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

12
13 In the Matter of the Accusation Against:

Case No. 6175

14 **SENIOR CARE PHARMACY SERVICES,**
15 **INC., KIM BANERJEE AND ALPESH**
PATEL OWNERS
16 **12600-12601 Hoover Street**
Garden Grove, CA 92841

SECOND AMENDED ACCUSATION

17 **Sterile Compounding License No. LSC**
99060

18 **Pharmacy Permit No. PHY 46000**

19 **SAMITENDU BANERJEE**
20 **P.O. Box 27638**
Anaheim, CA 92809

21 **Pharmacist License No. RPH 45184**

22 **ALPESH PATEL**
23 **8224 E. Marblehead Way**
Anaheim, CA 92808

24 **Pharmacist License No. RPH 48866**

25 **PO-AN LU**
26 **17053 Glenford Dr.**
Hacienda Heights, CA 91745

27 **Pharmacist License No. RPH 69811**
28

1 **KENNY TRAN**
2 **12600 Hoover Street**
3 **Garden Grove, CA 92841**

4 **Pharmacy Technician License No.**
5 **TCH 57643**

6 Respondents.

7 In the Matter of the Statement of Issues
8 Against:

9 **SENIOR CARE PHARMACY SERVICES,**
10 **INC.**

11 **Applicant for Renewal of Sterile**
12 **Compounding License**

13 Respondent.

14 In the Matter of the Statement of Issues
15 Against:

16 **SENIOR CARE PHARMACY SERVICES**
17 **HB, INC.**

18 **Applicant for Pharmacy Permit and Sterile**
19 **Compounding License**

20 Respondent.

Case No. 6409

SECOND AMENDED STATEMENT OF
21 **ISSUES**

Case No. 6156

SECOND AMENDED STATEMENT OF
22 **ISSUES**

23 Complainant alleges:

24 **PARTIES**

25 1. Anne Sodergren (Complainant) brings this Second Amended Accusation and these
26 Second Amended Statements of Issues solely in her official capacity as the Executive Officer of
27 the Board of Pharmacy, Department of Consumer Affairs.

28 2. On or about July 25, 2002, the Board of Pharmacy issued Pharmacy Permit Number
PHY 46000 to Senior Care Pharmacy Services, Inc., with Alpesh Patel designated as the
Pharmacist-in-Charge from July 25, 2002 to February 15, 2006, and November 22, 2010, through
January 1, 2015, Samitendu Banerjee designated as the Pharmacist-in-Charge from February 15,

1 2006 to November 22, 2010, and from March 1, 2015, to June 1, 2017, Po-An Lu designated as
2 the Pharmacist-in-Charge from June 1, 2017 to the present. From July 25, 2002, through August
3 19, 2002, Kim Banerjee was the one hundred percent owner. From August 19, 2002, through the
4 present, Kim Banerjee was designated as the President and the owner of fifty-five percent of the
5 outstanding shares, Alpesh Patel as the Chief Operating Officer and owner of thirty-five percent
6 of the outstanding shares and Daniel Zilafro as the owner of ten percent of outstanding shares
7 (Senior Care Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to
8 the charges brought herein and will expire on July 1, 2020, unless renewed.

9 3. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding
10 License Number LSC 99060 to Senior Care Pharmacy. The Sterile Compounding License was in
11 full force and effect at all times relevant to the charges brought herein and expired on July 1,
12 2017. On or about June 9, 2017, the Board informed Senior Care Pharmacy that its Sterile
13 Compounding License would not be renewed. The License was subsequently cancelled.

14 4. On or about January 23, 2017, the Board received an application for a pharmacy
15 permit and sterile compounding license from Senior Care Pharmacy Services HB, Inc. with Kim
16 Banerjee, Samitendu Banerjee and Daniel Zilafro identified as the owners of the outstanding
17 shares (Senior Care Pharmacy Huntington Beach). On or about January 19, 2017, Kim and
18 Samitendu Banerjee, on behalf of Senior Care Pharmacy Huntington Beach certified under
19 penalty of perjury to the truthfulness of all statements, answers, and representations in the
20 application. On or about March 13, 2017, the Board denied Senior Care Pharmacy Huntington
21 Beach's application.

22 5. On or about March 12, 1992, the Board of Pharmacy issued Pharmacist License
23 Number RPH 45184 to Samitendu Banerjee (Samitendu Banerjee). The Pharmacist License was
24 in full force and effect at all times relevant to the charges brought herein and will expire on
25 January 31, 2022, unless renewed.

26 6. On or about August 14, 1996, the Board of Pharmacy issued Pharmacist License
27 Number RPH 48866 to Alpesh Patel (Alpesh Patel). The Pharmacist License was in full force
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1 and effect at all times relevant to the charges brought herein and will expire on May 31, 2020,
2 unless renewed.

3 7. On or about September 30, 2013, the Board of Pharmacy issued Pharmacist License
4 Number RPH 69811 to Po-An Lu (Andy Lu). The Pharmacist License was in full force and
5 effect at all times relevant to the charges brought herein and will expire on March 31, 2021,
6 unless renewed.

7 8. On or about July 20, 2004, the Board of Pharmacy issued Pharmacy Technician
8 Registration Number TCH 57643 to Kenny Tran (Kenny Tran). The Pharmacy Technician
9 Registration was in full force and effect at all times relevant to the charges brought herein and
10 will expire on March 31, 2020, unless renewed.

11 **JURISDICTION**

12 9. This Second Amended Accusation and Second Amended Statements of Issues are
13 brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the
14 authority of the following laws. All section references are to the Business and Professions Code
15 unless otherwise indicated.

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

19 11. Section 4300, subdivision (a), of the Code provides that every license issued by the
20 Board may be suspended or revoked.

21 12. Section 4300, subdivision (c), of the Code states:

22 The board may refuse a license to any applicant guilty of unprofessional
23 conduct. The board may, in its sole discretion, issue a probationary license to any
24 applicant for a license who is guilty of unprofessional conduct and who has met all
other requirements for licensure. . .

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1 13. 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 render
7 a decision suspending or revoking the license.

8 **STATUTORY AND REGULATORY PROVISIONS**

9 14. Section 480, subdivision (a)(2) and (3)(A) of the Code states, in pertinent part:

10 (a) A board may deny a license regulated by this code on the grounds that the
11 applicant has one of the following:

12 (2) Done any act involving dishonesty, fraud, or deceit with the intent to
13 substantially benefit himself or herself or another or substantially injure another.

14 ...

15 (3)(A) Done any act which if done by a licentiate of the business or profession in
16 question, would be grounds for suspension or revocation of license.

17 ...

18 15. Section 4024, subdivision (a) of the Code states:

19 Except as provided in subdivision (b), 'dispense' means the furnishing of drugs
20 or devices upon a prescription from a physician, dentist, optometrist, podiatrist,
21 veterinarian, or naturopathic doctor pursuant to Section 3640.7, or upon an order to
22 furnish drugs or transmit a prescription from a certified nurse-midwife, nurse
23 practitioner, physician assistant, naturopathic doctor pursuant to Section 3640.5, or
24 pharmacist acting within the scope of his or her practice.

