12/27/2021__

Signature on File

ANNE SODERGREN
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:

DEL SUR PHARMACY, A CALIFORNIA CORPORATION, dba FAIRBANKS PHARMACY;
BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO;
CHARLES ADAM COVELLO, OFFICER,
Original Pharmacy Permit No. PHY 55594;

and

BERNARD GRAMLICH,
Pharmacist License No. RPH 53112,

Respondents.

Agency Case No. 7183

OAH No. 2022030854

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on February 8, 2023.

It is so ORDERED on January 9, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against: **DEL SUR PHARMACY, A CALIFORNIA CORPORATION, DBA FAIRBANKS PHARMACY; BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO; CHARLES ADAM COVELLO, OFFICER** **16089 San Dieguito Road # H102** **P. O. Box 9227** **Rancho Santa Fe, CA 92067** **Original Permit No. PHY 55594,** **and** **BERNARD GRAMLICH** **PO Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	Case No. 7183 OAH No. 2022030854 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT BERNARD GRAMLICH ONLY**

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Amie J. Flynn, Deputy Attorney General.

2. Bernard Gramlich (Respondent) is represented in this proceeding by attorney Edward Idell, Esq., whose address is: 355 South Grand Avenue, Suite 1750, Los Angeles, California 90071.

3. On or about September 26, 2001, the Board issued Pharmacist License No. RPH 53112 to Bernard J. Gramlich (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 7183, and will expire on August 31, 2023, unless renewed.

JURISDICTION

4. Accusation No. 7183 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on January 12, 2022. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7183 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7183. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine

the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded him by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 7183.

10. Respondent agrees that his Pharmacist License is subject to discipline and it agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

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

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

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary

Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 53112 issued to Respondent Bernard J. Gramlich is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5 years) on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other

requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7183 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

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Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the board in writing the name, physical address, and mailing address of each of Respondent's employers, and the name(s) and telephone number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning Respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7183, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7183, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 7183, and the terms and conditions imposed thereby in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number 7183, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether the Respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor at Respondent Del Sur Pharmacy's location only, but only if Respondent or Respondent Del Sur Pharmacy's retains, at Respondent Del Sur Pharmacy's expense, an independent consultant who shall be responsible for reviewing the operations of the Respondent Del Sur Pharmacy on a quarterly basis for compliance by Respondent and Respondent Del Sur Pharmacy's with state and federal laws and regulations governing the practice of Respondent Del Sur Pharmacy, and compliance by Respondent with the obligations of Respondent Del Sur Pharmacy supervisory

position. Respondent may serve in such a position at only one entity licensed by the board, only upon approval by the board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the board its costs of investigation and prosecution in the amount of $24,049.75. Respondent shall be jointly and severally liable with Respondent Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy; Bernard J. Gramlich, CEO/PRES, Secretary and Treasurer/CFO; and Charles Adam Covello, Officer.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If Respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the board or its designee.

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If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which Respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

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15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

16. **Remedial Education**

Within sixty (60) days of the effective date of this decision, Respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to the duties of a Pharmacist in Charge, pharmacy operations and pharmacy law and shall consist of at least 10 hours, which shall be completed within the first three (3) years of Respondent's probation at Respondent's own expense. The remedial education must be 50% in person or live webinar. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the Respondent, at his own expense, to take an approved examination to test the Respondent's knowledge of the course. If the Respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

17. **No New Ownership or Management of Licensed Premises**

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent may continue to serve in such capacity or hold

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that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Edward Idell, Esq. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

BERNARD J. GRAMLICH
Respondent

I have read and fully discussed with Respondent Bernard J. Gramlich the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

EDWARD IDELL, ESQ.
Attorney for Respondent

that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Edward Idell, Esq. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11-5-22

BERNARD J. GRAMLICH
Respondent

I have read and fully discussed with Respondent Bernard J. Gramlich the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11-5-22

EDWARD IDELL, ESQ.
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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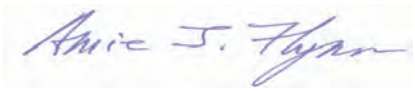
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: November 7, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General



AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7183

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
AMIE J. FLYNN
Deputy Attorney General
State Bar No. 149600
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9337
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against:	Case No. 7183
DEL SUR PHARMACY, A CALIFORNIA CORPORATION, **DBA FAIRBANKS PHARMACY** **BERNARD J. GRAMLICH, CEO/PRES, SECRETARY AND TREASURER/CFO** **CHARLES ADAM COVELLO, OFFICER** **16089 San Dieguito Road # H102** **P. O. Box 9227** **Rancho Santa Fe, CA 92067** **Original Permit No. PHY 55594,** **and** **BERNARD GRAMLICH** **P O Box 9227** **Rancho Santa Fe, CA 92067** **Pharmacist License No. RPH 53112** Respondents.	**ACCUSATION**

PARTIES

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

2. On or about May 25, 2017, the Board issued Original Permit Number PHY 55594 to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy (Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2022, unless renewed.

3. On or about May 25, 2017, the Board issued Original Permit Number PHY 55594 to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy (Respondent Pharmacy). Bernard J. Gramlich, 50% shareholder, is and has been Chief Executive Officer, President, Secretary and Treasurer/Chief Financial Officer since May 25, 2017. Charles Adam Covello, 50% shareholder, is and has been Vice-President since May 1, 2017.

4. On or about September 26, 2001, the Board issued Pharmacist License Number RPH 53112 to Bernard Gramlich (Respondent Gramlich). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2023, unless renewed. Bernard Gramlich is and has been the Pharmacist-in-Charge of Respondent Pharmacy since May 25, 2017.

JURISDICTION

5. Business and Professions Code (Code) section 4300 states, 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.
>
> …
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The

action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. Code section 4300.1 states:

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

STATUTORY AND REGULATORY PROVISIONS

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

8. Section 4035 of the Code states:

> "Person" includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

9. Code section 4052.2 states, in pertinent part:

> (a) Notwithstanding any other 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, licensed correctional clinic, 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 correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):
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> . . .
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> (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:
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> (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 correctional clinic, as defined in Section 4187, 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.

10. Code section 4059, states, in pertinent part:

(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.

….

11. Code section 4076 states, in pertinent part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

(4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

. . .

12. Section 4113 of the Code states in relevant part:

…

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

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13. Code section 4301 states in pertinent part:

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

. . .

(j) The violation of any of the statutes of this state, of 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.

. . .

14. Section 4307 of the Code states:

(a) 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 of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, 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.

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

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

15. Section 4210 of the Code states:

(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.

16. Health and Safety (H&S) Code section 11165 states, in pertinent part:

. . .

(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

(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 date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a 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) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, 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) Prescribing date of the prescription.

(10) Date of dispensing of the prescription.

. . .

17. California Code of Regulations (CCR), title 16, section 1707.2, subdivision (b)(1)(A), states that a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting which the patient or agent is present whenever the prescription drug has not been dispensed to a patient.

18. CCR, title 16, section 1707.3 states that prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

19. CCR, title 16, section 1761, subdivision (a), states that 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.

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DEFINITIONS

20. **Selective Serotonin Reuptake Inhibitors (SSRIs)** are a type of antidepressant that work by increasing levels of serotonin within the brain. Serotonin is a neurotransmitter that is often referred to as the "feel good hormone." SSRIs are typically used for the treatment of major depressive disorder, anxiety disorders, and other psychological conditions. Escitalopram and Fluoxetine are both SSRIs.

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B & PC 4022	CONTROLLED SUBSTANCE PER H & SC	INDICATIONS FOR USE
Lexapro	Escitalopram	Yes	No	SSRI antidepressant, anxiolytic
Prozac	Fluoxetine	Yes	No	SSRI antidepressant, anxiolytic
Zestril	Lisinopril	Yes	No	Hypertension

COST RECOVERY

21. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

22. Respondent Fairbanks Pharmacy is a pharmacy located in Rancho Santa Fe, California. During the relevant time, Respondent Gramlich was employed at Fairbanks Pharmacy as the Pharmacist-In-Charge.

Fluoxetine 20 mg and Escitalopram 10 mg Dispensed to Patient TG

23. TG is a patient who had Down Syndrome and resided at a senior living facility in the San Diego area. The facility required all residents to use the services of Respondent Pharmacy during the spring of 2018. Due to this agreement, Respondent Pharmacy would routinely fill and deliver prescriptions to patients at the facility.

