

1 ROB BONTA
Attorney General of California
2 ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
3 KRISTINA T. JARVIS
Deputy Attorney General
4 State Bar No. 258229
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-6088
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation, and Petition to
Revoke Probation Against:

13 **EMPOWER CLINIC SERVICES LLC**
14 **DBA EMPOWER PHARMACY;**
15 **ARTA SHAUN NOORIAN, MEMBER;**
16 **JORDAN BOWERS CUCCIA, PIC**
7601 N. Sam Houston Pkwy W. Suite 100
Houston, TX 77064

17 **Nonresident Pharmacy Permit**
18 **No. NRP 2567,**
Nonresident Sterile Compounding Permit
19 **No. NSC 101695**

20 Respondent.

Case No. 7437

ACCUSATION

AND

PETITION TO REVOKE PROBATION

21
22 **PARTIES**

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

26 2. On or about January 17, 2022, the Board issued Nonresident Pharmacy Permit
27 number NRP 2567 (NRP) to Empower Clinic Services LLC doing business as (dba) Empower
28 Pharmacy; with Arta Shaun Noorian, Member; Jordan Bowers Cuccia, PIC (Respondent). The

1 NRP was in full force and effect at all times relevant to the charges brought herein and will expire
2 on January 1, 2026, unless renewed.

3 3. On or about January 17, 2022, the Board issued Nonresident Sterile Compounding
4 Permit number NSC 101695 (NSC) to Respondent. The NSC was in full force and effect at all
5 times relevant to the charges brought herein and expired on January 1, 2024, and was not
6 renewed.

7 4. In a disciplinary action titled *In the Matter of the Accusation Against Empower Clinic*
8 *Services LLC, DBA Empower Pharmacy*, Case No. 7117, the Board issued a Decision and Order
9 effective January 18, 2023, in which Respondent's NRP and NSC were revoked. However, the
10 revocations were stayed and Respondent's NRP and NSC were placed on probation for four years
11 with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit A
12 and is incorporated herein by reference.

13 **JURISDICTION**

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

17 6. Section 4011 of the Code states:

18 The board shall administer and enforce this chapter and the Uniform Controlled Substances
19 Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

20 7. Section 4300 of the Code states in pertinent part:

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

22 ...

23 (c) The board may refuse a license to any applicant guilty of unprofessional
24 conduct. The board may, in its sole discretion, issue a probationary license to any
25 applicant for a license who is guilty of unprofessional conduct and who has met all
26 other requirements for licensure. The board may issue the license subject to any
27 terms or conditions not contrary to public policy, including, but not limited to, the
28 following:

(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.

1 8. Section 4300.1 of the Code states:

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

8 9. Section 4302 of the Code states:

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

14 10. Section 4303 of the Code states in pertinent part:

15 (b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy
16 registration, issue a citation or letter of admonishment to a nonresident pharmacy, or
17 take any other action against a nonresident pharmacy that the board may take against a
18 resident pharmacy license, on any of the same grounds upon which such action might
19 be taken against a resident pharmacy, provided that the grounds for the action are also
20 grounds for action in the state in which the nonresident pharmacy is permanently
21 located.

22 11. Section 4307 of the Code states in pertinent part:

23 (a) Any person who has been denied a license or whose license has been
24 revoked or is under suspension, or who has failed to renew his or her license while it
25 was under suspension, or who has been a manager, administrator, owner, member,
26 officer, director, associate, partner, or any other person with management or control
27 of any partnership, corporation, trust, firm, or association whose application for a
28 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.

...

1 12. Section 4342 of the Code states in pertinent part:

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

9 **STATUTORY PROVISIONS**

10 13. Section 4301 of the Code states in pertinent part:

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

14 ...

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

17 ...

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

23 14. Section 4022 of the Code states:

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

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

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

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

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

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

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1 16. Section 4126.8 of the Code states,

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

8 17. Section 4127.2 of the Code states in pertinent part:

9 ...

10 (e) A pharmacy licensed pursuant to this section shall do all of the following:

11 ...

12 (4) Advise the board of any complaint it receives from a provider, pharmacy, or
13 patient in California.

14 (f) Adverse effects reported or potentially attributable to a nonresident
15 pharmacy's sterile compounded drug product shall be reported to the board within 12
16 hours and immediately reported to the MedWatch program of the federal Food and
17 Drug Administration...

18 18. Section 4169 of the Code states in pertinent part:

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

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

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

27 19. Section 56.10 of the California Civil Code states in pertinent part:

28 (a) A provider of health care, health care service plan, or contractor shall
not disclose medical information regarding a patient of the provider of health care or
an enrollee or subscriber of a health care service plan without first obtaining an
authorization, except as provided in subdivision (b) or (c).

...

20. Section 565.001 of the Texas Pharmacy Act states in pertinent part:

(a) The board may discipline an applicant for or the holder of a current or expired license to
practice pharmacy if the board finds that the applicant or license holder has:

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(12) violated any pharmacy or drug statute or rule of this state, another state, or the United States;

...

HEALTH AND SAFETY CODE

21. Health and Safety Code section 11153, subdivision (a), states in pertinent part:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription...

22. 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.

23. 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.

24. 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.

25. 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).

26. Health and Safety Code section 111395 states in pertinent part:

Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug...

27. Health and Safety Code section 111430 states:

A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

1 28. Health and Safety Code section 111440 states:

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

4 **FEDERAL STATUTES AND REGULATIONS**

5 29. Title 21, United States Code (U.S.C.) section 351 states in pertinent part:

6 A drug or device shall be deemed to be adulterated—

7 (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

8 (1) If it consists in whole or in part of any filthy, putrid, or decomposed
9 substance; or

10 (2)(A) if it has been prepared, packed, or held under insanitary conditions
11 whereby it may have been contaminated with filth, or whereby it may have been
12 rendered injurious to health; or

13 (B) if it is a drug and the methods used in, or the facilities or controls used for,
14 its manufacture, processing, packing, or holding do not conform to or are not operated
15 or administered in conformity with current good manufacturing practice to assure that
16 such drug meets the requirements of this chapter as to safety and has the identity and
17 strength, and meets the quality and purity characteristics, which it purports or is
18 represented to possess...

19 30. 21 U.S.C. section 353a states in pertinent part:

20 ...

21 (b) Compounded drug

22 (1) Licensed pharmacist and licensed physician

23 A drug product may be compounded under subsection (a) if the licensed
24 pharmacist or licensed physician—

25 (A) compounds the drug product using bulk drug substances, as defined in
26 regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of
27 Federal Regulations—

28 ...

(ii) that are manufactured by an establishment that is registered under section 360
of this title (including a foreign establishment that is registered under section 360(i) of
this title)

...

(D) does not compound regularly or in inordinate amounts (as defined by the
Secretary) any drug products that are essentially copies of a commercially available drug
product.

...

1 31. Title 21, Code of Federal Regulations section 1306.03 states in pertinent part:

2 (a) A prescription for a controlled substance may be issued only by an individual
3 practitioner who is:

4 (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed
5 to practice his profession and

6 (2) Either registered or exempted from registration...

7 **REGULATORY PROVISIONS**

8 32. California Code of Regulations, title 16, (Regulations) section 1707.1 states in
9 pertinent part:

10 (a) A pharmacy shall maintain medication profiles on all patients who have
11 prescriptions filled in that pharmacy except when the pharmacist has reasonable
12 belief that the patient will not continue to obtain prescription medications from that
13 pharmacy.

14 (1) A patient medication record shall be maintained in an automated data
15 processing or manual record mode such that the following information is readily
16 retrievable during the pharmacy's normal operating hours.

17 (A) The patient's full name and address, telephone number, date of birth (or age)
18 and gender...

19 33. Regulations section 1707.3 states:

20 Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's
21 drug therapy and medication record before each prescription drug is delivered. The review shall
22 include screening for severe potential drug therapy problems.

23 34. Regulations section 1716 states:

24 Pharmacists shall not deviate from the requirements of a prescription except upon the prior
25 consent of the prescriber or to select the drug product in accordance with Section 4073 of the
26 Business and Professions Code.

27 35. Regulations section 1717 states in pertinent part:

28 ...

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist
shall reduce it to writing, and initial it, and identify it as an orally transmitted
prescription. If the prescription is then dispensed by another pharmacist, the

1 dispensing pharmacist shall also initial the prescription to identify him or herself. All
2 orally transmitted prescriptions shall be received and transcribed by a pharmacist
3 prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in
4 section 4019 of the Business and Professions Code are not subject to the provisions of
5 this subsection....

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10 36. Regulations section 1717.3 states in pertinent part:

11 ...

12 (b) A person may dispense a dangerous drug, that is not a controlled substance,
13 pursuant to a preprinted multiple checkoff prescription blank and may dispense more
14 than one dangerous drug, that is not a controlled substance, pursuant to such a blank
15 if the prescriber has indicated on the blank the number of dangerous drugs he or she
16 has prescribed.

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20 37. Regulations section 1735.1 states in pertinent part:

21 ...

