# 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 Permit No. LSC 99060, and Pharmacy Permit No. PHY 46000; and

SAMINTENDU BANERJEE,
Pharmacist License No. RPH 45184; and

ALPESH PATEL,
Pharmacist License No. RPH 48866; and

PO-AN LU, Pharmacist License No. RPH 69811; and

KENNY TRAN,
Pharmacy Technician License No. TCH 57643,

Respondents

Case No. 6175,

In the Matter of the Statement of Issues Against:

DECISION AND ORDER AS TO SENIOR CARE PHARMACY SERVICES, INC., SENIOR CARE PHARMACY SERVICES HB,
INC., SENIOR CARE PHARMACY SERVICES FAIRFIELD INC., AND SAMITENDU BANERIEE ONLY
(CASE NOS. 6175, 6156, 6409, 6161)

## 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,

SENIOR CARE PHARMACY SERVICES FAIRFIELD, INC., KIM E. BANERJEE, SAMITENDU BANERJEE, ANTONY P. THEKKEK, and PREMA P. THEKKEK, OWNERS AND OFFICERS
Pharmacy Permit No. PHY 50619,

SAMINTENDU BANERJEE, Pharmacist License No. RPH 45184,

VAN THAO MY NGUYEN, Pharmacist License No. RPH 66472,

### KALI WONG, Pharmacist License No. RPH 73152,

Respondents

Case No. 6161

OAH No. 2020110031

#### **DECISION AND ORDER**

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

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

It is so ORDERED on October 6, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA	
2	Attorney General of California GREGORY J. SALUTE	
	Supervising Deputy Attorney General	
3	JOSHUA A. ROOM Supervising Deputy Attorney General	
4	DESIREE I. KELLOGG Deputy Attorney General	
5	State Bar No. 126461	
6	KRISTEN T. DALESSIO Deputy Attorney General	
7	State Bar No. 149081 MICHAEL B. FRANKLIN	
8	Deputy Attorney General State Bar No. 136524	
	600 West Broadway, Suite 1800 455	Golden Gate Avenue, Suite 11000
9		Francisco, CA 94102-7004 lephone: (415) 510-3455
10		csimile: (415) 703-5480
11	Facsimile: (619) 645-2061	
12	Attorneys for Complainant BEFOR	RE THE
13	BOARD OF PHARMACY	
14	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
15		1
16	In the Matter of the Accusation Against:	Case No. 6175
17	SENIOR CARE PHARMACY SERVICES,	OAH No. 2019120088
18	INC., KIM BANERJEE AND ALPESH PATEL, OWNERS,	STIPULATED SURRENDER OF
19	SAMITENDU BANERJEE,	LICENSES AND ORDER AS TO SENIOR CARE PHARMACY SERVICES, INC.,
20		SENIOR CARE PHARMACY SÉRVIĆES HB, INC, SENIOR CARE PHARMACY
	ALPESH PATEL,	SERVICES FAIRFIELD INC., AND
21	PO-AN LU,	SAMITENDU BANERJEE, <u>ONLY</u>
22	KENNY TRAN,  Respondents.	
23	Respondents.	_
24	In the Matter of the Statement of Issues	Case No. 6409
25	Against:	
26	SENIOR CARE PHARMACY SERVICES,	
27	INC.,	
28	Respondent.	
20		
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	1	
1 2	In the Matter of the Statement of Issues Against:	Case No. 6156
3	SENIOR CARE PHARMACY SERVICES HB, INC.,	
4	Respondent.	
5		
6	In the Matter of the Accusation Against:	Case No. 6161
7	SENIOR CARE PHARMACY SERVICES FAIRFIELD INC., KIM E. BANERJEE,	OAH No. 2020110031
8	SAMITENDU BANERJEE, ANTONY P. THEKKEK, and PREMA P. THEKKEK,	
9	OWNERS AND OFFICERS,	
10	SAMITENDU BANERJEE,	
11	VAN THAO MY NGUYEN,	
12	KALI WONG,	
13	Dogwoodanta	
14	Respondents.	
15	The following stipulation is agreed to by and resolves administrative cases and civil matters	
16	pending as to Respondents Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services	
17	HB, Inc., Senior Care Pharmacy Services Fairfield Inc., and Samitendu Banerjee, only. It does	
18	not apply to or alter the administrative cases pending or resolved against Respondents Alpesh	
19	Patel, Po-An Lu, Kenny Tran, Van Thao My Nguyen, or Kali Wong.	
20	IT IS HEREBY STIPULATED AND AGREED by and between the above-named parties	
21	to the above-entitled proceedings that the following matters are true:	
22	<u>PARTIES</u>	
23	Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy	
24	(Board). She brought this action solely in her official capacity and is represented in this matter by	
25	Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg and Kristen T.	
26	Dalessio, Deputy Attorneys General, in Case Nos. 6175, 6409 and 6156, and by Michael B.	
27	Franklin, Deputy Attorney General, in Case No. 6	5161.
28	///	
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		nses and Order (Case Nos. 6175, 6156, 6409 and 6161)