24. On June 10, 2018, the Board received a complaint alleging that on May 3, 2018, Respondent Fairbanks Pharmacy dispensed two SSRIs, fluoxetine and escitalopram, together in the same bubble pill pack (also called a blister pack), to TG. The medication list from the facility did not show the date and physician who issued the prescription, the quantity to dispense, or initials of the pharmacist who received the approval for the prescription. Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions.

25. Respondent Gramlich failed to review TG's prescription profile when the prescription for escitalopram 10 mg and fluoxetine 20 mg were filled on or about June 2, 2018. TG's prescription for 20 mg of fluoxetine was discontinued by Dr. Y on December 20, 2017. TG's prescription for 10 mg of escitalopram was supposed to replace the previous fluoxetine prescription. Had Respondent Gramlich reviewed TG's prescription profile, he would have discovered that prescriptions for 20 mg of fluoxetine were filled on May 3, 2018 and May 22, 2018 based on prescriptions issued by Dr. H. Respondent Gramlich should have questioned the prescriptions for two different SSRIs by two doctors. Instead, Respondent Gramlich filled TG's fluoxetine prescription in addition to escitalopram, even though the medications were duplicative and prescribed by two different physicians.

26. Respondent Gramlich did not caution TG about the potential risks of taking two SSRIs at once. Because of the combination of these two drugs, which TG took for two months, TG suffered from stomach cramps and headaches and became irritable, anxious, angry and confused. When questioned about why both SSRIs were dispensed to TG, Respondent Gramlich responded that the pharmacy did not have the prescribing doctor's name at the time both medications were ordered by the facility. However, this statement was false because the name of the prescribing physicians was printed on top of the bubble pill pack.

27. On or about March 25, 2018, Dr. H prescribed 10 mg escitalopram to TG, which was subsequently dispensed at a different pharmacy on March 29, 2018. On or about May 25, 2018, this prescription was transferred to Respondent Fairbanks Pharmacy. On June 22, 2018, Dr. H called in an additional prescription for 20 mg escitalopram, which was processed on June 28, 2018 by Respondent Fairbanks Pharmacy.

28. The prescribing doctor, Dr. H, intended for the prescription for 10 mg escitalopram to be discontinued when TG received the prescription for 20 mg escitalopram, but the prescription was ambiguous. Respondent Gramlich failed to clarify this ambiguity with Dr. H, or to notify TG to stop taking the 10 mg escitalopram that was dispensed on June 22, 2018. Consequently, TG took 30 mg of escitalopram instead of the intended dose of 20 mg.

Other Prescriptions Dispensed to TB

29. Respondent Pharmacy filled several other prescriptions for TG. On or about April 30, 2018, Respondent Fairbanks Pharmacy filled prescriptions for clotrimazole cream; 20 mg of fluoxetine; 100 mg of allopurinol; 5 mg of lisinopril; and 20 mg of simvastatin. On or about May 3, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5 mg of lisinopril. On or about May 17, 2018, Respondent Fairbanks Pharmacy filled a prescription for 100 mg of allopurinol. On or about June 5, 2018, Respondent Fairbanks Pharmacy filled a prescription for 20 mg of simvastatin. For each of these prescriptions, Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions. Additionally, for each of the prescriptions that were filled on April 30, 2018, the medication list from the facility did not have annotations which showed the date and physician who issued the prescription, the quantity to dispense, or the initials of pharmacist who received the approval for the prescription, as required. Additionally, Respondent Gramlich failed to request the prescriptions from the physician.