22 (ae) "Quality" means the absence of harmful levels of contaminants, including
23 filth, putrid, or decomposed substances, the absence of active ingredients other than
24 those listed on the label, and the absence of inactive ingredients other than those
25 listed on the master formula document.

26
27
28 38. Regulations section 1735.2 states, in pertinent part:

...
29

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

31 ...

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

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

43 ...

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

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(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.

...

(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.

...

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

- (A) Method Suitability Test,
- (B) Container Closure Integrity Test, and
- (C) Stability Studies

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

...

39. 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:

...

(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 (I) shall apply.

...

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

...

1 (c) Active ingredients shall be obtained from a supplier registered with the
Food and Drug Administration (FDA).

2 ...

3
4 40. Regulations section 1735.4 states, in pertinent part:

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

7 ...

8 (5) The date compounded;

9 ...

10 41. Regulations section 1751.3 states, in pertinent part:

11 (a) Any pharmacy engaged in compounding sterile drug preparations shall
12 maintain written policies and procedures for compounding. Any material failure to
13 follow the pharmacy's written policies and procedures shall constitute a basis for
disciplinary action. In addition to the elements required by section 1735.5, there shall
be written policies and procedures regarding the following:

14 ...

15 (5) Compounded sterile drug preparation stability and beyond use dating.

16 42. Regulations section 1761 states in pertinent part:

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

20 43. Regulations section 1764 states:

21 No pharmacist shall exhibit, discuss, or reveal the contents of any prescription,
22 the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any
23 patient or any medical information furnished by the prescriber with any person other
than the patient or his or her authorized representative, the prescriber or other licensed
24 practitioner then caring for the patient, another licensed pharmacist serving the
patient, or a person duly authorized by law to receive such information.

25 44. Regulations section 1774 states in pertinent part:

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

28 ///

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

3 45. Regulations section 1793 states in pertinent part:

4 Only a pharmacist, or an intern pharmacist acting under the supervision of a
5 pharmacist, may:

6 (a) Receive a new prescription order orally from a prescriber or other person
7 authorized by law.

8 ...

9 (e) Consult with any prescriber, nurse or other health care professional or
10 authorized agent thereof.

11 **COST RECOVERY**

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

16 **DEFINITIONS**

17 47. Cholecalciferol is the active form of vitamin D3. Cholecalciferol can be compounded
18 into many forms and is considered to be a dietary supplement. It is a dangerous drug pursuant to
19 Code section 4022.

20 48. Coenzyme Q-10 (also known as CoQ10) is a common dietary supplement and
21 antioxidant that the human body produces naturally. Coenzyme Q-10 can be compounded into an
22 oral or an injectable form; however, the injectable form is not an FDA approved drug to treat any
23 disease or disorder. Coenzyme Q-10, in the injectable form, is a dangerous drug pursuant to Code
24 section 4022.

25 49. Cyanocobalamin is a form of vitamin B12. Cyanocobalamin can be compounded into
26 many forms including for oral, nasal, or injectable administration. In its injectable form, it is a
27 dangerous drug pursuant to Code section 4022.

28 50. Lipo-C, as compounded and sold by Respondent in 2022, is a compound of six active
ingredients methionine, inositol, choline Cl, carnitine, thiamine HCl, and dexpanthenol,

1 advertised as a lipotropic to reduce fat. In 2023, due to violations issued by the Board,
2 Respondent changed its formulation to remove inositol, and thereafter Lipo-C was a compound of
3 five active ingredients, methionine, choline Cl, carnitine, thiamine HCl, and dexpanthenol. Lipo-
4 C is not an FDA approved drug to treat any disease or disorder. Lipo-C is a dangerous drug
5 pursuant to Code section 4022.

6 51. Methylcobalamin (methyl vitamin B12) is the synthetic and active form of cobalamin
7 (vitamin B12). Methylcobalamin can be compounded into an oral or an injectable form;
8 however, the injectable form is not an FDA approved drug to treat any disease or disorder.
9 Methylcobalamin is a dangerous drug pursuant to Code section 4022.

10 52. Nicotinamide Adenine Dinucleotide (NAD) is a non-protein compound that is
11 necessary for the functioning of an enzyme. NAD occurs naturally in the human body. NAD can
12 be compounded into an oral or an injectable form; however, the injectable form is not an FDA
13 approved drug to treat any disease or disorder. NAD is a dangerous drug pursuant to Code
14 section 4022.

15 53. Phentermine is an anorectic drug used to reduce appetite and promote weight loss.
16 Phentermine is a Schedule IV controlled substance pursuant to Health and Safety Code section
17 11057, subdivision (f)(4), and a dangerous drug pursuant to Code section 4022.

18 54. Sermorelin acetate is a peptide (consisting of 29 amino acids) in the Growth Hormone
19 Releasing Hormone (GHRH) class. It is generally used to diagnose and treat poor growth in
20 human children. Sermorelin acetate can be compounded into an oral or an injectable form;
21 however, the injectable form is not an FDA approved drug to treat any disease or disorder.
22 Sermorelin acetate is a dangerous drug pursuant to Code section 4022.

23 **INTRODUCTION**

24 55. This case is about the compounding of prescription drugs, including those
25 designated for sterile administration, in a pharmacy. Pharmacy compounding is when a licensed
26 pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs
27 of an individual patient. (See e.g., Cal. Code Regs., tit. 16, § 1735.)

28 ///

1 56. Compounding is a form of drug manufacturing subject to the drug manufacturing
2 requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.].
3 Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by
4 section 503A of the FDCA [21 U.S.C. § 353a].

5 57. The Food and Drug Administration (FDA) oversees drug manufacturing, but does
6 not license pharmacies or pharmacists, nor control when or how their licenses permit
7 compounding. The states issue these licenses, and have primary jurisdiction. The states also set
8 compounding standards that complement FDA standards for compounding as a form of drug
9 manufacturing.

10 58. California law authorizes the Board to treat violations of federal statutes regulating
11 controlled substances and dangerous drugs, as well as federal laws and regulations governing
12 pharmacy practice, as grounds for discipline. (Bus. & Prof. Code §§ 4301, subs. (j), (o); 4342.)

13 59. Among the federal law requirements for pharmacy compounding is that bulk drug
14 substances used for compounding: (1) must comply with the standards of an applicable United
15 States Pharmacopeia (USP)¹ or National Formulary (NF) monograph, if a monograph exists, and
16 the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, must be
17 components of drugs already otherwise approved by the Secretary; or (3) if such a monograph
18 does not exist and the substance is not a component of a drug approved by the Secretary, must
19 appear on a list promulgated in regulation by the Secretary. (21 U.S.C. § 353a(b)(1)(A)(i).) Each
20 bulk drug substance must also be manufactured by an FDA registrant, and be accompanied by a
21 valid certificate of analysis. (21 U.S.C. § 353a(b)(1)(A)(ii) and (iii).)

22 60. Under both federal and California law, *any* manufactured drug, including a
23 pharmacy compound, must not be “adulterated” by containing “any filthy, putrid, or decomposed
24 substance” *or* by having been “prepared, packed, or held under insanitary conditions whereby it
25 *may have* been contaminated with filth, or whereby it *may have* been rendered injurious to
26 health.” (21 U.S.C. § 351(a)(1) and (a)(2)(A) [definitions of “adulterated”] (emphasis added); 21

27 _____
28 ¹ The USP was recently updated, so there is a 2008 version and a 2023 version. All
references in this document are to the 2008 version.

1 U.S.C. § 331(a), (b), (c) [adulterated drug prohibition]; Health & Saf. Code, §§ 11250, 11255
2 [definitions of “adulterated”] (emphasis added); Health & Saf. Code, § 11295 [adulterated drug
3 prohibition].)

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

9 62. California law allows all licensed pharmacists to compound *non-sterile* drug
10 products in licensed pharmacies. (See e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.)

11 63. An additional specialty license is required before any licensed pharmacy is
12 allowed to compound *sterile* drug products. (Bus. & Prof. Code, § 4127 *et seq.*) And particular
13 regulatory requirements apply to preparation, maintenance, and distribution of sterile drug
14 products. (Cal. Code Regs., tit. 16, § 1751 *et seq.*; see also Cal. Code Regs., tit. 16, § 1735 *et*
15 *seq.*)

16 64. All compounding, whether sterile or non-sterile, must be consistent with standards
17 in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-
18 National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus.
19 & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement
20 the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq.*, 4128 *et seq.*,
21 4129 *et seq.*, Cal. Code Regs., tit. 16, §§ 1735 *et seq.*, 1751 *et seq.*)

22 65. Each sterile compounding pharmacy must be inspected prior to each annual
23 renewal of a sterile compounding license to ensure compliance with all compounding and sterile
24 compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) Out-of-state sterile
25 compounding pharmacies must also have this specialty license, and are also annually inspected.
26 (Bus. & Prof. Code, § 4127.2, subd. (c).) All of this demonstrates the attention and resources
27 devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug
28 products. In 2012, for instance, a contaminated sterile drug compound was widely distributed,

1 and caused a nationwide fungal meningitis outbreak, killing 64 people and causing infections in
2 almost 800 others who received the drug.