- 2. Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services HB, Inc., and Senior Care Pharmacy Services Fairfield Inc., are acting in this proceeding through Samitendu Banerjee, officer and director of Senior Care Pharmacy Services, Inc. and shareholder, officer and director of Senior Care Pharmacy Services HB, Inc. and Senior Care Pharmacy Services Fairfield Inc., who has been designated and authorized to enter into this agreement on their behalf.
- 3. Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services HB, Inc., Senior Care Pharmacy Services Fairfield Inc., and Samitendu Banerjee, are represented in this proceeding by attorney Rachel L Fiset of Zweiback, Fiset & Coleman, LLP, whose address is: 523 W. 6<sup>th</sup> Street, Suite 450, Los Angeles, CA 90014.
- 4. On or about July 25, 2002, the Board issued Pharmacy Permit No. PHY 46000 to Senior Care Pharmacy Services, Inc., Kim Banerjee and Daniel Zilafro, Shareholders. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Second Amended Accusation No. 6175 and Second Amended Statement of Issues Nos. 6409 and 6156, and will expire on July 1, 2022, unless renewed.
- 5. On or about July 1, 2003, the Board issued Sterile Compounding License No. LSC 99060 to Senior Care Pharmacy Services, Inc. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Second Amended Accusation No. 6175 and Second Amended Statement of Issues No. 6409. On or about June 9, 2017, the Board informed Senior Care Pharmacy Services, Inc. that its Sterile Compounding License would not be renewed. It expired on July 1, 2017.
- 6. On or about January 23, 2017, the Board received an application for a pharmacy permit and sterile compounding license from Senior Care Pharmacy Services HB, Inc., Samitendu Banerjee, Daniel Zilafro, and Kim Banerjee, Shareholders. On March 13, 2017, the Board denied the application and subsequently filed Second Amended Statement of Issues No. 6156.
- 7. On or about April 28, 2011, the Board issued Pharmacy Permit No. PHY 50619 to Senior Care Pharmacy Services Fairfield Inc., Kim and Samitendu Banerjee, Shareholders. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6161, and will expire on April 1, 2022, unless renewed.

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#### PENDING CIVIL PROCEEDINGS

- 11. There is also now-pending civil litigation between all of the above-named Respondents, except for Senior Care Pharmacy Services HB, Inc. and Senior Care Pharmacy Services Fairfield Inc. and the Board.
- 12. Respondents, except for Senior Care Pharmacy Services HB, Inc. and Senior Care Pharmacy Services Fairfield Inc., and other plaintiffs filed suit against the Board and other defendants in *Senior Care Pharmacy Services, Inc. et al. v. California Board of Pharmacy, et al.*, Case No. 30-2020-01140931-CU-PO-CXC in Orange County Superior Court. That case was decided on the Board's Anti-SLAPP motion, resulting in an award of attorneys' fees and costs of \$75,643.95 payable by plaintiffs to the Board by order of the Superior Court dated February 26, 2021. Additional proceedings in that case, including debtor examinations and other enforcement proceedings, are still pending.
- 13. Respondents, except for Senior Care Pharmacy Services HB, Inc. and Senior Care Pharmacy Services Fairfield Inc., and other plaintiffs appealed that decision to the California Court of Appeal (Fourth District). That appeal, *Senior Care Pharmacy Services, Inc. et al. v. California Board of Pharmacy, et al.*, Case No. G059651, is partially briefed and still pending before the California Court of Appeal.