25 16. Section 4037, subdivision (a) of the Code states:

26 "Pharmacy" means an area, place or premises licensed by the board in which
27 the profession of pharmacy is practiced and where prescriptions are compounded.
28 "Pharmacy" includes, but is not limited to, any area, place or premises described in a
license issued by the board wherein controlled substances, dangerous drugs, or
dangerous devices are stored, possessed, prepared, manufactured, derived,
compounded, or repackaged, and from which the controlled substances, dangerous
drugs, or dangerous devices are furnished, sold or dispensed at retail.

17. Section 4081, subdivisions (a), (b) and (d) of the Code states in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of
dangerous drugs or dangerous devices shall be at all times during business hours open
to inspection by authorized officers of the law, and shall be preserved for at least
three years from the date of making. A current inventory shall be kept by every
manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician,

1 dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or
2 establishment holding a currently valid and unrevoked certificate, license, permit,
3 registration, or exemption under Division 2 (commencing with Section 1200) of the
4 Health and Safety Code or under Part 4 (commencing with Section 16000) of
5 Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous
6 drugs or dangerous devices.

7 (b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary
8 food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge
9 or representative-in-charge, for maintaining the records and inventory described in
10 this section.

11 ...

12 (d) Pharmacies that dispense nonprescription diabetes test devices pursuant to
13 prescriptions shall retain records of acquisition and sale of those nonprescription
14 diabetes test devices for at least three years from the date of making. The records
15 shall be at all times during business hours open to inspection by authorized officers of
16 the law.

17 18. Section 4105, subdivisions (a) and (b) of the Code state:

18 (a) All records or other documentation of the acquisition and disposition of
19 dangerous drugs and devices by any entity licensed by the board shall be retained on
20 the licensed premises in a readily retrievable form.

21 (f) When requested by an authorized officer of the law or by an authorized
22 representative of the board, the owner, corporate officer, or manager of an entity
23 licensed by the board shall provide the board with the requested records within three
24 business days of the time the request was made. The entity may request in writing an
25 extension of this timeframe for a period not to exceed 14 calendar days from the date
26 the records were requested. A request for an extension of time is subject to the
27 approval of the board. An extension shall be deemed approved if the board fails to
28 deny the extension request within two business days of the time the extension request
was made directly to the board.

19 19. Section 4110, subdivision (a) of the Code states:

20 No person shall conduct a pharmacy in the state of California unless he or she
21 has obtained a license from the board. A license shall be required for each of the
22 premises of any person operating a pharmacy in more than one location. The license
23 shall be renewed annually. The board, may by regulation, determine the
24 circumstances under which a license may be transferred.

25 20. Section 4113, subdivision (c), of the Code states:

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

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21. Section 4169 subdivisions (a)(2)-(5), of the Code state:

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

...

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

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

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

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

...

22. Section 4300, subdivision (c) of the Code states, in pertinent part:

The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure.

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

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

...

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

...

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

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

5 ...

6 (q) Engaging in any conduct that subverts or attempts to subvert an
7 investigation of the board.

8 ...

9 (t) The acquisition of a nonprescription diabetes test device from a person that
10 the licensee knew or should have known was not the nonprescription diabetes test
11 device's manufacturer or the manufacturer's authorized distributors as identified in
12 Section 4160.5.

13 (u) The submission of a reimbursement claim for a nonprescription diabetes test
14 device to a pharmaceutical benefit manager, health insurer, government agency, or
15 other third-party payor when the licensee knew or reasonably should have known that
16 the diabetes test device was not purchased either directly from the manufacturer or
17 from the nonprescription diabetes test device manufacturer's authorized distributors
18 as identified in section 4160.5.

19 24. Section 4302 of the Code states:

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

25 25. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

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

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

...
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30 26. Section 4307, subdivision (a) of the Code states that:

31 Any person who has been denied a license or whose license has been revoked
32 or is under suspension, or who has failed to renew his or her license while it was
33 under suspension, or who has been a manager, administrator, owner member, officer,
34 director, associate, or partner of any partnership, corporation, firm, or association
35 whose application for a license has been denied or revoked, is under suspension or
36 has been placed on probation, and while acting as the manger, administrator, owner,
37 member, officer, director, associate, or partner had knowledge or knowingly

1 participated in any conduct for which the license was denied, revoked, suspended, or
2 placed on probation, shall be prohibited from serving as a manger, administrator,
3 owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

9 27. Section 4342, subdivision (a) of the Code states that:

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

17 28. Health and Safety Code section 111255 states:

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

21 29. Health and Safety Code section 111295 states:

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

24 30. Health and Safety Code section 111330 states:

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

27 31. Health and Safety Code section 111335 states:

28 Any drug or device is misbranded if its labeling or packaging does not conform
with the requirements of Chapter 4.

32. Health and Safety Code section 111395, subdivision (c) states:

Any drug is misbranded in any of the following cases:

...

(c) The contents of the original package have been, wholly or partly, removed
and replaced with other material in the package.

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33. Health and Safety Code section 111440 states:

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

34. Section 1707.4 of title 16, California Code of Regulations states:

(a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:

(1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.

(2) The prescription container:

(A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;

(B) the name of the pharmacy refilling the prescription; and

(C) the name of the pharmacy that received the refill request.

(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.

(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or patient's agent or transmitted to it by a prescriber.

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35. Section 1704 of title 16, California Code of Regulations states:

Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

36. Section 1714, subdivisions (b) and (d) of title 16, California Code of Regulations state:

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

...

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

37. Section 1715 of title 16, California Code of Regulations states:

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
- (3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" or and on Form 17M-14 (Rev. 10/14) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

1 38. Section 1717.1, subdivisions (a), (b) and (d) of title 16, California Code of
2 Regulations states:

3 (a) For dangerous drugs other than controlled substances: Two or more
4 pharmacies may establish and use a common electronic file to maintain required
5 dispensing information. Pharmacies using such a common file are not required to
transfer prescriptions or information for dispensing purposes between or among
pharmacies participating in the same common prescription file.

6 (b) For controlled substances: To the extent permitted by Federal law, two or
7 more pharmacies may establish and use a common electronic file of prescriptions and
dispensing information.

8 ...

9 (d) Common electronic files as authorized by this section shall not permit
10 disclosure of confidential medical information except as authorized by the
Confidentiality of Medical Information Act (Civil Code 56 et seq.).

11 39. Section 1718 of title 16, California Code of Regulations states:

12 “Current Inventory” as used in Section 4081 and 4332 of the Business and
13 Professions Code shall be considered to include complete accountability for all
dangerous drugs handled by every licensee enumerated in Section 4081 and 4332.

14 The controlled substances inventories required by Title 21, CFR, Section 1304
15 shall be available for inspection upon request for at least three years.

