

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

In the Matter of the Accusation Against:

**SENIOR CARE PHARMACY SERVICES, INC., KIM BANERJEE
AND ALPESH PATEL, OWNERS,
Sterile Compounding License No. LSC 99060, and
Pharmacy Permit No. PHY 46000,**

**SAMINTENDU BANERJEE,
Pharmacist License No. RPH 45184,**

**ALPESH PATEL,
Pharmacist License No. RPH 48866,**

**PO-AN LU,
Pharmacist License No. RPH 69811,**

**KENNY TRAN,
Pharmacy Technician License No. TCH 57643,**

Respondents

Case No. 6175

In the Matter of the Statement of Issues Against:

**SENIOR CARE PHARMACY SERVICES, INC.,
Applicant for Renewal of Sterile Compounding License,
Respondent**

Case No. 6409

In the Matter of the Statement of Issues Against:

**SENIOR CARE PHARMACY SERVICES HB, INC.,
Applicant for Pharmacy Permit and
Sterile Compounding License,**

Respondent

Case No. 6156

OAH No. 2019120088

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on November 5, 2021.

It is so ORDERED on October 6, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" clearly distinguishable.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
State Bar No. 126461
4 KRISTEN T. DALESSIO
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7 *Attorneys for Complainant*

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

12 In the Matter of the Accusation Against:

13 **SENIOR CARE PHARMACY SERVICES,**
14 **INC., KIM BANERJEE AND ALPESH**
15 **PATEL, OWNERS,**

16 **SAMITENDU BANERJEE,**

17 **ALPESH PATEL,**

18 **PO-AN LU,**

19 **and**

20 **KENNY TRAN,**

21 Respondents.

22 In the Matter of the Statement of Issues
23 Against:

24 **SENIOR CARE PHARMACY SERVICES,**
25 **INC.,**

26 Respondent.

27 In the Matter of the Statement of Issues
28 Against:

SENIOR CARE PHARMACY SERVICES
HB, INC.,

Respondent.

Case No. 6175

OAH No. 2019120088

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO PO-
AN LU AKA ANDY LU, ONLY

Case No. 6409

Case No. 6156

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

3 **PARTIES**

4 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
5 (Board). She brought this action solely in her official capacity and is represented in this matter by
6 Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg and Kristen T.
7 Dalessio, Deputy Attorneys General.

8 2. Respondent Po-An Lu aka Andy Lu (Respondent) is represented in this proceeding by
9 attorney Rachel L. Fiset of Zweiback, Fiset & Coleman LLP, whose address is: 523 W. 6th
10 Street, Suite 450 Los Angeles, CA 90014.

11 3. On or about September 30, 2013, the Board issued Pharmacist License No. RPH
12 69811 to Respondent. The Pharmacist License was in full force and effect at all times relevant to
13 the charges brought in Second Amended Accusation No. 6175, and will expire on March 31,
14 2023, unless renewed.

15 **JURISDICTION**

16 4. Second Amended Accusation No. 6175 was filed before the Board, and is currently
17 pending against Respondent. Second Amended Accusation No. 6175 and all other statutorily
18 required documents were properly served on Respondent on April 14, 2020. Respondent timely
19 filed his Notice of Defense contesting Second Amended Accusation No. 6175. Respondent is not
20 named as a respondent in Second Amended Statement of Issues No. 6409 and Second Amended
21 Statement of Issues No. 6156.

22 5. A copy of Second Amended Accusation No. 6175 is attached as Exhibit A and
23 incorporated herein by reference.

24 **ADVISEMENT AND WAIVERS**

25 6. Respondent has carefully read, fully discussed with counsel, and understands the
26 charges and allegations in Second Amended Accusation No. 6175. Respondent has also carefully
27 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
28 Disciplinary Order.

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

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegation in Second Amended Accusation No. 6175, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

10. For the purpose of resolving Second Amended Accusation No. 6175 without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in Second Amended Accusation No. 6175, and that Respondent hereby gives up his right to contest those charges.