3 66. Many or all of the bulk drug substances at issue in this case have not met the
4 requirements of federal section 503A, because they are not the subject of an applicable USP or
5 NF drug monograph, are not a component of a drug already approved by the FDA, and are not on
6 the permissible “503A bulks list” identified by the FDA in regulation; they were not received
7 from FDA-registered manufacturing sites; and/or they were not accompanied by a valid
8 certificate of analysis. Many or all of the bulk drug substances at issue in this case are further
9 questionable for reasons including that they were not intended by the manufacturers (i.e., they
10 were not “graded”) for use in pharmaceutical products, let alone sterile compounds. Some were
11 graded for dietary use, a quite different standard. Some were graded for topical use. Some were
12 not graded at all.

13 67. Lastly, some of the bulk drug substances at issue in this case have been nominated,
14 but not yet included, on a list of bulk drug substances identified by the FDA as “Category 1.”
15 Over the last several years, the FDA has engaged in a process to receive and review nominations
16 for bulk drug substances to appear on the “503A bulks list” developed by the Secretary via
17 regulation under the third option identified above—bulk drug substances appropriate for section
18 503A compounding that are neither the subject of an applicable USP or NF drug monograph nor a
19 component of an approved drug. This “503A bulks list” is codified at 21 Code of Federal
20 Regulations § 216.23(a). It includes only six bulk drug substances approved for use in section
21 503A compounding,² and four disapproved.³ Accordingly, only those six bulk drug substances
22 listed in this regulation are approved for use in compounding under section 503A.⁴ *Any other*

23 ² (1) Brilliant Blue G, aka Coomassie Brilliant Blue G-250; (2) Cantharidin (topical use only); (3)
24 Diphenylcyclopropanone (topical use only); (4) N-acetyl-D-glucosamine (topical use only); (5)
25 Squaric acid dibutyl ester (topical use only); and (6) Thymol iodide (topical use only).

26 ³ (1) Oxitriptan; (2) Piracetam; (3) Silver Protein Mild; and (4) Tranilast.

27 ⁴ Even this approval for use in compounding is expressly limited by 21 Code of Federal
28 Regulations § 216.23, subdivision (d): Based on evidence currently available, there are
inadequate data to demonstrate the safety or efficacy of any drug product compounded using any
of the drug substances listed in paragraph (a) of this section, or to establish general recognition of
(continued...)

1 bulk drug substance that is not the subject of an applicable USP or NF drug monograph, or a
2 component of an approved drug, cannot be used.

3 68. The FDA has received hundreds of nominations for bulk drug substances to be added
4 to this “503A bulks list.” While they are under consideration, nominated bulk drug substances
5 are placed into one of three categories, depending on the amount of information/documentation
6 received along with the nomination, and whether it presents a significant safety risk.

7 69. The FDA has said that bulk drug substances included in “Category 1” are those that
8 *may be eligible* for inclusion on the “503A bulks list,” were nominated with sufficient supporting
9 information for the FDA to evaluate them, and do not appear to present significant safety risks.

10 70. However, bulk drug substances included on the Category 1 list have not been
11 approved by the FDA for use in compounding under section 503A. By definition, bulk drug
12 substances on this list are not the subject of an applicable USP or NF drug monograph, are not
13 components of FDA-approved drugs, and have not been added to the “503A bulks list.” They are
14 therefore not deemed appropriate for use in compounding by the FDA under section 503A.
15 However, the FDA has released a draft guidance document for industry indicating that it would
16 not take regulatory action against pharmacies that compound with bulk drug substances included
17 on the Category 1 list. This draft guidance for industry does not bind the California Board of
18 Pharmacy in any way.

19 71. In this case, Respondent has engaged in significant compounding of drug products
20 intended for sterile administration. In numerous instances, they have done so utilizing active
21 pharmaceutical ingredients (APIs) received as bulk drug substances. In many or all cases, they
22 have taken non-sterile bulk drug substances and used them to create compounded preparations
23 intended for sterile administration. Non-sterile to sterile compounding is the most high-risk, and
24 warrants extra precautions, including end-product sterilization and testing. And the quality of the
25 components used in sterile compounding is important. But Respondent has repeatedly used bulk
26 _____
27 the safety or effectiveness of any such drug product. Any person who represents that a
28 compounded drug made with a bulk drug substance that appears on this list is FDA approved, or
otherwise endorsed by FDA generally or for a particular indication, will cause the drug to be
misbranded under section 502(a) and/or 502(bb) of the Federal Food, Drug, and Cosmetic Act.
(21 C.F.R. § 216.23(d).) In other words, no resulting compound is “FDA-approved.”

1 drug substances that have either or both (1) not met the requirements of section 503A, and/or (2)
2 not been graded for pharmaceutical use. The resulting compounds are “adulterated” drug
3 products and lack the quality required to dispense to patients in the State of California.

4 **BACKGROUND INFORMATION**

5 72. Respondent owns and operates a pharmacy in the State of Texas which is licensed as
6 a nonresident pharmacy by the Board. A nonresident pharmacy license allows Respondent to
7 ship non-sterile drug preparations into California for use by California consumers. Respondent
8 also applied for and was granted a nonresident sterile compounding pharmacy permit which
9 allowed them to ship sterile compounded drug products into California for use by California
10 consumers.

11 73. The accusation in the prior matter which lead to Respondent’s probation arose from
12 events that occurred from 2019 through 2021. The stipulated settlement whereby Respondent
13 agreed to probation was entered into on September 16, 2022. The first investigation giving rise to
14 the instant Accusation and the Petition to Revoke Probation was completed in November 2022.
15 Therefore, all of the investigations in this pleading were not completed until after the stipulated
16 settlement was executed and under consideration by the Board and none of the charges could
17 have been brought in that proceeding.

18 **November 29, 2022 Investigation**

19 74. This investigation relates to events occurring prior to the effective date of
20 Respondent’s probation and therefore applies only to the accusation.

21 75. Between February 3, 2022, and September 2, 2022, the Board received five emails
22 from Respondent reporting adverse drug effects (ADEs), consumer complaints, or mis-filled
23 prescriptions for compounded preparations shipped into California for use by California
24 consumers. The ADEs, complaints, and mis-fills included:

- 25 a. RX # 6542544 for non-sterile compounded estradiol 0.1 mg/ml, which
26 Respondent mis-filled as 1 mg/ml, 10 times the dosage amount. The patient reported side
27 effects such as increased acne, head congestion, weight gain, and her estradiol, ferritin, and
28 liver enzymes were “off.”

1 b. RX # 60415985 for sterile compounded testosterone cypionate 200 mg/ml, with
2 directions to inject intramuscularly (IM) every 2 weeks, Respondent mis-filled by providing
3 directions to inject twice every week. The patient reported no side effects.

4 c. RX # 60538433 for sterile compounded testosterone cypionate 200 mg/ml.
5 Patient suffered an adverse effect in that they experienced pain and swelling at injection site
6 and was treated at urgent care. The patient had used the vial past the recommended 28 days
7 following initial sterile seal puncture.

8 d. RX # 23339878 for sterile compounded Tri-Mix (papaverine HCl,
9 phentolamine mesylate, prostaglandin E1). The patient reported no effect from
10 compounded drug.

11 e. RX # 60425135 for sterile compounded testosterone cypionate 200 mg/ml.
12 Patient reported itching and a lump at the injection site approximately 1 day following
13 injection, which would last approximately 2 days from onset.

14 76. During the investigation, Inspector A.P. requested information regarding all
15 complaints received by Respondent from California patients, pharmacies, or prescribers.
16 Respondent provided a spreadsheet of 938 complaints received between January 1, 2022, and
17 September 16, 2022. The spreadsheet divided the complaints into three categories; (1) 878
18 customer service complaints, (2) 50 product quality complaints, and (3) 10 ADEs.

19 77. Inspector A.P. also reviewed compounding logs and purchase records relating to
20 sterile compounding of three drug substances: methylcobalamin, coenzyme Q-10, and NAD.
21 Inspector A.P. discovered multiple violations of pharmacy law including assigning unsupported
22 extended beyond use dates to compounded drug products, failing to maintain the quality of
23 compounded sterile preparations, compounding, holding for sale, and dispensing adulterated drug
24 preparations, failing to obtain drug substances from a registered manufacturer, failing to report
25 patient or medical provider complaints to the Board, and failing to report adverse drug effects to
26 the board, and disclosure of patients' confidential medical information.

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1 **Causes for Discipline Relating to November 29, 2022 Investigation**

2 **FIRST CAUSE FOR DISCIPLINE**

3 **(Assignment of Unsupported Extended Beyond Use Dates)**

4 78. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
5 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
6 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section
7 1735.2, subdivision (i). The circumstances are that Respondent compounded and assigned a
8 beyond use date of approximately 365 days (1 year) to at least one batch, #119923, which
9 contained at least 85 prescriptions and 158 vials of non-sterile to sterile Methylcobalamin 10,000
10 mcg without having identical specific and essential compounding steps between the finished
11 compounded drug preparation and the compounded drug preparations tested and studied to
12 establish the beyond use date. A total of 3,400 vials, which consists of 1,425 prescriptions is also
13 believed to have used the same compounding steps as batch #119923 and was furnished into
14 California between January 1, 2022 and September 11, 2022, based on Respondent's dispensing
15 records.