16 40. Section 1735.1, subdivision (af), of title 16, California Code of Regulations states:

17 “Segregated sterile compounding area” means a designated space for sterile-to-
18 sterile compounding where a PEC is located within either a demarcated area (at least
three foot perimeter) or in a separate room. Such area or room shall not contain and
19 shall be void of activities and materials that are extraneous to sterile compounding.
The segregated sterile compounding area shall not be in a location that has unsealed
20 windows or doors that connect to the outdoors, in a location with high traffic flow, or
in a location that is adjacent to construction sites, warehouses, or food preparation.
21 The segregated sterile compounding area shall not have a sink, other than an
emergency eye-washing station, located within three feet of a PEC. The segregated
22 sterile compounding area shall be restricted to preparation of sterile-to-sterile
compounded preparations.

23 (1) The BUD of a sterile drug preparation made in a segregated sterile
24 compounding area is limited to 12 hours or less as defined by section 1751.8(d).

25 (2) When the PEC in the segregated sterile compounding area is a CAI or a
26 CACI and the documentation provided by the manufacturer shows it meets the
requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with
section 1751.8(a-b) or (d).

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1 41. Section 1735.2, subdivision (e)(2)(3)(4)(8) of title 16, California Code of Regulations
2 states:

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

5 (2) Equipment to be used.

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

8 (4) Inactive ingredients to be used.

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

10 42. Section 1735.2, subdivision (k) of title 16, California Code of Regulations states:

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

19 43. Section 1735.3, subdivision (a)(2)(E)(F) of title 16, California Code of Regulations in
20 pertinent parts states:

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

22 . . .

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

25 . . .

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

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1 (F) The manufacturer, expiration date and lot number of each component. If
2 the manufacturer name is demonstrably unavailable, the name of the supplier may be
3 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 (1) shall apply.

4 44. Section 1735.5, subdivision (c)(10) of title 16, California Code of Regulations states:

5 The policies and procedures shall include at least the following:

6 ...

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

9 45. Section 1751.3, subdivision (a)(5) of title 16, California Code of Regulations states:

10 (a) Any pharmacy engaged in compounding sterile drug preparations shall
11 maintain written policies and procedures for compounding. Any material failure to
12 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:

13 ...

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

15 46. Section 1751.4, subdivisions (d) and (j), of title 16, California Code of Regulations
16 states:

17 (d) Cleaning shall be done using a germicidal detergent and sterile water. The
18 use of a sporicidal agent is required to be used at least monthly.

19 (1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the
cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using
20 a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces,
carts, and counters.

21 (2) Walls, ceilings, storage shelving, tables, stools, and all other items in the
ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

22 (3) Cleaning shall also occur after any unanticipated event that could increase
23 the risk of contamination.

24 (4) All cleaning materials, such as wipers, sponges, and mops, shall be non-
shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile
25 compounding areas and shall not be removed from these areas except for disposal.

26 ...

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1 (j) Viable surface sampling shall be done at least every six months for all
2 sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile
3 compounding. Viable air sampling shall be done by volumetric air sampling
4 procedures which test a sufficient volume of air (400 to 1,000 liters) at each location
5 and shall be done at least once every six months. Viable surface and viable air
6 sampling shall be performed by a qualified individual who is familiar with the
7 methods and procedures for surface testing and air sampling. Viable air sampling is to
8 be performed under dynamic conditions that simulate actual production. Viable
9 surface sampling is to be performed under dynamic conditions of actual
10 compounding. When the environmental monitoring action levels are exceeded, the
11 pharmacy shall identify the CFUs at least to the genus level in addition to conducting
12 an investigation pursuant to its policies and procedures. Remediation shall include, at
13 minimum, an immediate investigation of cleaning and compounding operations and
14 facility management.

9 47. Section 1751.7, subdivision (b)(1) of title 16, California Code of Regulations states:

10 The pharmacy and each individual involved in the compounding of sterile drug
11 preparations must successfully demonstrate competency on aseptic technique and
12 aseptic area practices before being allowed to prepare sterile drug preparations. The
13 validation process shall be carried out in the same manner as normal production,
14 except that an appropriate microbiological growth medium is used in place of the
15 actual product used during sterile preparation. The validation process shall be
16 representative of the types of manipulations, products and batch sizes the individual is
17 expected to prepare and include a media-fill test. The validation process shall be as
18 complicated as the most complex manipulations performed by staff and contain the
19 same amount or greater amount of volume transferred during the compounding
20 process. The same personnel, procedures, equipment, and materials must be used in
21 the testing. Media used must have demonstrated the ability to support and promote
22 growth. Completed medium samples must be incubated in a manner consistent with
23 the manufacturer's recommendations. If microbial growth is detected, then each
24 individual's sterile preparation process must be evaluated, corrective action taken and
25 documented, and the validation process repeated.

19 48. Section 1751.8, subdivision (d) of title 16, California Code of Regulations states:

20 (d) The beyond use date shall specify that storage and exposure periods cannot
21 exceed 12 hours where the sterile compounded drug preparation is compounded
22 solely with aseptic manipulations and all of the following apply:

22 (1) The preparation was compounded entirely within an ISO Class 5 PEC that is
23 located in a segregated sterile compounding area and restricted to sterile
24 compounding activities, using only sterile ingredients, components, and devices, by
25 personnel properly cleansed and garbed; and

25 (2) The compounding process involves simple transfer of not more than three
26 commercially manufactured packages of sterile nonhazardous preparations or
27 diagnostic radiopharmaceutical preparations from the manufacturer's original
28 containers; and

27 (3) The compounding process involves not more than two entries into any one
28 container or package (e.g., bag, vial) of sterile infusion solution or administration
29 container/device.

1 49. Section 1304.11, subdivisions (a) and (c) of title 21, Code of Federal Regulations
2 state:

3 (a) General requirements. Each inventory shall contain a complete and accurate
4 record of all controlled substances on hand on the date the inventory is taken, and
5 shall be maintained in written, typewritten, or printed form at the registered location.
6 An inventory taken by use of an oral recording device must be promptly transcribed.
7 Controlled substances shall be deemed to be “on hand” if they are in the possession of
8 or under the control of the registrant, including substances returned by a customer,
9 ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the
10 registrant, and substances in the possession of employees of the registrant and
11 intended for distribution as complimentary samples. A separate inventory shall be
12 made for each registered location and each independent activity registered, except as
13 provided in paragraph (e)(4) of this section. In the event controlled substances in the
14 possession or under the control of the registrant are stored at a location for which
15 he/she is not registered, the substances shall be included in the inventory of the
16 registered location to which they are subject to control or to which the person
17 possessing the substance is responsible. The inventory may be taken either as of
18 opening of business or as of the close of business on the inventory date and it shall be
19 indicated on the inventory.

20 (c) Biennial inventory date. After the initial inventory is taken, the registrant
21 shall take a new inventory of all stocks of controlled substances on hand at least every
22 two years. The biennial inventory may be taken on any date which is within two
23 years of the previous biennial inventory date.

24 50. Section 1317.40, subdivision (a) of title 21, Code of Federal Regulations states:

25 Manufacturers, distributors, reverse distributors, narcotic treatment programs,
26 hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be
27 collectors shall modify their registration to obtain authorization to be a collector in
28 accordance with §1301.52(f) of this chapter. Authorization to be a collector is subject
to renewal. If a registrant that is authorized to collect ceases activities as a collector,
such registrant shall notify the Administration in accordance with §1301.52(f) of this
chapter.