11. Respondent agrees that his Pharmacist License Number RPH 69811 is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or

effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 69811 issued to Respondent Po-An Lu aka Andy Lu is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime

- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

2. Report to the Board

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

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

3. Interview with the Board

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

4. Cooperate with Board Staff

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

1 **5. Continuing Education**

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

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

5 During the period of probation, respondent shall notify all present and prospective
6 employers of the decision in case number 6175 and the terms, conditions and restrictions imposed
7 on respondent by the decision, as follows:

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

19 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
20 respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b)
21 his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other
22 compliance supervisor, and (c) the owner or owner representative of his employer, to report to the
23 board in writing acknowledging that the listed individual(s) has/have read the decision in case
24 number 6175, and terms and conditions imposed thereby. If one person serves in more than one
25 role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's
26 responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the
27 event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term
28 of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in

1 writing within fifteen (15) days of the change acknowledging that he or she has read the decision
2 in case number 6175, and the terms and conditions imposed thereby.

3 If respondent works for or is employed by or through an employment service, respondent
4 must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board
5 of the decision in case number 6175, and the terms and conditions imposed thereby in advance of
6 respondent commencing work at such licensed entity. A record of this notification must be
7 provided to the board upon request.

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

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

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

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

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

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

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

27 During the period of probation, respondent shall not supervise any intern pharmacist, be the
28 pharmacist-in-charge, designated representative-in-charge, responsible manager or other

1 compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption
2 of any such unauthorized supervision responsibilities shall be considered a violation of probation.

3 **9. Reimbursement of Board Costs**

4 As a condition precedent to successful completion of probation, respondent shall pay to the
5 board its costs of investigation and prosecution in the amount of \$10,000.00. Respondent shall
6 make said payments as follows:

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

10 There shall be no deviation from this schedule absent prior written approval by the board or
11 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
12 probation.

13 **10. Probation Monitoring Costs**

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

18 **11. Status of License**

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

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

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

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

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

17 **13. Practice Requirement - Extension of Probation**

18 Except during periods of suspension, respondent shall, at all times while on probation, be
19 employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar
20 month. Any month during which this minimum is not met shall extend the period of probation by
21 one month. During any such period of insufficient employment, respondent must nonetheless
22 comply with all terms and conditions of probation, unless respondent receives a waiver in writing
23 from the board or its designee.

24 If respondent does not practice as a pharmacist in California for the minimum number of
25 hours in any calendar month, for any reason (including vacation), respondent shall notify the
26 board in writing within ten (10) days of the conclusion of that calendar month. This notification
27 shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the
28 interruption or reduction in practice; and the anticipated date(s) on which respondent will resume

1 practice at the required level. Respondent shall further notify the board in writing within ten (10)
2 days following the next calendar month during which respondent practices as a pharmacist in
3 California for the minimum of hours. Any failure to timely provide such notification(s) shall be
4 considered a violation of probation.

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

9 **14. Violation of Probation**

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

16 If respondent violates probation in any respect, the board, after giving respondent notice
17 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
18 was stayed. If a petition to revoke probation or an accusation is filed against respondent during
19 probation, or the preparation of an accusation or petition to revoke probation is requested from
20 the Office of the Attorney General, the board shall have continuing jurisdiction and the period of
21 probation shall be automatically extended until the petition to revoke probation or accusation is
22 heard and decided, and the charges and allegations in Second Amended Accusation No. 6175
23 shall be deemed true and correct.

24 **15. Completion of Probation**

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

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1 **16. Remedial Education**

2 Within sixty (60) calendar days of the effective date of this decision, respondent shall
3 submit to the board or its designee, for prior approval, a program of remedial education related to
4 the role of the pharmacist-in-charge, pharmacy law and operations and the conduct in this case.
5 The program of remedial education shall consist of at least ten (10) hours per year of probation,
6 with fifty (50) percent of the remedial education program completed by respondent in-person or
7 during a live webinar. All remedial education shall be completed within each year of probation at
8 respondent's own expense. All remedial education shall be in addition to, and shall not be
9 credited toward, continuing education (CE) courses used for license renewal purposes for
10 pharmacists.