16 **SECOND CAUSE FOR DISCIPLINE**

17 **(Failure to Maintain Quality of Compounded Sterile Preparations)**

18 79. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
19 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
20 pharmacy and regulating dangerous drugs in that Respondent compounded drugs that lacked
21 quality and were adulterated and dispensed those drugs to patients in violation of Regulations
22 sections 1735.1, subd. (ae), and 1735.2, subd. (g), and Health and Safety Code sections 111250
23 and 111255. The circumstances are that Respondent compounded, and then from approximately
24 July 22, 2022 to September 22, 2022, furnished into California the following drug preparations
25 and which lacked quality:

26 a. At least 85 prescriptions of Methylcobalamin 10,000 mcg, lot # 119923.
27 Respondent compounded this lot using Japanese Pharmacopeia (JP) grade, and marked "Not for
28 Drug Use."

1 **FIFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Report Complaints to the Board)**

3 82. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
4 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
5 pharmacy and regulating dangerous drugs by violating Code section 4127.2, subdivision (e), in
6 that between January 1, 2022 and September 16, 2022, Respondent received at least 938
7 complaints from patients, pharmacies, or prescribers in California which were never reported to
8 the California Board of Pharmacy, and instead were discovered by inspectors during an
9 inspection.

10 **SIXTH CAUSE FOR DISCIPLINE**

11 **(Failure to Report Potential Adverse Drug Effects to the Board)**

12 83. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
13 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
14 pharmacy and regulating dangerous drugs by violating Code section 4127.2, subdivision (f), in
15 that between July 15, 2022 and September 8, 2022, Respondent received five reports of possible
16 adverse drug effects (ADEs), and failed to report any of them to the Board within 12 hours, and
17 failed to report four of them at all.

18 **SEVENTH CAUSE FOR DISCIPLINE**

19 **(Disclosure of Medical Information)**

20 84. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
21 Code section 4301, subdivision (o), for failing to follow laws and regulations governing
22 pharmacy by violating Civil Code section 56.10 and Regulations section 1764, by disclosing
23 prescription information and personal health information of two patients. The circumstances are
24 that between July 21, 2022, and September 8, 2022, Respondent received reports it had mailed,
25 and caused to be delivered, medications labeled with those patients' prescription and personal
26 information to clinics unassociated with those patients.

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1 **February 23, 2023 Investigation**

2 85. This investigation relates to events occurring prior to the effective date of
3 Respondent's probation and therefore applies only to the accusation.

4 86. At some point prior to December 20, 2022, Inspector S.K. was notified by a Drug
5 Enforcement Agency (DEA) Diversion Investigator that a physician, Dr. F, had surrendered his
6 DEA registration on August 18, 2022, and therefore was not authorized to prescribe controlled
7 substances after that date.

8 87. The Controlled Substance Utilization Review and Evaluation System (CURES) is
9 California's Prescription Drug Monitoring System, and all pharmacies licensed in California,
10 regardless of their physical location, are required to report all filled prescriptions for Schedule II-
11 V controlled substances to CURES on a daily basis.

12 88. The CURES report related to Dr. F showed that between approximately August 18,
13 2022, and December 9, 2022, Respondent filled and dispensed 16 prescriptions written by Dr. F,
14 for California patients of the controlled substance phentermine.

15 **Cause for Discipline Relating to February 23, 2023 Investigation**

16 **EIGHTH CAUSE FOR DISCIPLINE**

17 **(Failure to Exercise Corresponding Responsibility)**

18 89. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
19 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
20 pharmacy and regulating dangerous drugs by violating Health and Safety Code section 11153, for
21 failing to ensure that a prescription for a controlled substance shall only be dispensed for a
22 legitimate medical purpose, and 21 C.F.R. 1306.03, for failing to ensure that the prescriber
23 issuing a prescription was fully licensed and registered. The circumstances are that Respondent
24 issued 16 prescriptions for the controlled substance phentermine when the prescriber issuing the
25 prescriptions did not have valid DEA registration as set forth in paragraphs 86 through 88, above.

26 **April 28, 2023 Investigation**

27 90. This investigation relates to events occurring prior to the effective date of
28 Respondent's probation and therefore applies only to the accusation.

1 91. Between November 3, 2022, and December 16, 2022, Respondent emailed the Board
2 six times, four emails contained reports of potential ADEs, one email with consumer complaints,
3 and one reporting a dispensing error. The ADEs, complaints, and dispensing error included:

4 a. RX # 23806772 for sterile Sermorelin Acetate (LYO) 9mg injectable, with
5 directions to reconstitute with 4.5 ml of bacteriostatic water and inject 0.2 ml subcutaneously at
6 bedtime. The prescriber reported that the patient experienced an anaphylactic reaction,
7 experiencing itching and hives at the injection site, diarrhea, itchy eyes, and closing throat. The
8 patient went to the emergency department and received an epinephrine injection which resolved
9 the reaction. Patient chose to discontinue use of medication.

10 b. RX # unknown because multiple prescriptions may have been involved, for
11 testosterone cypionate 5ml sterile injectable, reported by a medical provider treating a patient for
12 oozing lesions on his skin which the patient attributed to the testosterone injections. The patient
13 discontinued the medication and was under the treatment of a dermatologist.

14 c. RX # 23839906 for sermorelin acetate (LYO) injectable 15mg, reported by the
15 prescriber because the patient presented with a rash and hives at the injection site. Patient was
16 treated by the prescriber's office with Benadryl and a topical cream. The patient discontinued the
17 medication.

18 d. RX unknown because no record was found of this patient or prescriber and
19 Respondent questions whether the product was theirs. The patient reported a hard lump at the
20 injection site in response to a zinc sulfate injection.

21 e. Respondent provided a spreadsheet of 354 complaints received from October
22 and November 2022 from patients residing in California.

23 f. RX # 60678493 for testosterone cypionate 20mg/ml in grapeseed oil as a sterile
24 injectable. When the prescriber called in an oral prescription for this patient, while conversing
25 with a pharmacist employed by Respondent, it was discovered that this prescription was
26 dispensed as 200 mg/ml instead of 20mg/ml. The prescriber reported that the patient's
27 testosterone levels were high and they would run additional labs and monitor the patient closely.

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1 **TENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Obtain Drug Substances from Registered Manufacturer)**

3 95. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
4 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
5 pharmacy and regulating dangerous drugs by violating 21 U.S.C. section 353a, subdivision
6 (b)(1)(A)(ii), and Regulations section 1735.3, subdivision (c). The circumstances are that on
7 October 24, 2022, Respondent dispensed and shipped into California a compounded Lipo-C
8 injectable, which was compounded using three active pharmaceutical ingredients, methionine,
9 inositol, and thiamine HCl sourced from manufacturers that were not registered with the FDA.

10 **ELEVENTH CAUSE FOR DISCIPLINE**

11 **(Disclosure of Medical Information)**

12 96. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
13 Code section 4301, subdivision (o), for failing to follow laws and regulations governing
14 pharmacy by violating Civil Code section 56.10 and Regulations section 1764, by disclosing
15 prescription information and personal health information of at least seven patients. The
16 circumstances are that between October 11, 2022, and November 18, 2022, Respondent received
17 reports that it had mailed and caused to be delivered medications labeled with those patients'
18 prescription and personal information to clinics unassociated with those patients.

19 **May 26, 2023 Investigations**

20 97. These investigations relate to events occurring after the date Respondent's probation
21 became effective and therefore applies to both the accusation and the petition to revoke probation.

22 98. On or about March 8, and April 3, 2023, the Board received notifications from
23 Respondent that two patients had suffered ADEs after being injected with their compounded drug
24 product semaglutide with cyanocobalamin.

25 99. Patient B.K. reported that she suffered from bloating, headaches, burping, and
26 vomiting so severe that she went to urgent care. Her symptoms lasted for approximately five
27 days.

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1 on or about February 27, 2023, and March 8, 2023, dispensed and shipped into California
2 semaglutide with cyanocobalamin, and failed to include on the prescription label the date of
3 compounding.

4 **FOURTEENTH CAUSE FOR DISCIPLINE**

5 **(Dispensing Pursuant to Non-Conforming Pre-Printed Prescription Blank)**

6 104. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
7 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
8 pharmacy and regulating dangerous drugs by violating Regulations section 1717.3, subdivision
9 (b). The circumstances are that on or about February 27, 2023 and March 8, 2023, Respondent
10 dispensed semaglutide with cyanocobalamin and syringes for administration from a pre-printed,
11 multiple check-off prescription blank that did not contain an area for the prescriber to indicate the
12 total number of dangerous drugs or devices prescribed.

13 **June 8, 2023 Investigation**

14 105. This investigation relates to events occurring after the date Respondent's probation
15 became effective and therefore applies to both the accusation and the petition to revoke probation.

16 106. On April 10, 2023, the Board received notification from Respondent that an ADE
17 occurred with their compounded drug product semaglutide with cyanocobalamin.