COST RECOVERY

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

FACTUAL ALLEGATIONS

52. At all times relevant herein, Alpesh Patel, Samitendu Banerjee and Andy Lu were the
Pharmacists-in-Charge of Senior Care Pharmacy, Kenny Tran was the Operations Manager of

1 Senior Care Pharmacy, and Alpesh Patel, Daniel Zilafro and Kim Banerjee were the owners of
2 the majority of outstanding shares of Senior Care Pharmacy.

3 53. Senior Care Pharmacy was a closed door pharmacy which dispensed dangerous
4 drugs, including controlled substances to patients who resided in assisted living and skilled
5 nursing facilities.

6 54. Senior Care Pharmacy also compounded and dispensed sterile injectable drug
7 products to patients who resided in assisted living and skilled nursing facilities.

8 55. On or about January 23, 2017, Senior Care Pharmacy Huntington Beach filed an
9 application for a pharmacy permit and sterile compounding license. The outstanding shares of
10 Senior Care Pharmacy Huntington Beach were owned by Kim and Samitendu Banerjee.

11 **Using Unlicensed Entity to Dispense Drugs**

12 56. Novasys Health Systems Private Limited (Novasys) is located in Hyderabad, India
13 and is not licensed with the Board. From at least 2011 to July 2018, Senior Care Pharmacy
14 utilized Novasys to dispense dangerous drugs to patients. It provided Novasys with access to
15 confidential patient medical information in Senior Care Pharmacy's computer software systems
16 (QS1) and its patient profiles which contained patients' medical, contact and insurance
17 information, including patient prescription history. Novasys accessed common electronic files
18 shared with Senior Care Pharmacy to update information relevant to the dispensing of dangerous
19 drugs.

20 57. With Senior Care Pharmacy's knowledge and consent, Novasys processed new
21 prescriptions to be dispensed when Senior Care Pharmacy was short-staffed. With Senior Care's
22 knowledge and consent, Novasys also initiated the process of re-filling prescriptions for
23 dangerous drugs.

24 58. On May 2, 2018, the Board issued a "cease and desist" order requiring Novasys to
25 cease and desist practicing any activity under Pharmacy Law which requires licensure, including
26 initiating the dispensing process for new prescriptions and prescription refills and the sharing of
27 common electronic files in "QS1" and other electronic files. On May 22, 2018, the Board issued
28 an order upholding the cease and desist order.

1 59. However, after the issuance of the order upholding the cease and desist order, Senior
2 Care continued to use Novasys to dispense prescription refills and to share common electronic
3 files, including in QS1. During a follow-up inspection by the Board in July 2018, Respondents
4 Lu and Tran falsely represented to Board inspectors that all prescription refills were processed by
5 employees of Senior Care, but did admit that Novays had access to confidential information of
6 patients at assisted living or skilled nursing facilities in California.

7 **Dispensing Recycled Drugs**

8 60. From as early as 2012 through at least 2017, Senior Care Pharmacy accepted returns
9 of dangerous drugs, including controlled substances from skilled nursing and/or assisted living
10 facilities. It recycled or repackaged the returned dangerous drugs and re-dispensed them. In the
11 dispensing area of Senior Care Pharmacy, Senior Care Pharmacy maintained plastic containers of
12 dangerous drugs packaged in “bubble packs or cards,” organized alphabetically by the name of
13 the drug contained within the bubble card. Some of the bubble cards had tablets missing from
14 them and some of the bubble cards were marked as returns from skilled nursing or assisted living
15 facilities. Other bubble packs or cards of dangerous drugs were labeled with the names of other
16 pharmacies. In the dispensing area and/or the Operations Manager’s Office, Senior Care
17 Pharmacy also maintained plastic totes of drugs containing prescription drug vials. Trash bags
18 with “punched out”¹ bubble cards or packs were also found in the back-storage area. There were
19 also plastic totes that were filled with manufacturer drug bottles (both empty and filled with
20 drugs) in the dispensing area. Expired drugs were also maintained in the back-storage area.

21 61. Manufacturer drug bottles were overfilled or contained a larger quantity of tablets
22 than was indicated on the labels of the manufacturing bottles. Insurance billing charges for
23 dangerous drugs returned from skilled nursing and assisted living facilities were not reversed.

24 62. During the investigation, Kim Banerjee falsely represented to Board inspectors that
25 while Senior Care Pharmacy accepted returns of drugs from skilled nursing and assisted living
26 facilities for destruction, Senior Care Pharmacy would not re-dispense them to patients. In

27 ¹ “Punched out” refers to the activity of pharmacy personnel taking drugs out of the
28 bubble cards or packs. This is a common practice for pharmacies who reuse returned medications
from skilled nursing and assisted living facilities.

1 contrast, Samitendu Banerjee and pharmacy technicians admitted to Board inspectors that when
2 drugs were returned from skilled nursing and assisted living facilities, those drugs would be taken
3 out of their packaging, placed in prescription vials and would go back into active drug stock.

4 63. Senior Care Pharmacy stored the drugs returned from skilled nursing and assisted
5 living facilities in an area with a temperature of 83 degrees Fahrenheit even though both drug
6 manufacturers and the United States Pharmacopeia recommend that dangerous drugs be stored at
7 60 to 77 degrees Fahrenheit. Senior Care Pharmacy continued to store drugs in an area with a
8 temperature above 77 degrees Fahrenheit even after being informed by the Board inspectors to
9 cease that practice.

10 64. Controlled substances were not labeled with the name of the medication, strength, lot
11 number, expiration dates and the initials of the verifying pharmacists in Senior Care Pharmacy's
12 records. In 2017, drugs in bubble cards were labeled with two separate expiration dates on the
13 front and back label.

14 65. From January 1, 2015 through June 15, 2017, more dangerous drugs, gabapentin
15 300mg, risperidone 1mg and metformin 500mg were dispensed than purchased. Again, there
16 were overages in the inventory of such dangerous drugs as 10,695 capsules of gabapentin 300mg,
17 4,002 tablets of risperidone 1mg and 7,933.5 tablets of metformin 500mg. There were no records
18 of acquisition and disposition for the overages of those drugs.

19 66. From September 2014 through 2017, Senior Care Pharmacy was not registered as a
20 collector of controlled substances with the Drug Enforcement Administration. However, Senior
21 Care Pharmacy accepted returns of controlled substances.

22 **Failure to Retain Diabetes Test Device Records and Fraudulent Billing of Diabetes**

23 **Test Devices**

24 67. From July 31, 2017 through December 6, 2017, Senior Care Pharmacy did not retain
25 the records of acquisition and disposition for nonprescription diabetes test devices it dispensed
26 pursuant to a prescription.

27 68. From July 31, 2017 through December 6, 2017, Senior Care Pharmacy billed more
28 nonprescription diabetes test devices than it acquired. Namely, Senior Care Pharmacy billed

1 33,200 of these diabetes test devices to insurance carriers and/or government agencies more than
2 it purchased.