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

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

20 **17. Ethics Course**

21 Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
22 in a course in ethics, at respondent's expense, approved in advance by the board or its designee
23 that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall
24 provide proof of enrollment upon request. Within five (5) days of completion, respondent shall
25 submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll
26 in an approved ethics course, to initiate the course during the first year of probation, to
27 successfully complete it before the end of the second year of probation, or to timely submit proof
28 of completion to the board or its designee, shall be considered a violation of probation.

1 **18. Supervised Practice**

2 Term 18 shall apply only during the first two years of Respondent's probation. Within
3 thirty (30) days of the effective date of this decision, respondent shall submit to the board or its
4 designee, for prior approval, the name of a Pharmacist by and not on probation with the board, to
5 serve as respondent's practice supervisor. As part of the documentation submitted, respondent
6 shall cause the proposed practice supervisor to report to the board in writing acknowledging that
7 he or she has read the decision in case number 6175, and is familiar with the terms and conditions
8 imposed thereby, including the level of supervision required by the board or its designee. This
9 level will be determined by the board or its designee, will be communicated to the respondent on
10 or before the effective date of this decision and shall be one of the following:

11 Continuous – At least 75% of a work week

12 Substantial - At least 50% of a work week

13 Partial - At least 25% of a work week

14 Daily Review - Supervisor's review of probationer's daily activities within 24 hours

15 Respondent may practice only under the required level of supervision by an approved
16 practice supervisor. If, for any reason, including change of employment, respondent is no longer
17 supervised at the required level by an approved practice supervisor, within ten (10) days of this
18 change in supervision respondent shall submit to the board or its designee, for prior approval, the
19 name of a Pharmacist by and not on probation with the board, to serve as respondent's
20 replacement practice supervisor. As part of the documentation submitted, respondent shall cause
21 the proposed replacement practice supervisor to report to the board in writing acknowledging that
22 he or she has read the decision in case number 6175, and is familiar with the terms and conditions
23 imposed thereby, including the level of supervision required.

24 Any of the following shall result in the automatic suspension of practice by a respondent
25 and shall be considered a violation of probation:

26 Failure to nominate an initial practice supervisor, and to have that practice supervisor report
27 to the board in writing acknowledging the decision, terms and conditions, and supervision level,
28 within thirty (30) days;

1 Failure to nominate a replacement practice supervisor, and to have that practice supervisor
2 report to the board in writing acknowledging the decision, terms and conditions, and supervision
3 level, within ten (10) days;

4 Practicing in the absence of an approved practice supervisor beyond the initial or
5 replacement nomination period; or

6 Any failure to adhere to the required level of supervision.

7 Respondent shall not resume practice until notified in writing by the board or its designee.

8 During any suspension, respondent shall not enter any pharmacy area or any portion of the
9 licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug
10 retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or
11 any area where dangerous drugs and/or dangerous devices or controlled substances are
12 maintained. Respondent shall not practice pharmacy nor do any act involving drug selection,
13 selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall
14 respondent manage, administer, or be a consultant to any licensee of the board, or have access to
15 or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or
16 dangerous devices or controlled substances.

17 During any suspension, respondent shall not engage in any activity that requires the
18 professional judgment and/or licensure as a Pharmacist. Respondent shall not direct or control
19 any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or
20 retailing of dangerous drugs and/or dangerous devices or controlled substances.

21 Failure to comply with any suspension shall be considered a violation of probation.

22 **19. No Ownership or Management of Licensed Premises**

23 Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager,
24 administrator, member, officer, director, trustee, associate, or partner of any business, firm,
25 partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell
26 or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90)
27 days following the effective date of this decision and shall immediately thereafter provide written
28

1 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide
2 documentation thereof shall be considered a violation of probation.

3 **20. Letter of Apology to the Board**

4 Within sixty (60) days of the effective date of this decision, Respondent shall author, sign
5 under penalty of perjury, and submit to the board, a letter of apology regarding his conduct in this
6 case. This letter must be approved in advance of submission by the board or its designee. Failure
7 to submit a letter that is satisfactory to the board or its designee to meet this requirement within
8 the specified time period shall be considered a violation of probation.

9 The board or its designee may publish this letter, including in *The Script*, or make other use
10 thereof, and may edit the letter for length or clarity for any use made of the letter.