18 107. Patient J.S. reported suffering from tiredness, lethargy, blurry vision, nausea, and
19 vomiting. Patient J.S. went to urgent care for medical assistance. He stopped taking the
20 compounded drug product dispensed by Respondent and over the course of two weeks the
21 symptoms slowly decreased; however, he still suffers from headaches and acid reflux.
22 Additionally, Patient J.S. developed a rash at the site on his stomach where he injected the
23 compounded drug product, which spread to various parts of his body and he required treatment by
24 a dermatologist.

25 108. Inspector J.F. investigated the ADE and reviewed compounding logs and prescription
26 information, and found violations of pharmacy law including failing to comply with
27 compounding limitations and requirements, variation from prescription, and incomplete labeling
28 of a compounded drug preparation.

1 109. The prescriber of this compounded drug product is located in and has a medical
2 license in Washington State. The patient resides in California. The prescription provided no
3 clinical justification for the compounded semaglutide with cyanocobalamin, and no diagnosis for
4 the patient was included on the prescription.

5 **Causes for Discipline Relating to June 8, 2023 Investigation**

6 **FIFTEENTH CAUSE FOR DISCIPLINE**

7 **(Variation from Prescription)**

8 110. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
9 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
10 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section 1716.
11 The circumstances are that on or about March 18, 2023, Respondent dispensed to patient J.S.
12 vials of semaglutide with cyanocobalamin with prescription labeled direction to “inject 0.25ml
13 subcutaneously once a month” when the original prescription was written with direction to “inject
14 0.25ml subcutaneously once a week.”

15 **SIXTEENTH CAUSE FOR DISCIPLINE**

16 **(Failure to Properly Document Compounded Drug Preparation)**

17 111. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
18 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
19 pharmacy and regulating dangerous drugs by violating Regulations section 1735.3, subdivisions
20 (a)(2)(F) and (I). The circumstances are that on or about February 3, 2023, Respondent
21 compounded semaglutide with cyanocobalamin and documented compounding 4,829 vials, but
22 documented using zero vials in the compounding process.

23 **SEVENTEENTH CAUSE FOR DISCIPLINE**

24 **(Incomplete Labeling of a Compounded Drug Preparation)**

25 112. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
26 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
27 pharmacy and regulating dangerous drugs by violating Regulations section 1735.4, subdivision
28 (a)(5). The circumstances are that on or about February 3, 2023, Respondent compounded, and

1 on or about March 18, 2023, dispensed and shipped into California semaglutide with
2 cyanocobalamin, and failed to include the date of compounding on the prescription label.

3 **October 9, 2023 Investigation**

4 113. This investigation relates to events occurring after the date Respondent’s probation
5 became effective and therefore applies to both the accusation and the petition to revoke probation.

6 114. On May 24, 2023, the Board received notification from Respondent of ADEs for ten
7 patients of one prescriber “the Lam Clinic,” all of whom suffered from itchiness after they were
8 administered Coenzyme Q-10 compounded and dispensed by Respondent.

9 115. On May 25 and May 26, 2023, the Board received notification from Respondent of
10 ADEs for five patients of one prescriber “the De Luz Clinic,” all of whom suffered cellulitis,
11 severe arm pain, infection, redness, and swelling after they were administered Lipo-C injectable
12 compounded and dispensed by Respondent.

13 116. Patient A.V. from the De Luz Clinic was administered Lipo-C, and had severe
14 enough symptoms to be admitted to the hospital, although she was discharged later the same day.

15 117. Inspector J.F. investigated these ADEs and also reviewed compounding logs and
16 prescription information, and found violations of pharmacy law including failing to obtain drug
17 substances from a registered manufacturer, failing to maintain quality of compounded sterile drug
18 preparations, compounding, holding for sale, and dispensing adulterated drug preparations,
19 assigning an unsupported extended beyond use date, failing to perform a drug utilization review,
20 allowing pharmacy technicians to perform duties outside their scope of practice, failing to clarify
21 administration directions, dispensing prescriptions with incorrect administration directions, and
22 failing to maintain accurate patient records.

23 118. Respondent had no prescription information for patient A.V. from the De Luz Clinic.
24 Further investigation showed that both the De Luz and the Lam Clinics were ordering
25 compounded drugs from Respondent under one patient’s name and information, and then would
26 administer the compounded drugs to multiple patients.

27 119. Four of the patient profiles in Respondent’s computer records system for patients of
28 the Lam Clinic had the Lam Clinic’s telephone number listed as “patient telephone number.”

1 120. Prescriptions for two patients of the Lam Clinic, M.L. and E.L., provided that the
2 compounded drugs were to be administered intramuscularly (IM) or subcutaneously (SQ). The
3 labels on the compounded drugs, however, provided direction to the patients to administer
4 intravenously (IV). IV administration is more dangerous than IM or SQ, as IV administration
5 injects the drug directly into the patient's blood supply with quicker and more potent access to the
6 patient's organs.

7 121. On or about May 16, 2023, a pharmacy technician working for Respondent, T.B.
8 noted on M.L.'s prescription that all prescriptions for this patient were changed via telephone by
9 the office manager for the Lam Clinic for the medication to be administered IV.

10 122. On or about June 6, 2023, a pharmacist working for Respondent, A.H., noted on
11 M.L.'s prescription that all prescriptions for this patient were changed via telephone by the office
12 manager for the Lam Clinic for the medication to be administered IM.

13 123. On or about June 8, 2023, Respondent dispensed two compounded injectable drug
14 products to patient M.L. with the directions indicating that they should be administered IV,
15 however, the directions should have stated IM per the June 6, 2023 notation.

16 124. A review of the dispensing records for Coenzyme Q-10 for patient M.L. shows that
17 Respondent dispensed a 150-day supply on December 22, 2022, then 50 days later dispensed
18 another 150-day supply. Fifteen days later, a 280-day supply was dispensed. Fifty-two days
19 later, another 280-day supply was dispensed, 28 days later another 280-day supply was dispensed,
20 and then 23 days later, a 28-day supply was dispensed. Overall, in 168 days, Respondent
21 provided a 1,168-day supply of Coenzyme Q-10 to patient M.L. without any documentation
22 regarding any medical reason the patient would need such high quantities of this product.

23 125. In addition to providing these high volumes of Coenzyme Q-10 to patient M.L., some
24 of the vials dispensed to this patient had a beyond use date (BUD) that would expire before
25 patient M.L. could have used the product. For example, on February 25, 2023, Respondent
26 dispensed a 280-day supply of Coenzyme Q-10 to M.L., however, the BUD was only 248 days
27 later, on October 31, 2023. Similarly, on April 18, 2023, Respondent dispensed a 280-day

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1 supply, but the BUD was only 196 days later. On May 16, 2023, Respondent dispensed a 280-
2 day supply, but the BUD was only 168 days later.

3 126. A review of the dispensing records for cholecalciferol for patient M.L. shows that
4 Respondent dispensed a 90-day supply on December 22, 2022, then 33 days later dispensed a
5 150-day supply. Seventeen days later, Respondent dispensed a 150-day supply. Fifteen days
6 after that, Respondent dispensed a 280-day supply. Fifty-two days later, Respondent dispensed
7 another 280-day supply. Twenty-eight days later, another 280-day supply was dispensed, and
8 twenty-three days later a 14-day supply was dispensed. Overall, in 168 days, Respondent
9 provided a 1,244-day supply of cholecalciferol to patient M.L. without any documentation
10 regarding any medical reason the patient would need such high quantities of this product.

11 127. The dispensing patterns outlined in paragraphs 128 through 130 are present in several
12 other patients Respondent dispensed drugs to as well.

13 128. Inspector J.F. contacted another patient, M.D., who was listed in the ADE for the De
14 Luz Clinic. M.D. stated she went to the De Luz Clinic only twice for microblading, a
15 dermatological procedure, and that she never received any injections from the De Luz Clinic, had
16 never had a prescription for Lipo-C, and had never received drug products from Respondent.

17 129. An employee of the De Luz Clinic, D.P., stated she was responsible for ordering
18 compounded drug products from Respondent and that neither she nor anyone else at the clinic
19 was aware, or had ever been informed by Respondent, that orders could only be placed for
20 specific patients based on specified medical need. Therefore, it was the De Luz Clinic's practice
21 to simply use the information for a recent patient of the clinic for ordering, and then administer
22 the medication supply obtained to multiple patients. D.P. asserted that patient M.D.'s name, as
23 discussed in paragraph 132, was selected at random.

24 **Causes for Discipline Relating to October 9, 2023 Investigation**

25 **EIGHTEENTH CAUSE FOR DISCIPLINE**

26 **(Failure to Obtain Drug Substances from Registered Manufacturer)**

27 130. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
28 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing

1 pharmacy and regulating dangerous drugs by violating 21 U.S.C. section 353a, subdivision
2 (b)(1)(A)(ii), and Regulations section 1735.3, subdivision (c). The circumstances are as follows:

3 a. On October 31, 2022, and April 26, 2023, Respondent dispensed and shipped
4 into California Coenzyme Q-10 injectable, which was compounded using an active
5 pharmaceutical ingredient sourced from a manufacturer that was not registered with the FDA.