3 **Unsafe Compounding of Sterile Injectable Drugs**

4 69. Between March 23, 2017, and May 15, 2017, Senior Care Pharmacy compounded
5 “sterile to sterile”² drug preparations (low and medium risk compounding) for medically fragile
6 patients in skilled nursing facilities and one assisted living facility.

7 70. Between March 23, 2017, and May 15, 2017, Senior Care Pharmacy dispensed at
8 least 68 sterile drug preparations compounded in a laminar flow hood located in a segregated
9 compounding area, labeled with beyond use dates greater than 12 hours and of those, at least 32
10 compounded sterile drug preparations where the compounding process involved more than two
11 entries into any one container or package of sterile infusion solution or administration
12 container/device.

13 71. Senior Care Pharmacy’s assigning of unsafe and illegal expiration dates or “beyond
14 use dates” to their sterile-to-sterile compounds resulted in them compounding 194 compounded
15 sterile preparation units of adulterated drugs on at least 98 occasions. Senior Care Pharmacy
16 dispensed at least 68 units with unsafe beyond use dates over a two-month period (one without a
17 beyond use date).

18 72. The drugs assigned dangerous beyond use dates were life-saving antibiotics intended
19 to be administered intravenously in order to treat severe systemic bacterial infections and Total
20 Parenteral Nutrition used to feed seriously ill and elderly patients. Patients requiring intravenous
21 antibiotics are typically ill from rapidly progressing infections, have a weak compromised
22 immune system or are not able to process or tolerate oral antibiotics. Administration of sub-
23 potent antibiotic infusions are clinically correlated with treatment failure as well as development
24 of antibiotic resistance. These were the drugs labeled with the improper beyond use date.

25
26
27 ² Sterile compounding is the preparation of a drug from chemical or bulk drug substances
28 into a form that will be infused directly into the bloodstream or body tissue. Sterile-to-sterile
compounding refers to a situation when a pharmacy uses a sterile “start” ingredient, and
compounds it in order to make a sterile end-product.

1 73. Senior Care Pharmacy continued to compound sterile drug preparations after being
2 told by a Board inspector to stop their practices and they promised under penalty of perjury to do
3 so).

4 74. Senior Care Pharmacy did not possess written policies and procedures for
5 compounded sterile preparation stability and beyond use dating and temperature variations.

6 75. Senior Care Pharmacy compounded sterile drug products (i.e., vancomycin
7 750mg/NS 250ml and vancomycin 1gm/NS/NS 250ml) without first preparing master formulas
8 which specified a laminar flow hood as equipment, an appropriate beyond use date, sterile water
9 for injection as an active ingredient and instructions for storage and handling.

10 76. Senior Care Pharmacy compounded and dispensed vancomycin 750mg/NS 250ml
11 and vancomycin 1gm/NS 250ml without documenting the quantity, manufacturer, expiration date
12 and lot number of the sterile water for injection used as a component in a compounding log.

13 77. In April 2017, Senior Care Pharmacy did not use a germicidal detergent to clean the
14 laminar flow hood in the compounding area.

15 78. Between January 1, 2017 and May 9, 2017, Senior Care Pharmacy did not perform
16 viable air sampling by volumetric sampling procedures.

17 79. Between October 12, 2016 to March 10, 2017, Senior Care Pharmacy performed
18 media fill validation by incubating for seven days rather than fourteen days.

19 80. On May 15, 2017, the Board issued a Cease and Desist Order to halt Senior Care
20 Pharmacy's sterile compounding operations. Senior Care Pharmacy agreed to an extension of
21 that cease and desist order until after the date of the expiration of its Sterile Compounding
22 License. In June 2017, the Board informed Senior Care Pharmacy that the Board would not
23 renew Senior Care Pharmacy's sterile compounding license.

24 **Lack of Drug Security and Reporting**

25 81. In 2016 through 2017, pharmacy technicians possessed keys to the areas where
26 dangerous drugs were stored at Senior Care Pharmacy.

27 82. On February 8, 2016, Senior Care Pharmacy did not possess self-assessments for
28 compounding and community pharmacies, completed prior to July 1, 2015.

1 83. In 2019, Senior Care Pharmacy did not possess on-site all of the records of
2 acquisition and disposition for drugs from the last three years.

3 **Conduct During Investigations**

4 84. On December 6, 2017, Senior Care Pharmacy refused to allow Board inspectors to
5 conduct an inspection of the entire premises licensed with the Board. Kenny Tran attempted to
6 coerce Board inspectors to sign a statement conceding that Senior Care Pharmacy had not
7 impeded the Board's investigation and waiving the Board's right to inspect drawers and cabinets
8 in the entirety of the licensed premises.

9 85. On July 11, 2018, while Board inspectors were asking questions about Senior Care
10 Pharmacy's common electronic dispensing files, QS1, Senior Care Pharmacy disconnected the
11 QS1 server and prevented the Board inspectors from completing their inspection that day. Senior
12 Care Pharmacy also altered the initials in QS1 of Novasys employees who processed refills, after
13 the inspection on July 11, 2018.

14 86. On July 11, 2018, Kenny Tran refused to allow a pharmacy technician to complete
15 and sign a written statement the pharmacy technician intended to provide Board inspectors.

16 87. On or about October 30, 2019, Po-An Lu refused to provide pharmacy records
17 requested by Board inspectors in connection with the Board's investigation of Senior Care
18 Pharmacy.

19 **Change in Location of Pharmacy**

20 88. In 2019, Senior Care Pharmacy changed locations from 12600-12601 Hoover Street
21 to 12600 Hoover Street without filing an application for a change of permit with the Board.

22 **SECOND AMENDED ACCUSATION**

23 **FIRST CAUSE FOR DISCIPLINE**

24 **(Sold, Delivered, Held or Offered for Sale Adulterated Drugs Against All Respondents)**

25 89. Respondents are subject to disciplinary action under Code section 4301, subdivisions
26 (j) and (o), for violating Health and Safety Code section 111295 and Code section 4169,
27 subdivision (a)(2), in that they sold, delivered, held or offered for sale dangerous drugs (*i.e.*, re-
28 dispensed dangerous drugs), that were adulterated within the meaning of Health and Safety Code

1 section 111255, as set forth in paragraphs 52 through 88, which are incorporated herein by
2 reference.

3 **SECOND CAUSE FOR DISCIPLINE**

4 **(Sale of Pharmaceutical Preparations and Drugs Not in Conformance with Standards and**
5 **Tests as to Quality and Strength in USP Against All Respondents)**

6 90. Respondents are subject to disciplinary action under Code section 4301, subdivision
7 (o), for violating Code section 4342, subdivision (a), in that they sold pharmaceutical preparations
8 and drugs not in conformance with standards and tests as to quality and strength, provided in the
9 latest edition of the United States Pharmacopoeia, as set forth in paragraphs 52 through 88, which
10 are incorporated herein by reference.

11 **THIRD CAUSE FOR DISCIPLINE**

12 **(Received Returns of Controlled Substances Without Proper Registration Against All**
13 **Respondents)**

14 91. Respondents are subject to disciplinary action under Code section 4301, subdivision
15 (j), for violating Code of Federal Regulations, title 21, sections 1317.40, subdivision (a), in that
16 they received returns of controlled substances without being registered as a collector with the
17 Drug Enforcement Administration, as set forth in paragraphs 52 through 88, which are
18 incorporated herein by reference.