11 The letter shall be written in such manner that it may serve to educate and prepare other
12 board licensees, including those who have taken on Pharmacist in Charge or other managerial
13 positions, or are considering doing so, particularly early in their careers. The letter shall include,
14 at least: (a) a full accounting of Respondent's culpability for the conduct in this case; (b) a full
15 accounting of the culpability of any others for the conduct in this case; (c) an accounting of why
16 or how the conduct in this case took place while Respondent served as Pharmacist in Charge; (d)
17 an explanation of the proper role of a Pharmacist in Charge; and (e) a description of lessons
18 learned by Respondent from the conduct at issue in this case and his participation therein.

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ACCEPTANCE

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

DATED: _____

PO-AN LU, AKA ANDY LU
Respondent

I have read and fully discussed with Respondent Po-An Lu, aka Andy Lu the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

RACHEL L. Fiset
Attorney for Respondent

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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1 ACCEPTANCE

2 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
3 discussed it with my attorney, Rachel L. Fiset. I understand the stipulation and the effect it will
4 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order
5 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
6 Board of Pharmacy.

7 DATED: 09/02/2021

8 Andy Lu
9 PO-AN LU, AKA ANDY LU
Respondent

10 I have read and fully discussed with Respondent Po-An Lu, aka Andy Lu the terms and
11 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
12 I approve its form and content.

13 DATED: 9/2/2021

14 Rachel L. Fiset
15 RACHEL L. FISET
Attorney for Respondent

16 ENDORSEMENT

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

19
20 DATED: 9/2/21

Respectfully submitted,

21 ROB BONTA
22 Attorney General of California
23 GREGORY J. SALUTE
Supervising Deputy Attorney General

24
25 DESIREE I. KELLOGG
26 Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 6175

1 XAVIER BECERRA
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 MORGAN MALEK
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San Diego, CA 92186-5266
Telephone: (619) 738-9429
8 Facsimile: (619) 645-2061
Attorneys for Complainant

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**
18 **99060**

19 **Pharmacy Permit No. PHY 46000**

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

22 **Pharmacist License No. RPH 45184**

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

25 **Pharmacist License No. RPH 48866**

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

28 **Pharmacist License No. RPH 69811**

KENNY TRAN
12600 Hoover Street
Garden Grove, CA 92841

Pharmacy Technician License No.
TCH 57643

Respondents.

In the Matter of the Statement of Issues
Against:

**SENIOR CARE PHARMACY SERVICES,
INC.**

**Applicant for Renewal of Sterile
Compounding License**

Respondent.

In the Matter of the Statement of Issues
Against:

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

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

Respondent.

Case No. 6409

**SECOND AMENDED STATEMENT OF
ISSUES**

Case No. 6156

**SECOND AMENDED STATEMENT OF
ISSUES**

Complainant alleges:

PARTIES

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

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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13. Section 4300.1, of the Code states:

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

STATUTORY AND REGULATORY PROVISIONS

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

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

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

...

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

...

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

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

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

"Pharmacy" means an area, place or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "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,

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

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

...

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

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

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

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

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

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

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

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

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

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

3 ...

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

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

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

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

15 ...

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

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

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

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

25 ...

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

29 ...

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

32 ...

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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
agency.

4 ...

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

7 ...

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

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

14 24. Section 4302 of the Code states:

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

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

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

20 Acts or omissions that involve, in whole or in part, the inappropriate exercise of
his or her education, training, or experience as a pharmacist, whether or not the act or
21 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
22 the board.

23 ...

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

25 Any person who has been denied a license or whose license has been revoked
or is under suspension, or who has failed to renew his or her license while it was
26 under suspension, or who has been a manager, administrator, owner member, officer,
director, associate, or partner of any partnership, corporation, firm, or association
27 whose application for a license has been denied or revoked, is under suspension or
has been placed on probation, and while acting as the manger, administrator, owner,
28 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,
owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

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

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

11 28. Health and Safety Code section 111255 states:

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

14 29. Health and Safety Code section 111295 states:

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

17 30. Health and Safety Code section 111330 states:

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

20 31. Health and Safety Code section 111335 states:

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

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

24 Any drug is misbranded in any of the following cases:

25 ...