6 b. On December 9, 2022, Respondent dispensed and shipped into California Lipo-
7 C injectable, which was compounded using an active pharmaceutical ingredient, methionine,
8 sourced from a manufacturer that was not registered with the FDA.

9 **NINETEENTH CAUSE FOR DISCIPLINE**

10 **(Failure to Maintain Quality of Compounded Sterile Preparations)**

11 131. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
12 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
13 pharmacy and regulating dangerous drugs in that Respondent compounded drugs that lacked
14 quality and were adulterated and dispensed those drugs to patients in violation of Regulations
15 sections 1735.1, subd. (a)(e), and 1735.2, subd. (g) and Health and Safety Code sections 111250
16 and 111255. The circumstances are that Respondent compounded and furnished into California
17 the following drug preparations which lacked quality:

18 a. On or about October 31, 2022, and April 26, 2023, Respondent compounded,
19 and later shipped to the Lam Clinic for administration to various patients, a Coenzyme Q-10
20 injectable that lacked quality and was adulterated as a result of use of inappropriate active
21 pharmaceutical ingredients. This preparation was compounded using active pharmaceutical
22 ingredients that are graded as dietary supplements, which resulted in the final product lacking the
23 requisite quality for administration.

24 b. On or about December 21, 2022, Respondent compounded, and on April 5,
25 2023, shipped, Lipo-C injectable that lacked quality and was adulterated as a result of use of
26 inappropriate active pharmaceutical ingredients. This preparation was compounded using active
27 pharmaceutical ingredients that are graded as dietary supplements, which resulted in the final
28 product lacking the requisite quality for administration.

1 **TWENTIETH CAUSE FOR DISCIPLINE**

2 **(Adulterated Preparations)**

3 132. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
4 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
5 pharmacy and regulating dangerous drugs by violating Code section 4169, subdivision (a), and
6 Health and Safety Code sections 111250, 111255, and 111295, by compounding, selling, and
7 dispensing adulterated drugs. The circumstances are that Respondent compounded, dispensed
8 and sold Coenzyme Q-10 and Lipo-C sterile compounded drugs to California patients which were
9 compounded with dietary grade active pharmaceutical ingredients and therefore were or could
10 have been adulterated as set forth in paragraph 130 and 131, above.

11 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

12 **(Assignment of Unsupported Extended Beyond Use Dates)**

13 133. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
14 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
15 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section
16 1735.2, subdivision (i). The circumstances are that Respondent compounded and assigned a
17 beyond use date of approximately 168 days to at least one lot, #153165, of non-sterile to sterile
18 Lipo-C without having a current stability study, or a stability study where all of the ingredients
19 were identical to lot #153165.

20 **TWENTY-SECOND CAUSE FOR DISCIPLINE**

21 **(Failure to Perform Drug Utilization Review)**

22 134. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
23 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
24 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section 1707.3
25 by failing to review a patient's drug therapy and medication record, also known as performing a
26 drug utilization review (DUR) prior to dispensing and delivering the drug to the patient. The
27 circumstances are that Respondent dispensed compounded drug products to multiple patients of
28 the Lam Clinic in quantities that far exceeded the required amounts for the patients to receive

1 clinically effective doses, and in addition failed to take into account that the BUD of these
2 compounded drug medications would expire prior to use.

3 **TWENTY-THIRD CAUSE FOR DISCIPLINE**

4 **(Non-Permitted Pharmacy Technician Duties)**

5 135. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
6 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
7 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections 1717,
8 subdivision (c), and 1793.1, subdivisions (a) and (e). The circumstances are that Respondent
9 allowed a pharmacy technician to take an oral order from the Lam Clinic's office manager
10 changing all prescriptions to be administered IV instead of IM or SQ. Two of the prescriptions
11 were dispensed to patients in California with directions to be administered IV, even though the
12 substances were designed to be administered via IM or SQ only.

13 **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

14 **(Failure to Clarify Administration Directions)**

15 136. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
16 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
17 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections 1761,
18 subdivision (a). The circumstances are that Respondent allowed a pharmacy technician to take an
19 oral order from the Lam Clinic's office manager changing all prescriptions to be administered IV
20 instead of IM or SQ. Two of the prescriptions were dispensed to patients in California with
21 directions to be administered IV, even though the substances were designed to be administered
22 via IM or SQ only.

23 **TWENTY-FIFTH CAUSE FOR DISCIPLINE**

24 **(Dispensing Prescriptions with Incorrect Administration Directions)**

25 137. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
26 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
27 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections 1716.
28 The circumstances are that on or about June 6, 2023, Respondent documented on two prescription

1 records a clarifying note that the medications should be dispensed with directions to be
2 administered IM or SQ. On or about June 8, 2023, Respondent dispensed two prescriptions with
3 directions to be administered IV.

4 **TWENTY-SIXTH CAUSE FOR DISCIPLINE**

5 **(Failure to Maintain Accurate Patient Records)**

6 138. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
7 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
8 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections
9 1707.1, subdivision (a)(1)(A). The circumstances are that Respondent documented patient
10 telephone numbers for patients M.L., E.L., A.B., and S.P. as the telephone number for the Lam
11 Clinic instead of the patients' actual telephone numbers.

12 **November 27, 2023 Investigation**

13 139. This investigation relates to events occurring after the date Respondent's probation
14 became effective and therefore applies to both the accusation and the petition to revoke probation.

15 140. On June 6, 2023, the Board received notification from Respondent of an ADE that
16 occurred with compounded sermorelin acetate injectable, that caused patient D.T. to suffer
17 redness and itchiness at the injection site.

18 **Causes for Discipline Relating to November 27, 2023 Investigation**

19 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE**

20 **(Failure to Support Assigned Beyond Use Date)**

21 141. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
22 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
23 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections
24 1735.2, subdivisions (i)(3) and (i)(4). The circumstances are that Respondent assigned an
25 extended BUD of 365 days for compounded sermorelin acetate lot #162290, without having the
26 appropriate and required stability studies.

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1 **December 1, 2023 Investigation**

2 142. This investigation relates to events occurring after the date Respondent’s probation
3 became effective and therefore applies to both the accusation and the petition to revoke probation.

4 143. On September 19, 2023, Board Inspector J.F. conducted a probation inspection of
5 Respondent’s facility in conjunction with Board Inspector A.P.’s nonresident sterile
6 compounding license renewal inspection. Before, during, and after the inspection, Inspector J.F.
7 requested and received documents from Respondent.

8 144. Inspector J.F. discovered that Respondent was compounding cyanocobalamin
9 injections, even though cyanocobalamin is commercially available and not on the FDA’s drug
10 shortage list.

11 **Causes for Discipline Relating to December 1, 2023 Investigation**

12 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE**

13 **(Compounding a Commercially Available Product)**

14 145. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
15 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
16 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section
17 1735.2, subdivision (d) (3), as well as Health and Safety Code section 111395, subdivision (a),
18 misbranding a compounded preparation because it is an imitation of another drug, and Code
19 section 4169, subdivision (a), and Health and Safety Code section 111440, unlawful sale of
20 misbranded preparations. The circumstances are that on or about August 18, 2023, Respondent
21 furnished 3 vials of compounded cyanocobalamin to a patient in California which is an imitation
22 of a commercially available product and therefore is misbranded.

23 **January 4, 2024 Investigation**

24 146. This investigation relates to events occurring after the date Respondent’s probation
25 became effective and therefore applies to both the accusation and the petition to revoke probation.

26 147. On September 19, 2023, Board Inspector A.P. conducted a nonresident sterile
27 compounding license renewal inspection at Respondent’s facility.

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1 148. Both before and after the onsite inspection, Inspector A.P. requested and received
2 documents from Respondent.

3 149. The inspection found that many of the sterile compounded drug products being
4 compounded by Respondent were compounded using bulk drug substances that were, or could
5 have been adulterated, in that the bulk drug substances were not appropriate for sterile
6 compounding. Some of the bulk drug substances were dietary grade, reagent grade, or had no
7 grade established at all.

8 **Causes for Discipline Relating to January 4, 2024 Investigation**

9 **TWENTY-NINTH CAUSE FOR DISCIPLINE**

10 **(Failure to Obtain Drug Substances from Registered Manufacturer)**

11 150. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
12 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
13 pharmacy and regulating dangerous drugs by violating 21 U.S.C. section 353a, subdivision
14 (b)(1)(A)(ii), and Regulations section 1735.3, subdivision (c). The circumstances are as follows:

15 a. Between September 1, 2022 and July 5, 2023, Respondent furnished to
16 California patients at least 475 prescriptions of non-sterile to sterile compounded Lipo-B
17 (methionine/inositol/ choline chloride/cyanocobalamin) using two raw materials, methionine and
18 inositol from two different manufacturers who were not registered with the FDA.

19 b. Between September 1, 2022 and July 5, 2023, Respondent furnished to
20 California patients at least 520 prescription of NAD+ (nicotinamide adenine dinucleotide) using a
21 raw material, NAD, sourced from a manufacturer that was not registered with the FDA.