19 **FOURTH CAUSE FOR DISCIPLINE**

20 **(Sold, Delivered, Held or Offered for Sale Misbranded Drugs All Respondents)**

21 92. Respondents are subject to disciplinary action under Code sections 4301, subdivisions
22 (j) and (o), for violating Health and Safety Code sections 111330 and 111440 and Code sections
23 4169, subdivisions (a)(3) and (a)(4), in that they sold, delivered, held or offered for sale
24 dangerous drugs (*i.e.*, re-dispensed dangerous drugs and/or compounded sterile drug preparations
25 which were assigned improper beyond use dates), that were misbranded within the meaning of
26 Health and Safety Code sections 111335 and 111395, subdivision (c), as set forth in paragraphs
27 52 through 88, which are incorporated herein by reference.

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1 **FIFTH CAUSE FOR DISCIPLINE**

2 **(Commission of Acts Involving Dishonesty, Fraud or Deceit Against All Respondents)**

3 93. Respondents are subject to disciplinary action under Code section 4301, subdivision
4 (f), for committing acts involving dishonesty, fraud or deceit, as set forth in paragraphs 52
5 through 88, which are incorporated herein by reference.

6 **SIXTH CAUSE FOR DISCIPLINE**

7 **(Aiding and Abetting Unlicensed Practice of Pharmacy Against All Respondents)**

8 94. Respondents are subject to disciplinary action under Code section 4301, subdivision
9 (o), in that, Respondents directly or indirectly, assisted in or abetted the violation of, or conspired
10 to violate, the laws governing pharmacy, when Respondents solicited, encouraged, assisted in,
11 abetted, or conspired toward activities violating sections 4110, subdivision (a) and 4037,
12 subdivision (a) of the Code, when Respondents used an unlicensed entity, Novasys to practice
13 activities requiring licensure, namely, dispensing as defined by Code section 4024, subdivision
14 (a), as set forth in paragraphs 52 through 88, which are incorporated herein by reference.

15 **SEVENTH CAUSE FOR DISCIPLINE**

16 **(Sharing Common Files with Unlicensed Entity Against All Respondents)**

17 95. Respondents are subject to disciplinary action under Code sections 4301, subdivision
18 (o), for violating California Code of Regulations, title 16, section 1717.1, in that Respondents
19 established and used a common electronic file to maintain required dispensing information with
20 an unlicensed entity, Novasys and not a pharmacy as defined by section 4037, subdivision (a), as
21 set forth in paragraphs 52 through 88, which are incorporated herein by reference.

22 **EIGHTH CAUSE FOR DISCIPLINE**

23 **(Processing Requests for Refill of Prescriptions Received by Unlicensed Entity
24 Against All Respondents)**

25 96. Respondents are subject to disciplinary action under Code section 4301, subdivision
26 (o), for violating California Code of Regulations, title 16, section 1707.4, in that Respondents
27 processed requests for refills of prescriptions received by an unlicensed entity, Novasys and not a
28

1 pharmacy as defined by section 4037, subdivision (a), as set forth in paragraphs 52 through 88,
2 which are incorporated herein by reference.

3 **NINTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct Against All Respondents)**

5 97. Respondents are subject to disciplinary action under Code section 4301 for
6 unprofessional conduct in that they engaged in the activities described in paragraphs 52 through
7 88 above, which are incorporated herein by reference.

8 **TENTH CAUSE FOR DISCIPLINE**

9 **(Failure to Maintain Current Inventory and Records of Acquisition and Disposition of
10 Dangerous Drugs and Controlled Substances against Senior Care Pharmacy, Patel, Lu and
11 Banerjee)**

12 98. Respondents Senior Care Pharmacy, Alpesh Patel and Samitendu Banerjee are
13 subject to disciplinary action under Code section 4301, subdivision (o), for violating Code
14 sections 4081, subdivision (a) and 4105, subdivision (a) and title 16, California Code of
15 Regulations, section 1718, in that they did not maintain a current inventory of dangerous drugs
16 and/or records open for inspection or retained on the premises in a readily retrievable form, as set
17 forth in paragraphs 52 through 88 above, which are incorporated herein by reference.

18 **ELEVENTH CAUSE FOR DISCIPLINE**

19 **(Failure to Maintain Accurate Inventory of Controlled Substances against Senior Care
20 Pharmacy, Patel and Banerjee)**

21 99. Respondents Senior Care Pharmacy, Alpesh Patel and Samitendu Banerjee are
22 subject to disciplinary action under Code section 4301, subdivision (j), for violating Code of
23 Federal Regulations, title 21, sections 1304.11, subdivisions (a) and (c), in that they failed to
24 maintain a complete and accurate inventory of all controlled substances on hand, as set forth in
25 paragraphs 52 through 88, which are incorporated herein by reference.

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1 **TWELFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Current Inventory of Dangerous Drugs against Senior Care**
3 **Pharmacy, Patel and Banerjee)**

4 100. Respondents Senior Care Pharmacy, Alpesh Patel and Samitendu Banerjee are
5 subject to disciplinary action under Code section 4301(o), for violating Code sections 4081,
6 subdivision (a), 4169, subdivision (a)(5) and title 16, California Code of Regulations, section
7 1718, in that they did not maintain a current inventory of gabapentin 300 mg, risperidone 1 mg
8 and metformin, as set forth in paragraphs 52 through 88 above, which are incorporated herein by
9 reference.

10 **THIRTEENTH CAUSE FOR DISCIPLINE**

11 **(Failure to Maintain Security of Drugs against Senior Care Pharmacy, Patel and Banerjee)**

12 101. Respondents Senior Care Pharmacy, Alpesh Patel and Samitendu Banerjee are
13 subject to disciplinary action under Code section 4301(o), for violating title 16, California Code
14 of Regulations, section 1714, subdivision (b), in that there was from January 1, 2015 through June
15 15, 2017 overages of 10,695 capsules of gabapentin 300 mg, 4,002 tablets of risperidone 1mg and
16 11,933.5 tablets of metformin 500mg, as set forth in paragraphs 52 through 88 above, which are
17 incorporated herein by reference.

18 **FOURTEENTH CAUSE FOR DISCIPLINE**

19 **(Assignment of Improper Beyond Use Dates to Sterile Injectable Drugs Against Senior Care**
20 **Pharmacy and Banerjee)**

21 102. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
22 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
23 Regulations, title 16, section 1751.8, subdivision (d) as defined in part by section 1735.1,
24 subdivision (af) for assigning improper beyond use dates to sterile injectable drug products, as set
25 forth in paragraphs 52 through 88 above, which are incorporated herein by reference.