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

28 ///

1 33. Health and Safety Code section 111440 states:

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

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

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

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

(2) The prescription container:

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

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

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

18 (4) Both pharmacies maintain complete and accurate records of the refill,
19 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.

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

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

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

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

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

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

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

14 ...

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

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

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

27 (b) In addition to the self-assessment required in subdivision (a) of this section,
28 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
CACI and the documentation provided by the manufacturer shows it meets the
26 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-
Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16,
15 Division 17, of the California Code of Regulations. That form contains a first section
16 applicable to all compounding, and a second section applicable to sterile injectable
17 compounding. The first section must be completed by the pharmacist-in-charge
18 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
19 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
20 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.

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

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

24 ...

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

27 ...

28 (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
4 component, the records shall include the date of receipt of the component in the
5 pharmacy, and the limitations of section 1735.2, subdivision (1) shall apply.

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

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

8 ...

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

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

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

18 ...

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

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

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

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

28 (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.

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

(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
compounding areas and shall not be removed from these areas except for disposal.

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in 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 licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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.

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

Dispensing Recycled Drugs

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

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

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

¹ “Punched out” refers to the activity of pharmacy personnel taking drugs out of the 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

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

Unsafe Compounding of Sterile Injectable Drugs

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

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

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

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

² Sterile compounding is the preparation of a drug from chemical or bulk drug substances 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.

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

Conduct During Investigations

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

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

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

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

Change in Location of Pharmacy

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

SECOND AMENDED ACCUSATION

FIRST CAUSE FOR DISCIPLINE

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

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

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

TWENTY-FIFTH CAUSE FOR DISCIPLINE

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

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

TWENTY-SIXTH CAUSE FOR DISCIPLINE

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

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

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

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

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

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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.

1 120. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
2 RPH 48866 issued to Alpesh Patel, Alpesh Patel shall be prohibited from serving as a manager,
3 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
4 Pharmacist License Number RPH 48866 is placed on probation or until Pharmacist License
5 Number RPH 48866 is reinstated if it is revoked.

6 121. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
7 RPH 45184 issued to Samitendu Banerjee, Samitendu Banerjee shall be prohibited from serving
8 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
9 for five years if Pharmacist License Number RPH 45184 is placed on probation or until
10 Pharmacist License Number RPH 45184 is reinstated if it is revoked.

11 122. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
12 RPH 69811 issued to Po-An Lu, Po-An Lu shall be prohibited from serving as a manager,
13 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
14 Pharmacist License Number RPH 69811 is placed on probation or until Pharmacist License
15 Number RPH 69811 is reinstated if it is revoked.

16 123. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Technician
17 Registration No. TCH 57643 issued to Kenny Tran, Kenny Tran shall be prohibited from serving
18 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
19 for five years if Pharmacy Technician Registration Number TCH 57643 is placed on probation or
20 until Pharmacy Technician Registration Number TCH 57643 is reinstated if it is revoked.

21 **DISCIPLINARY CONSIDERATIONS**

22 124. To determine the degree of discipline, if any, to be imposed on Alpesh Patel,
23 Complainant alleges that on June 17, 2017, the Board issued Citation number CI 2014 65695
24 against Alpesh Patel for violating California Code of Regulations, section 1716 for deviating
25 from the requirements of a prescription. The Board issued a fine which Alpesh Patel paid.

26 125. To determine the degree of discipline, if any to be imposed on Respondents,
27 Complainant alleges that the Executive Office of the Board issued a Cease and Desist on May 2,
28 2018 that was upheld in the Decision After Hearing to Contest Cease and Desist Order, effective

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

SECOND AMENDED STATEMENT OF ISSUES AGAINST:

SENIOR CARE PHARMACY HUNTINGTON BEACH

CAUSE FOR DENIAL

(Various)

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

SECOND AMENDED STATEMENT OF ISSUES AGAINST:

SENIOR CARE PHARMACY-

RENEWAL OF STERILE COMPOUNDING LICENSE

CAUSE FOR DENIAL

(Various)

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

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 46000, issued to Senior Care Pharmacy Services, Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99060, issued to 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

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

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

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

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

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

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

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

DATED: April 14, 2020



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

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