Other Prescriptions Dispensed

30. On or about February 28, 2019, the Board conducted an inspection of Respondent Fairbanks Pharmacy. Following the Board's inspection, the Board investigator reviewed a CURES Report of the prescriptions prescribed between June 30, 2017 and December 30, 2018. The review of CURES showed that most of the prescriptions were for the administration of vaccines. However, the following prescriptions, which were not for vaccines, were processed, filled, and dispensed with Respondent Gramlich identified as the prescriber:

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Patient	Drug	Rx #	Initial Fill	Refill	Refill
MS	Bi-est 80/20 5mg/ml	100702	11/3/2017	1/29/2018	6/27/2018
KD	Dextroamphetamine 10 mg	100948	12/4/2017		
CS	Gentamicin 0.03% ophthalmic drops	103870	6/19/2018		
HL	Amlodipine-denazepril 5/20 mg	103581	6/25/2018		
HL	Omeprazole 20 mg	103582	6/25/2018		
CA	Cyanocobalamin 1,000 mcg	100376	9/28/2017		

31. On or about November 3, 2017, Respondent Fairbanks Pharmacy filled a prescription for 30 mg of Bi-Est 80/20. The prescription was prescribed by Dr. G for patient MS. However, the prescription was processed under the name of Respondent Gramlich instead of the actual prescriber.

32. On or about December 1, 2017, Respondent Fairbanks Pharmacy filled a prescription for 10 mg of dextroamphetamine. The prescription was prescribed by Dr. M for patient KD. However, the prescription was processed under the name of Respondent Gramlich instead of the actual prescriber.

33. On or about June 19, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5 ml of gentamicin 0.3% ophthalmic drops for patient CS. Respondent Gramlich was listed as the prescriber; however, he was not authorized to write or issue prescriptions.

34. On or about May 31, 2018, Respondent Fairbanks Pharmacy filled prescriptions for 5/20 mg of benazepril, as well as 20 mg of omeprazole, for Patient HL. The prescription was processed under the name of Respondent Gramlich instead of the actual prescriber, and Respondent Gramlich failed to confirm the identity of HL's current physician. On or about June 25, 2018, Respondent Fairbanks Pharmacy filled a prescription for 5/20 mg of benazepril. This prescription was prescribed by Dr. M for patient HL. For each of these prescriptions, the medication list from the facility did not have annotations which showed the date and physician who approved the prescription, the quantity to dispense, and the initials of pharmacist who received the approval for the prescription, as required.

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Qualifications of Respondent Gramlich

35. On or about September 28, 2017, Respondent Gramlich prescribed and administered 1000 mcg of Vitamin B-12 to a patient, pursuant to Respondent Fairbanks Pharmacy's Collaborative Practice Agreement, which provides in part that a pharmacist "[u]nder protocol and professional judgment may perform the injection."

36. During its investigation, the Board determined that Respondent Gramlich did not complete a clinical residency training, and was unable to provide proof that he previously worked as a paramedic. Respondent Gramlich also stated that he did not pursue a postgraduate residency program, but instead received clinical experience in direct patient care training. The doctor who provided clinical training, Dr. L, is a naturopathic doctor, not a physician.

37. Pursuant to Code section 4210, subdivision (a)(2)(C), clinical training can only be provided by a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system. Consequently, the training received by Respondent Gramlich from Dr. L was not valid, and did not qualify Respondent Gramlich for the issuance of an Advance Practice Pharmacist license.

FIRST CAUSE FOR DISCIPLINE

(Failure to Transmit CURES Data as Required)

38. Respondents are subject to discipline under Health & Safety Code section 11165, subdivision (d), and Code section 4113, in that they failed to submit CURES data of controlled substance prescriptions filed at Fairbanks Pharmacy within the required reporting parameter. The circumstances are as follows:

39. On March 4, 2019, the Board obtained a CURES report from May 25, 2017 to March 4, 2019, which showed that a total of 998 prescriptions for controlled substances were transmitted. The CURES report of Respondent Pharmacy for the controlled substances dispensed from January 1, 2018 to December 31, 2018, were reported to the Department of Justice after the Board's inspection on December 7, 2018, and not within the required reporting parameter.

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SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating State Laws and Regulations Governing Pharmacy)

40. Respondents are subject to discipline under Code section 4301, subdivisions (j) and (o), in conjunction with Code sections 4052.2(a), 4059(a), 4076(a)(4), and 4210(a)(2)(C); Health & Safety Code section 11165(d); and, CCR, title 16, sections 1707.2, 1707.3 and 1761(a); in that Respondent Gramlich acted with unprofessional conduct, in that he violated state laws and regulations governing pharmacy when he prescribed prescriptions in an unauthorized manner, as set forth in paragraphs 22 through 34, above.