22 c. Between September 1, 2022 and July 5, 2023, Respondent furnished to
23 California patients at least 328 prescriptions of Tri-Amino (arginine hcl/citrulline/ornithine hcl)
24 using two raw materials, arginine and ornithine, from two different manufacturers who were not
25 registered with the FDA.

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1 **THIRTIETH CAUSE FOR DISCIPLINE**

2 **(Manufacturing, Selling, Delivering Adulterated Drug Preparations)**

3 151. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
4 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
5 pharmacy and regulating dangerous drugs in that Respondent violated Code section 4169,
6 subdivision (a) and Health and Safety Code sections 111250 and 111295. The circumstances are
7 as follows:

8 a. Between September 1, 2022 and July 5, 2023, Respondent furnished to
9 California patients at least 475 prescriptions consisting of 595 vials of Lipo-B which were
10 compounded with bulk drug substances that were not appropriate for sterile compounding. The
11 bulk drug substance was manufactured as a “dietary supplement” resulting in a final drug product
12 that was, or could have been, adulterated.

13 b. Between September 1, 2022 and July 5, 2023, Respondent furnished to
14 California patients at least 308 prescriptions consisting of 981 vials of Lipo-C which were
15 compounded with bulk drug substances that were not appropriate for sterile compounding. The
16 bulk drug substance was manufactured as a “dietary supplement” resulting in a final drug product
17 that was, or could have been, adulterated.

18 c. Between September 1, 2022 and July 5, 2023, Respondent furnished to
19 California patients at least 328 prescriptions consisting of 962 vials of Tri-Amino which were
20 compounded with bulk drug substances that were not appropriate for sterile compounding. One
21 of the bulk drug substances used in compounding Tri-Amino was manufactured as a “dietary
22 supplement” and one was not authorized by the FDA in any way to be compounded, resulting in a
23 final drug product that was, or could have been, adulterated.

24 **THIRTY-FIRST CAUSE FOR DISCIPLINE**

25 **(Failure to Support Assigned Beyond Use Date)**

26 152. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
27 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
28 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections

1 1735.2, subdivisions (i)(3) and (i)(4). The circumstances are that Respondent extended BUDs as
2 follows, without having the appropriate and required stability studies:

3 a. Ascorbic acid lot #145609 compounded on September 26, 2022, was given an
4 extended BUD of 365 days without having studies that were identical in specific and essential
5 compounding steps.

6 b. Glutathione lot #146318 compounded on October 3, 2022, was given an
7 extended BUD of 270 days without having studies that were identical in specific and essential
8 compounding steps.

9 c. Lipo-C lot #168849 compounded on May 12, 2023, was given an extended
10 BUD of 180 days without having studies that had identical ingredients.

11 d. Methylcobalamin lot #145418 compounded on September 29, 2022, was given
12 an extended BUD of 365 days without having studies that were identical in specific and essential
13 compounding steps.

14 **THIRTY-SECOND CAUSE FOR DISCIPLINE**

15 **(Disclosure of Medical Information)**

16 153. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
17 Code section 4301, subdivision (o), for failing to follow laws and regulations governing
18 pharmacy by violating Civil Code section 56.10 and Regulations section 1764, by disclosing
19 prescription information and personal health information of six patients. The circumstances are
20 that between May 10, 2023, and June 13, 2023, Respondent was notified it had mailed, and
21 caused to be delivered, medications labeled with those patients' prescription and personal
22 information to clinics or other patients unassociated with those patients.

23 **THIRTY-THIRD CAUSE FOR DISCIPLINE**

24 **(Furnishing Dangerous Drugs and Controlled Substances without a Prescription)**

25 154. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
26 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
27 pharmacy and regulating dangerous drugs in that Respondent violated Code section 4059,
28 subdivision (a), by furnishing dangerous drugs and controlled substances to California patients

1 pursuant to invalid prescriptions issued by medical providers who are not licensed in the state of
2 California. The time period evaluated was four months between May 1, 2023, and September 1,
3 2023, and this is true for at least 286 prescriptions for three providers.

4 **THIRTY-FOURTH CAUSE FOR DISCIPLINE**

5 **(Failing to Prepare a Compliant Master Formula Before Compounding)**

6 155. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
7 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
8 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section
9 1735.2, subdivision (e), in that Respondent was required to prepare a written master formula that
10 includes the maximum allowable BUD for the preparation and the rationale or reference source
11 justifying its determination. Respondent failed to do so for the following compounded sterile
12 drug preparations:

- 13 a. Ascorbic acid, formula ID 74512.
- 14 b. Bacteriostatic water, formula ID 80909.
- 15 c. Glutathione, formula ID 76078.
- 16 d. Glycine, formula ID 75512.
- 17 e. Lipo-B, formula ID 75434
- 18 f. Lipo-C, formula ID82615.
- 19 g. Methylcobalamin, formula ID 73763.
- 20 h. NAD+, formula ID 76894.
- 21 i. Tri-Amino, formula ID 75270.

22 **THIRTY-FIFTH CAUSE FOR DISCIPLINE**

23 **(Failing to Follow Policies and Procedures)**

24 156. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
25 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
26 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section
27 1751.3, subdivision (a), in that Respondent failed to follow their own policies and procedures.
28 On May 12, 2023, Respondent compounded Lipo-C lot #168849, and assigned a BUD of 180

1 days without the BUD being supported by valid scientific stability information for the specific
2 compounded preparation. At least 308 prescriptions and 981 vials of this sterile compounded
3 preparation was dispensed to California patients.

4 **January 8, 2024 Investigation**

5 157. This investigation relates to events occurring after the date Respondent's probation
6 became effective and therefore applies to both the accusation and the petition to revoke probation.

7 158. On August 27, 2023, the Board received an online complaint from a consumer with
8 the initials P.S., the complaint was assigned to Board Inspector J.F. to investigate.

9 159. P.S. lives in California, and went to a wellness clinic located in Fairfield, California
10 (Fairfield Clinic), for a consultation. P.S. was provided with a prescription for semaglutide for
11 weight loss. P.S.'s pharmacy was unable to fill the prescription, and when P.S. called around to
12 other pharmacies they were also unable to fill it. When P.S. informed the Fairfield Clinic of this
13 issue, the Fairfield Clinic offered to obtain the drug for P.S. themselves.

14 160. On or about August 26, 2023, P.S. was informed by UPS that a package in P.S.'
15 name, from Respondent, could not be delivered to an address in Reno, Nevada. P.S. contacted
16 the Fairfield Clinic, which stated that once the package was received in Reno, Nevada, someone
17 else would overnight the package to the Fairfield Clinic, where P.S. could pick it up.

18 161. During Inspector J.F.'s investigation of Respondent, he reviewed pharmacy records
19 maintained by Respondent. In those records, Inspector J.F. discovered that 15 different patients
20 of the Fairfield Clinic all had their patient addresses listed as the same address in Reno, Nevada,
21 as the address listed for P.S. However, the address for the Fairfield Clinic and the prescriber was
22 correctly listed as being located in California.

23 162. The Fairfield Clinic informed Inspector J.F. that they were aware that Respondent
24 was not shipping to California; however, that Respondent's representative, E.E., had informed the
25 Fairfield Clinic that as long as the Fairfield Clinic had a prescriber licensed in Nevada and an
26 address in Nevada, that they would ship drugs to Nevada for the Fairfield Clinic to pick up and
27 transport themselves into California for administration to California patients.

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1 163. Respondent had previously notified the Board that they would stop shipping
2 compounded products to California effective March 20, 2023; however, Inspector J.F. discovered
3 7 patients in California who had received compounded semaglutide directly from Respondent
4 between March 22, 2023, and July 5, 2023.

5 164. Inspector J.F. also investigated a patient with the initials S.M. because S.M. resides in
6 California, however the physician address on the prescription is in Austin, Texas. It was
7 ultimately discovered that S.M.'s physician is licensed in California as well as Texas, and there is
8 a clinic in California that S.M. has visited as well as one in Texas (Texas Clinic) where the
9 physician is physically located. However, S.M.'s prescription was mailed by Respondent to the
10 Texas Clinic, after which the Texas Clinic re-packaged the prescription drugs and shipped them
11 to S.M. in California in a clear attempt to avoid Respondent direct-shipping this prescription into
12 California. Respondent's records show that for 36 prescriptions for patients residing in
13 California, shipping instructions directing that the drugs should be shipped to the Texas Clinic
14 instead of to the California patients directly.

15 **Causes for Discipline Relating to January 8, 2024 Investigation**

16 **THIRTY-SIXTH CAUSE FOR DISCIPLINE**

17 **(Failure to Maintain Accurate Patient Records)**

18 165. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
19 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
20 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections
21 1707.1, subdivision (a)(1)(A). The circumstances are that Respondent documented patient
22 addresses for 15 patients residing in California as the address for the Fairfield Clinic's alternative
23 Nevada mailing address instead of the patients' actual mailing or residential addresses.

24 **THIRTY-SEVENTH CAUSE FOR DISCIPLINE**

25 **(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

26 166. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
27 Code section 4301, subdivision (f), for dishonesty and deceit for informing the Board that they
28 would not ship semaglutide with cyanocobalamin into California after March 20, 2023, and then

1 continuing to do so for at least 7 different patients between March 22, 2023 and July 5, 2023.
2 The circumstances are as set forth in paragraph 163, above.