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1 **FIFTEENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Possess Policies and Procedures for Compounding Sterile Drug Preparations**
3 **Against Senior Care Pharmacy and Banerjee)**

4 103. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
5 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
6 Regulations, title 16, sections 1751.3, subdivision (a)(5) and 1735.5, subdivision (c)(10) because
7 they failed to have written policies and procedures for compounded sterile drug preparation
8 stability and beyond use dating and for ensuring appropriate function of refrigeration devices,
9 monitoring refrigeration device temperatures and actions to take regarding any out of range
10 temperature variations within the pharmacy, as set forth in paragraphs 52 through 88 above,
11 which are incorporated herein by reference.

12 **SIXTEENTH CAUSE FOR DISCIPLINE**

13 **(Compounded with Incomplete Master Formulas Against Senior Care Pharmacy and**
14 **Banerjee)**

15 104. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
16 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
17 Regulations, title 16, section 1735.2, subdivision (e)(2)(3)(4)(8), in that they compounded sterile
18 injectable drug preparations without a written master formula which included at least the
19 equipment to be used, the maximum allowable beyond use date for the preparation and the
20 rationale or reference source justifying the beyond use date determination, inactive ingredients to
21 be used and instructions for storage and the handling of the sterile injectable drug preparations, as
22 set forth in paragraphs 52 through 88, which are incorporated herein by reference.

23 **SEVENTEENTH CAUSE FOR DISCIPLINE**

24 **(Failure to Maintain Compounding Log Against Senior Care Pharmacy and Banerjee)**

25 105. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
26 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
27 Regulations, title 16, section 1735.3, subdivision (a)(2)(E)(F), in that they compounded sterile
28 injectable drug preparations without a compounding log which contained the quantity,

1 manufacturer, expiration date and lot number of each component used to compound, as set forth
2 in paragraphs 52 through 88, which are incorporated herein by reference.

3 **EIGHTEENTH CAUSE FOR DISCIPLINE**

4 **(Failure to Properly Clean Compounding Facility and Equipment Against Senior Care
5 Pharmacy and Banerjee)**

6 106. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
7 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
8 Regulations, title 16, section 1751.4, subdivision (d), in that they cleaned the laminar flow hood
9 with 70% isopropyl alcohol and not a germicidal detergent and sterile water, as set forth in
10 paragraphs 52 through 88, which are incorporated herein by reference.

11 **NINETEENTH CAUSE FOR DISCIPLINE**

12 **(Failure to Demonstrate Sterile Compounding Staff's Competency in Aseptic Technique
13 and Area Practices Against Senior Care Pharmacy and Banerjee)**

14 107. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
15 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
16 Regulations, title 16, section 1751.7, subdivision (b)(1), in that the compounding staff lacked
17 competency in aseptic technique when they performed media fill validation with an incubation
18 period of 7 days rather than 14 days as required by the manufacturer, as set forth in paragraphs 52
19 through 88, which are incorporated herein by reference.

20 **TWENTIETH CAUSE FOR DISCIPLINE**

21 **(Failure to Conduct Viable Air Sampling Against Senior Care Pharmacy and Banerjee)**

22 108. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
23 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
24 Regulations, title 16, section 1751.4, subdivision (j), in that they failed to conduct viable air
25 sampling every six months for all sterile-to-sterile compounding by volumetric sampling
26 procedures, as set forth in paragraphs 52 through 88, which are incorporated herein by reference.

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1 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

2 **(Failure to Complete Compounding Self-Assessment Against Senior Care Pharmacy**
3 **and Banerjee)**

4 109. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
5 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
6 Regulations, title 16, section 1735.2, subdivision (k), in that Samitendu Banerjee failed to
7 complete a compounding self-assessment prior to July 1, 2015, as set forth in paragraphs 52
8 through 88, which are incorporated herein by reference.

9 **TWENTY-SECOND CAUSE FOR DISCIPLINE**

10 **(Failure to Complete Pharmacy Self-Assessment Against Senior Care Pharmacy and**
11 **Banerjee)**

12 110. Respondents Senior Care Pharmacy and Samitendu Banerjee are subject to
13 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
14 Regulations, title 16, section 1715, in that Samitendu Banerjee failed to complete a pharmacy
15 self-assessment prior to July 1, 2015, as set forth in paragraphs 52 through 88, which are
16 incorporated herein by reference.

17 **TWENTY-THIRD CAUSE FOR DISCIPLINE**

18 **(Failure to Maintain Diabetes Test Device Records Against Senior Care Pharmacy and Lu)**

19 111. Respondents Senior Care Pharmacy and Po-An Lu are subject to disciplinary action
20 under Code section 4301, subdivision (o), for violating Code section 4081, subdivision (d), in that
21 Respondents Senior Care Pharmacy and Po-An Lu failed to maintain records for nonprescription
22 diabetes test devices dispensed pursuant to prescriptions, as set forth in paragraphs 52 through 88,
23 which are incorporated herein by reference.

24 **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

25 **(Subverting Investigations Against Senior Care Pharmacy, Tran and Lu)**

26 112. Respondents Senior Care Pharmacy, Kenny Tran and Po-An Lu are subject to
27 disciplinary action under Code section 4301, subdivision (q), for subverting an investigation of
28 the Board when they refused to allow the Board to inspect the entirety of the premises in

1 December 2017 and July 2018, refused to allow employees to submit written statements during
2 inspections, altered dispensing records, disconnected QS1 and refused to provide all requested
3 records, as set forth in paragraphs 52 through 88 above, which are incorporated herein by
4 reference.

5 **TWENTY-FIFTH CAUSE FOR DISCIPLINE**

6 **(Possession of Key to Pharmacy by Pharmacy Technicians Against**
7 **Senior Care Pharmacy, Tran and Lu)**

8 113. Respondents Senior Care Pharmacy, Kenny Tran and Po-An Lu are subject to
9 disciplinary action under Code section 4301, subdivision (o), for violating California Code of
10 Regulations, title 16, section 1714, subdivision (d) for allowing pharmacy technicians to possess
11 keys to the pharmacy where dangerous drugs and controlled substances are stored, as set forth in
12 paragraphs 52 through 88 above, which are incorporated herein by reference.

13 **TWENTY-SIXTH CAUSE FOR DISCIPLINE**

14 **(Failure to Exercise or Implement Best Professional Judgment against**
15 **Patel, Banerjee and Lu)**

16 114. Respondents Alpesh Patel, Samitendu Banerjee and Po-An Lu are subject to
17 disciplinary action under Code section 4301(o), for violating Business and Professions Code
18 section 4306.5, subdivision (a), in that they failed to exercise or implement their best professional
19 judgment when compounding and/or dispensing dangerous drugs, as set forth in paragraphs 52
20 through 88 above, which are incorporated herein by reference.

21 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE**

22 **(Failure to Submit Change of Permit Application against Senior Care Pharmacy and Lu)**

23 115. Respondents Senior Care Pharmacy and Po-An Lu are subject to disciplinary action
24 under Code section 4301(o), for violating title 16, California Code of Regulations, section 1704,
25 in that they failed to submit a change of permit application when Senior Care Pharmacy changed
26 locations, as set forth in paragraphs 52 through 88 above, which are incorporated herein by
27 reference.