THIRD CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

41. Respondents are subject to discipline under Code sections 4301, subdivision (o), and CCR, title 16, section 1761, subdivision (a), in that Respondent Gramlich dispensed multiple prescriptions which contained omissions and ambiguity, and failed to clarify ambiguities on multiple prescriptions, as set forth in paragraphs 22 through 34, above.

FOURTH CAUSE FOR DISCIPLINE

(Unauthorized Furnishing of Dangerous Drugs)

42. Respondents are subject to discipline under Code sections 4301, subdivision (j) and (o), and 4059, subdivision (a), in that Respondent Gramlich dispensed numerous prescriptions when he was not authorized to do so, as set forth in paragraphs 22 through 34, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Review Drug Therapy and Patient Medication Record)

43. Respondents are subject to discipline under Code sections 4301, subdivision (o), and CCR, sections 1707.2 and 1707.3, in that Respondent Gramlich failed to review patient TG's Prescription Profile before delivering prescription drugs resulting in the dispensing of discontinued medications, as set forth in paragraphs 22 through 34, above.

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SIXTH CAUSE FOR DISCIPLINE

(Failure to Provide Consultation)

44. Respondents are subject to discipline under Code section 4301, subdivision (o), and CCR, section 1707.2, subdivision (b)(1)(A), in that Respondent Gramlich failed to provide consultation to patient TG on June 22, 2018, which resulted in TG taking both escitalopram and fluoxetine, as set forth in paragraphs 22 through 34, above.

SEVENTH CAUSE FOR DISCIPLINE

(Dispensing of Prescription Label with the Wrong Prescriber)

45. Respondents are subject to discipline under Code section 4301, subdivision (o), and 4076, subdivision (a)(4), in that Respondent Gramlich dispensed prescriptions with labels bearing the wrong prescriber on two separate occasions, as set forth in paragraphs 31 through 32, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure of the Pharmacist to Adhere to Approved Protocol)

46. Respondents are subject to discipline under Code sections 4301, subdivision (o), and 4052.2, subdivision (a), in that Pharmacist Gramlich prescribed and administered Vitamin B-12 shots under a Collaborative Practice Agreement that was inadequate for the following reasons, as set forth below and in paragraphs 35 through 37, above:

a. The Collaborative Practice Agreement did not indicate the requirement that the supervising physician or primary physician be notified in writing within 24 hours of any initiation, change, adjustment, or discontinuation of therapy.

b. The Collaborative Practice Agreement did not indicate the requirement that the procedures to be performed by the pharmacist is related to a condition for which the patient has been seen by a physician.

c. Respondent Gramlich completed his training in providing clinical services to patients under the supervision of Dr. L, who is a naturopathic doctor.

d. Respondent Gramlich has not completed a clinical residency training or other program which demonstrated clinical experience in direct patient care delivery. Therefore, he was not qualified to administer vitamin B-12 injections.

OTHER MATTERS

75. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

76. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, and Respondent Gramlich, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 55594 was revoked, suspended, or placed on probation, Respondent Gramlich shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

77. Pursuant to Section 4307, if Pharmacy Permit Number PHY 55594 issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy is suspended, revoked or placed on probation, and Charles Adam Covello, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 55594 was revoked, suspended, or placed on probation, Charles Adam Covello shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

78. Pursuant to Section 4307, if Pharmacist License Number RPH 53112 issued to Bernard J. Gramlich is suspended or revoked, Respondent Gramlich shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

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PRAYER

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

1. Revoking or suspending Original Permit Number PHY 55594, issued to Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 53112, issued to Bernard Gramlich;

3. Ordering Del Sur Pharmacy, a California Corporation, dba Fairbanks Pharmacy and Bernard Gramlich 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;

4. Ordering that Respondent Bernard Gramlich is prohibited from serving as an officer, director, associate, partner, manager, qualifying individual or member of the personnel of record of a licensee pursuant to Code section 4307;

5. Ordering that Respondent Charles Adam Covello is prohibited from serving as an officer, director, associate, partner, manager, qualifying individual or member of the personnel of record of a licensee pursuant to Code section 4307; and,

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

DATED: 12/27/2021___

Signature on File

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

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