3 **THIRTY-EIGHTH CAUSE FOR DISCIPLINE**

4 **(Violation of Regulations Governing Pharmacy)**

5 167. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
6 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
7 pharmacy and regulating dangerous drugs in that Respondent violated Regulations section 1713,
8 subdivisions (a) and (b), for participating in an arrangement or agreement to deliver prescription
9 medications to a place that is not the residence of the patient and is not licensed as a retail
10 pharmacy as set forth below:

11 a. Respondent engaged in an arrangement with the Fairfield Clinic whereby
12 Respondent delivered semaglutide with cyanocobalamin for 15 patients to an alternative
13 addressed in Reno, Nevada, while knowing that the Fairfield Clinic would transport the drugs
14 from Nevada into California for administration to California patients, paragraphs 158-164 are
15 incorporated herein as though fully set forth.

16 b. Respondent engaged in an arrangement with the Texas Clinic whereby
17 Respondent delivered semaglutide with cyanocobalamin for 36 patients to the clinic in Texas
18 while knowing that the patients all resided in California and were not being administered these
19 drugs in Texas, paragraph 164 is incorporated herein as though fully set forth.

20 **January 16, 2024 Investigation**

21 168. This investigation relates to events occurring after the date Respondent's probation
22 became effective and therefore applies to both the accusation and the petition to revoke probation.

23 169. On or about September 11, 2023, the Board received notification from Respondent of
24 an ADE that occurred with compounded cyanocobalamin injectable, that caused patient J.K. to
25 suffer burning and stinging with the injection.

26 170. The lot of cyanocobalamin injected into patient J.K. had been given an extended
27 BUD of 166 days.

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1 **Causes for Discipline Relating to January 16, 2024 Investigation**

2 **THIRTY-NINTH CAUSE FOR DISCIPLINE**

3 **(Failure to Support Assigned Beyond Use Date)**

4 171. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
5 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
6 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections
7 1735.2, subdivisions (i)(3) and (i)(4). The circumstances are that Respondent assigned an
8 extended BUD of 166 days to lot # 171710, without having the appropriate required stability
9 studies.

10 **March 21, 2024 Investigation**

11 172. This investigation relates to events occurring after the date Respondent's probation
12 became effective and therefore applies to both the accusation and the petition to revoke probation.

13 173. On December 4, 2023, the Board received notification from Respondent of an ADE
14 that occurred with compounded Riboflavin (B2) injectable, that caused patient A.N. to suffer
15 swollen eyes, ear itchiness, and a hot throat. However, Respondent had no record of a
16 prescription for A.N. and had last shipped this drug to the administrating physician approximately
17 3 months prior to this report.

18 174. This drug expired on November 18, 2023, and according to the prescriber, the drug
19 was administered to A.N. on October 31, 2023. The prescriber refused to cooperate with the
20 Board's investigation regarding how this drug was administered to A.N. without a valid
21 prescription. There is no indication as to why A.N. would wait approximately 5 weeks to report
22 this ADE.

23 **Causes for Discipline Relating to March 21, 2024 Investigation**

24 **FORTIETH CAUSE FOR DISCIPLINE**

25 **(Failure to Support Assigned Beyond Use Date)**

26 175. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
27 Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing
28 pharmacy and regulating dangerous drugs in that Respondent violated Regulations sections

1 1735.2, subdivisions (i)(3) and (i)(4). The circumstances are that Respondent assigned extended
2 BUDs of 247 days to riboflavin lot # 163001 and 110 days to riboflavin lot #177614, without
3 having the appropriate required stability studies.

4 **March 10, 2025 Investigation**

5 176. This investigation relates to events occurring after the date Respondent’s probation
6 became effective and therefore applies to both the accusation and the petition to revoke probation.

7 177. On July 30, 2024, the Board received notification from Respondent of a recall
8 initiated by Respondent for the compounded sterile drug product estradiol cypionate injectable
9 that was compounded on or about August 15 and 16, 2023 and given a BUD of 365 days or
10 August 14, 2024.

11 178. On or about September 7, 2023, Respondent discovered that the second filter used in
12 compounding the estradiol cypionate had failed during the compounding process. Despite this
13 discovery, Respondent proceeded to dispense the estradiol cypionate to approximately 70
14 consumers in California in September and October 2023.

15 179. When Respondent initiated the recall approximately 2 weeks prior to the BUD of the
16 estradiol cypionate, Respondent stated it had done a “retrospective review” of the compounding
17 records. Respondent failed to investigate the root cause of the filter failure, or why the product
18 was able to be dispensed despite the filter failure.

19 **FORTY-FIRST CAUSE FOR DISCIPLINE**

20 **(Unprofessional Conduct – Dispensing Product with Compounding Failure)**

21 180. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
22 Code section 4301, for dispensing a product into California despite being aware that one of the
23 two filters used in the compounding process failed during the compounding process as set forth in
24 paragraphs 177-179, above.

25 **FORTY-SECOND CAUSE FOR DISCIPLINE**

26 **(Violation of Regulations Governing Pharmacy)**

27 181. Respondent is subject to disciplinary action for unprofessional conduct pursuant to
28 Code section 4301, subdivision (o), for failing to follow regulations governing pharmacy, in that

1 Respondent violated Regulations section 1774, subdivision (a)(1), for failing to obey all laws and
2 regulations substantially related to the practice of pharmacy, as set forth in paragraphs 74 through
3 180, above.

4 **PETITION TO REVOKE PROBATION**

5 182. This Petition to Revoke Probation is brought pursuant to the Disciplinary Order in
6 Case No. 7117, paragraph 16, as referenced in this Accusation and Petition to Revoke Probation's
7 paragraph 4 above, which states:

8 **Violation of Probation**

9 If a respondent has not complied with any term or condition of probation, the board shall
10 have continuing jurisdiction over respondent, and probation shall be automatically extended, until
11 all terms and conditions have been satisfied or the board has taken other action as deemed
12 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
13 to impose the penalty that was stayed.

14 If respondent violates probation in any respect, the board, after giving respondent notice
15 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
16 was stayed. If a petition to revoke probation or an accusation is filed against respondent during
17 probation, the board shall have continuing jurisdiction and the period of probation shall be
18 automatically extended until the petition to revoke probation or accusation is heard and decided.

19 **CAUSE TO REVOKE PROBATION**

20 **(Failure to Obey All Laws)**

21 183. At all times after the effective date of Respondent's probation, Condition 2 stated, in
22 pertinent part: Respondent shall obey all state and federal laws and regulations.

23 184. Respondent's probation is subject to revocation because it failed to comply with
24 probation Condition 2, as set forth in paragraphs 97 through 182 above, incorporated herein by
25 reference.

26 **OTHER MATTERS**

27 185. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy
28 Permit Number NRP 2567 or on Nonresident Sterile Compounding Pharmacy Permit Number

1 NSC 101695 issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun
2 Noorian, member, and Jordan Bowers Cuccia, Pharmacist in Charge, then Empower Clinic
3 Services LLC, Arta Shaun Noorian, and Jordan Bowers Cuccia shall each be prohibited from
4 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
5 licensee for 1) a period not to exceed five years if either or both of the pharmacy permits are
6 placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition
7 shall continue until either of the permits are reinstated.

8 **PRAYER**

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

11 1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 2567, issued to
12 Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, Member; Jordan
13 Bowers Cuccia, PIC;

14 2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC
15 101695, issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian,
16 100% Shareholder and Member; Jordan Bowers Cuccia, PIC;

17 3. Revoking the probation that was granted by the Board of Pharmacy in Case No. 7117
18 and imposing the disciplinary order that was stayed, thereby revoking Nonresident Pharmacy
19 Permit Number NRP 2567 and Nonresident Sterile Compounding Permit Number NSC 101695,
20 issued to Empower Clinic Services LLC dba Empower Pharmacy; Arta Shaun Noorian, 100%
21 Shareholder and Member; Jordan Bowers Cuccia, PIC;

22 4. Prohibiting Empower Clinic Services LLC dba Empower Pharmacy from serving as a
23 manager, administrator, owner, member, officer, director, associate, partner, or in any other
24 position with management or control of any pharmacy licensee;

25 5. Prohibiting Arta Shaun Noorian from serving as a manager, administrator, owner,
26 member, officer, director, associate, partner, or in any other position with management or control
27 of any pharmacy licensee;

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1 6. Prohibiting Jordan Bowers Cuccia from serving as a manager, administrator, owner,
2 member, officer, director, associate, partner, or in any other position with management or control
3 of any pharmacy licensee;

4 7. Ordering Empower Clinic Services LLC dba Empower Pharmacy to pay the Board of
5 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
6 Business and Professions Code section 125.3; and,

7 8. Taking such other and further action as deemed necessary and proper.

8
9 DATED: 11/24/2025

Sodergren, Digitally signed by
Anne@DCA Sodergren, Anne@DCA
 Date: 2025.11.24
 08:57:36 -08'00'

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

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26 Exhibit A: Decision and Order in Case No. 7117

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