#### **ADVISEMENT AND WAIVERS**

- 14. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Second Amended Accusation No. 6175, Second Amended Statement of Issues Nos. 6409 and 6156, and First Amended Accusation No. 6161. Respondents have also carefully read, fully discussed with counsel, and understand this Stipulated Surrender of Licenses and Order.
- 15. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation, Second Amended Statements of Issues, and the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their 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.

- 16. Respondents are also fully aware of their legal rights in the pending civil matters, including to pursue their appeal in Court of Appeal Case No. G059651, and any remaining rights in Orange County Superior Court Case No. 30-2020-01140931-CU-PO-CXC, or otherwise.
- 17. Respondents hereby voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

#### SATISFACTION AND DISMISSAL OF PENDING CIVIL PROCEEDINGS

- 18. Respondents acknowledge and accept their obligation to pay to the Board the award of attorneys' fees and costs of \$75,643.95 ordered in Orange County Superior Court Case No. 30-2020-01140931-CU-PO-CXC. In partial consideration for this agreement, the Board agrees to the following discount for early payment: if the entire debt is paid within ninety (90) days of the effective date of the Decision and Order issued by the Board in this matter, the Board will accept \$71,861.75 (a 5% reduction) in full satisfaction of this obligation. Failure to make full payment within that time period will cause the obligation to revert to the full amount of \$75,643.95.
- 19. Respondents agree that, within five (5) days of the effective date of a decision in this case, they will cause to be filed papers necessary to waive and abandon all rights they may have to contest or appeal that award or otherwise continue litigating. This will include the filing of a Request for Dismissal (Form CIV-110), with prejudice, in Orange County Superior Court Case No. 30-2020-01140931-CU-PO-CXC, and the filing of a Stipulated Request for Dismissal, also with prejudice, in California Court of Appeal Case No. G059651. The filing of the dismissals will not excuse Respondents from the obligation to pay the award of attorneys' fees and costs of \$75,643.95 to the Board as ordered by the Superior Court on February 26, 2021, or the reduced amount of \$71,861.75 if full payment is made within ninety (90) days. The Board may enforce the full award in any appropriate court, in addition to any other rights the Board may have.

#### **CULPABILITY**

20. Respondents Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services Fairfield, Inc., and Samitendu Banerjee hereby understand and agree that the charges and

allegations in Second Amended Accusation No. 6175 and First Amended Accusation No. 6161, if proven at a hearing, constitute cause for imposing discipline upon their respective Pharmacy Permits and Pharmacist License. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services HB, Inc., hereby understand and agree that the charges and allegations in Second Amended Statement of Issues Nos. 6409 and 6156, if proven at a hearing, constitute cause for denial of their applications for Sterile Compounding Licenses and a Pharmacy Permit.

- 21. For the purpose of resolving these cases without the expense and uncertainty of further proceedings, Respondents Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services HB, Inc., Senior Care Pharmacy Services Fairfield Inc., and Samitendu Banerjee, hereby agree that, at a hearing, Complainant could establish a factual basis for the charges and allegations in Second Amended Accusation No. 6175, Second Amended Statement of Issues Nos. 6409 and 6156, and First Amended Accusation No. 6161, that those charges constitute cause for discipline or denial, and that Respondents hereby give up their right to contest those charges.
- 22. Respondents Senior Care Pharmacy Services, Inc., Senior Care Pharmacy Services HB, Inc., Senior Care Pharmacy Services Fairfield Inc., and Samitendu Banerjee, understand that by signing this stipulation, they enable the Board to issue an order accepting the surrender of their Pharmacy Permits and Pharmacist License, and affirming license denials, without further process.

#### **CONTINGENCY**

23. This stipulation shall be subject to approval by the Board. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their 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, this Stipulated Surrender of Licenses and 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.