28 ///

1 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE**

2 **(Failure to Provide Requested Records against Senior Care Pharmacy and Lu)**

3 116. Respondents Senior Care Pharmacy and Po-An Lu are subject to disciplinary action
4 under Code section 4301(o), for violating Business and Professions Code section 4105,
5 subdivision (f), in that they failed to provide the Board with all requested records within three
6 business days of the time the request was made, as set forth in paragraphs 52 through 88 above,
7 which are incorporated herein by reference.

8 **OTHER MATTERS**

9 117. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
10 46000 issued to Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services, Inc. shall
11 be prohibited from serving as a manager, administrator, owner, member, officer, director,
12 associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46000 is placed
13 on probation or until Pharmacy Permit Number PHY 46000 is reinstated if it is revoked.

14 118. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
15 Number PHY 46000 issued to Senior Care Pharmacy Services, Inc. while Kim Banerjee has been
16 an officer and owner and had knowledge of or knowingly participated in any conduct for which
17 the licensee was disciplined, Kim Banerjee shall be prohibited from serving as a manager,
18 administrator, owner, member, officer, director, associate, or partner of a licensee for five years
19 if Pharmacy Permit Number PHY 46000 is placed on probation or until Pharmacy Permit
20 Number PHY 46000 is reinstated if it is revoked.

21 119. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
22 46000 issued to Senior Care Pharmacy Services, Inc. while Alpesh Patel has been an officer and
23 owner and had knowledge of or knowingly participated in any conduct for which the licensee was
24 disciplined, Alpesh Patel shall be prohibited from serving as a manager, administrator, owner,
25 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
26 Number PHY 46000 is placed on probation or until Pharmacy Permit Number PHY 46000 is
27 reinstated if it is revoked.

1 May 22, 2018. On May 15, 2017, the Executive Officer of the Board also issued a Cease and
2 Desist Order that was extended by stipulation.

3 **SECOND AMENDED STATEMENT OF ISSUES AGAINST:**

4 **SENIOR CARE PHARMACY HUNTINGTON BEACH**

5 **CAUSE FOR DENIAL**

6 **(Various)**

7 126. Respondent Senior Care Pharmacy Huntington Beach's applications are subject to
8 denial under Code sections 480, subdivision (a)(2), 480, subdivision (a)(3)(A), 4300, subdivision
9 (c), 4301, subdivisions (f), (j), (o), (q), (t) and (u) and 4302 for violating the statutes and
10 regulations referenced in the Second Amended Accusation, which are incorporated herein by
11 reference.

12 **SECOND AMENDED STATEMENT OF ISSUES AGAINST:**

13 **SENIOR CARE PHARMACY-**

14 **RENEWAL OF STERILE COMPOUNDING LICENSE**

15 **CAUSE FOR DENIAL**

16 **(Various)**

17 127. Respondent Senior Care Pharmacy's application to renew its sterile compounding
18 license is subject to denial under Code sections 480, subdivision (a)(2), 480, subdivision
19 (a)(3)(A), 4300, subdivision (c), 4301, subdivisions (f), (j), (o), (q), (t) and (u) and 4302 for
20 violating the statutes and regulations referenced in the Second Amended Accusation, which are
21 incorporated herein by reference.

22 **PRAYER**

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

- 25 1. Revoking or suspending Pharmacy Permit Number PHY 46000, issued to Senior Care
26 Pharmacy Services, Inc.;
- 27 2. Revoking or suspending Sterile Compounding License Number LSC 99060, issued to
28 Senior Care Pharmacy Services, Inc.;

1 3. Prohibiting Senior Care Pharmacy Services, Inc., from serving as a manager,
2 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
3 Pharmacy Permit Number PHY 46000 is placed on probation or until Pharmacy Permit Number
4 PHY 46000 is reinstated if Pharmacy Permit Number PHY 46000 issued to Senior Care
5 Pharmacy Services, Inc. is revoked;

6 4. Prohibiting Kim Banerjee from serving as a manager, administrator, owner, member,
7 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
8 PHY 46000 is placed on probation or until Pharmacy Permit Number PHY 46000 is reinstated if
9 Pharmacy Permit Number 46000 issued to Senior Care Pharmacy Services, Inc. is revoked;

10 5. Revoking or suspending Pharmacist License Number RPH 45184, issued to
11 Samitendu Banerjee;

12 6. Prohibiting Samitendu Banerjee from serving as a manager, administrator, owner,
13 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
14 Number RPH 45184 is placed on probation or until Pharmacist License Number RPH 45184 is
15 reinstated if Pharmacist License Number RPH 45111 issued to Samitendu Banerjee is revoked;

16 7. Revoking or suspending Pharmacist License Number RPH 48866, issued to Alpesh
17 Patel;

18 8. Prohibiting Alpesh Patel from serving as a manager, administrator, owner, member,
19 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
20 PHY 46000 is placed on probation or until Pharmacy Permit Number PHY 46000 is reinstated if
21 Pharmacy Permit Number PHY 46000 issued to Senior Care Pharmacy Services, Inc. is revoked

22 9. Prohibiting Alpesh Patel from serving as a manager, administrator, owner, member,
23 officer, director, associate, or partner of a licensee for five years if Pharmacist License Number
24 RPH 48866 is placed on probation or until Pharmacist License Number RPH 48866 is reinstated
25 if Pharmacist License Number RPH 48866 issued to Alpesh Patel is revoked;

26 10. Revoking or suspending Pharmacist License Number RPH 69811, issued to Po-An
27 Lu;

28

1 11. Prohibiting Po-An Lu from serving as a manager, administrator, owner, member,
2 officer, director, associate, or partner of a licensee for five years if Pharmacist License Number
3 RPH 69811 is placed on probation or until Pharmacist License Number RPH 69811 is reinstated
4 if Pharmacist License Number RPH 69811 issued to Po-An Lu is revoked;

5 12. Revoking or suspending Pharmacy Technician Registration Number TCH 57643,
6 issued to Kenny Tran;

7 13. Prohibiting Kenny Tran from serving as a manager, administrator, owner, member,
8 officer, director, associate, or partner of a licensee for five years if Pharmacy Technician
9 Registration Number TCH 57643 is placed on probation or until Pharmacy Technician
10 Registration Number TCH 57643 is reinstated if Pharmacy Technician Registration Number TCH
11 57643 issued to Kenny Tran is revoked;

12 14. Ordering Senior Care Pharmacy Services, Inc., Samitendu Banerjee, Alpesh Patel,
13 Po-An Lu and Kenny Tran to pay the Board of Pharmacy the reasonable costs of the investigation
14 and enforcement of this case, pursuant to Business and Professions Code section 125.3;

15 15. Denying the Application of Senior Care Pharmacy Services, Inc. for the renewal of
16 Sterile Compounding License Number LSC 99060;

17 16. Denying the Applications of Senior Care Pharmacy Services HB, Inc. for a pharmacy
18 permit and sterile compounding license; and,

19 17. Taking such other and further action as deemed necessary and proper.

20
21 DATED: April 14, 2020



22 ANNE SODERGREN
23 Executive Officer
24 Board of Pharmacy
25 Department of Consumer Affairs
26 State of California
27 *Complainant*

28 SD2017802833
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