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- 24. This Stipulated Surrender of Licenses and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of Licenses and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 25. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of Licenses and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 26. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

#### **ORDER**

#### AS TO THE SENIOR CARE PHARMACY RESPONDENTS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 46000, issued to Respondent Senior Care Pharmacy Services, Inc., and Pharmacy Permit No. PHY 50619, issued to Senior Care Pharmacy Services Fairfield Inc., are surrendered and accepted by the Board. However, the surrenders will be stayed for a period of six (6) months from the effective date of the Order adopting this Stipulated Surrender, by which time those pharmacies shall be sold or closed. In addition, for the purposes of ensuring appropriate oversight during the six months that is afforded for sale or closure, Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. shall each, within five (5) days of the effective date of this decision: (a) designate a Pharmacist-in-Charge who is not a Respondent in these proceeding; and (b) retain an independent consultant approved in advance by the Board or its designee, at Respondents' expense, who shall be responsible for conducting inspections to review the operations of the pharmacies on a monthly basis for compliance with state and federal pharmacy and drug laws.

1. In the event that Respondent Senior Care Pharmacy Services, Inc. or Respondent Senior Care Pharmacy Services Fairfield Inc. is not sold within six months from the effective date of this decision, any unsold pharmacy shall, within ten (10) days of the lapse of six months from

the effective date, arrange for the destruction of, the transfer to, sale of, or storage in a facility licensed and approved by the Board, all controlled substances and dangerous drugs and/or dangerous devices. The pharmacy shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the Board. The pharmacy shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to Board guidelines.

- 2. In the event that Respondent Senior Care Pharmacy Services, Inc. or Respondent Senior Care Pharmacy Services Fairfield Inc. is not sold within six months from the effective date of this decision, any unsold pharmacy shall also, within ten (10) days of the lapse of six months from the effective date, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to ongoing patients, the pharmacy shall provide a copy of the written notice to the Board. "Ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the prior ninety days.
- 3. The surrender of Respondent Senior Care Pharmacy Services, Inc.'s and Respondent Senior Care Pharmacy Services Fairfield Inc.'s Pharmacy Licenses and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. This stipulation constitutes a record of the discipline and shall become a part of Respondent Senior Care Pharmacy Services, Inc.'s and Respondent Senior Care Pharmacy Services Fairfield Inc.'s license history with the Board of Pharmacy.
- 4. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. shall lose all rights and privileges as pharmacies in California as of the effective date of the Board's Decision and Order.

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- 5. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. are jointly and severally liable with all other Respondents in these matters, for the costs of investigation and prosecution in case numbers 6175 and 6161. Neither shall be issued a new or reinstated license until the Board has received payment of its costs of investigation and enforcement in the amount of \$640,267.25.
- 6. Pursuant to Business and Professions Code section 4307, the following shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of any entity licensed by the Board until Respondent Senior Care Pharmacy Services, Inc. and Respondent Senior Care Pharmacy Services Fairfield Inc.'s pharmacy licenses are reissued or reinstated: Respondent Senior Care Pharmacy Services, Inc.; Respondent Senior Care Pharmacy Services Fairfield Inc.; owners and/or officers Kim Banerjee and Samitendu Banerjee.
- 7. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. understand and agree that if they ever file an application for licensure of a licensed premises or a petition for reinstatement in the State of California, the Board shall treat the application or petition as a new application for licensure.
- 8. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy
  Services Fairfield Inc. may not reapply for any license from the Board for three (3) years from the
  effective date of this decision. They stipulate that should they apply for any license from the
  Board on or after the effective date of this decision, all allegations set forth in Second Amended
  Accusation No. 6175 and First Amended Accusation No. 6161 shall be deemed to be true, correct
  and admitted by the applicant when the Board determines whether to grant or deny an application.
- 9. If either Respondent Senior Care Pharmacy Services, Inc. or Respondent Senior Care Pharmacy Services Fairfield Inc. applies for any license from the Board, it shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board.
- 10. If either Respondent Senior Care Pharmacy Services, Inc. or Respondent Senior Care Pharmacy Services Fairfield Inc. ever applies or reapplies for a license or certification by any other health care licensing agency in the State of California, all of the charges and allegations contained in Second Amended Accusation No. 6175 and First Amended Accusation No. 6161

shall be deemed to be true, correct, and admitted by them for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

11. Respondents Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy Services Fairfield Inc. shall relinquish their respective pharmacy permits, and any indicia of licensure issued by the Board, including but not limited to wall and renewal license certificates, within five (5) days of the lapse of six months from the effective date of this decision.

IT IS FURTHER HEREBY ORDERED THAT the denials of the applications for renewal of Sterile Compounding License No. 99060 by Respondent Senior Care Pharmacy Services, Inc., and for a pharmacy permit and sterile compounding license by Respondent Senior Care Pharmacy Services HB, Inc., are hereby affirmed and made final, as of the effective date of this decision, and this will finally resolve Statement of Issues Case Nos. 6409 and 6156.

#### AS TO RESPONDENT SAMITENDU BANERJEE

IT IS FURTHER HEREBY ORDERED that Pharmacist License No. RPH 45184, issued to Respondent Samitendu Banerjee, is surrendered and accepted by the Board.

- 1. The surrender of the Pharmacist License, and the acceptance of the surrendered license by the Board, shall constitute the imposition of discipline against Respondent Samitendu Banerjee. This stipulation constitutes a record of the discipline and shall become a part of Respondent Samitendu Banerjee's license history with the Board.
- 2. Respondent Samitendu Banerjee shall lose all rights and privileges as a Pharmacist in California as of the effective date of the Board's Decision and Order. Respondent shall cause to be delivered to the Board his Pharmacist pocket licenses and, if one was issued, his wall certificate, on or before the effective date of the Decision and Order.
- 3. Respondent Samitendu Banerjee is jointly and severally liable with all other Respondents in these matters for the costs of investigation and prosecution in case numbers 6175 and 6161. He shall not be issued a new or reinstated license until the Board has received payment of its costs of investigation and enforcement in the amount of \$640,267.25.
- 4. Respondent Samitendu Banerjee may not apply for any license, permit, or registration from the Board for a period of three (3) years from the effective date of the Decision and Order.

If he ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Second Amended Accusation No. 6175 and First Amended Accusation No. 6161 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. If Respondent Samitendu Banerjee should ever apply or reapply for a license or certification by any other health care licensing agency in the State of California, all of the charges and allegations contained in Second Amended Accusation No. 6175 and First Amended Accusation No. 6161 shall be deemed to be true, correct and admitted by Respondent when the agency determines whether to grant or deny the application.

#### **ACCEPTANCE**

I, Samitendu Banerjee, officer, director and/or shareholder of Senior Care Pharmacy
Services, Inc., Senior Care Pharmacy Services HB, Inc., and Senior Care Pharmacy Services
Fairfield Inc., am acting on those entities' behalf and in my individual capacity. I have carefully
read the above Stipulated Surrender of Licenses and Order and have fully discussed it with my
counsel, Rachel L. Fiset. I understand the stipulation and the effect it will have on my Pharmacist
License, on the Permits issued to Senior Care Pharmacy Services, Inc. and Senior Care Pharmacy
Services Fairfield Inc., and on the applications filed by Senior Care Pharmacy Services, Inc. and
Senior Care Pharmacy Services HB, Inc. On behalf of myself and on behalf of the above-listed
entities as their authorized representative, I enter into this Stipulated Surrender of Licenses and
Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order
of the Board of Pharmacy.

SAMITENDU BANERJEE, for himself and
for SENIOR CARE PHARMACY SERVICES, INC., SENIOR CARE PHARMACY SERVICES HB, INC., and SENIOR CARE PHARMACY SERVICES FAIRFIELD INC. Respondents

1	I have read and fully discussed with I	Respondents Senior Care Pharmacy Services, Inc.,
2	Senior Care Pharmacy Services HB, Inc., S	enior Care Pharmacy Services Fairfield Inc., and
3	Samitendu Banerjee, the terms and condition	ons and other matters contained in this Stipulated
4	Surrender of Licenses and Order. I approve	e its form and content.
5	DATED:	
6		RACHEL L. FISET Attorney for Respondents
7	ENI	DORSEMENT
8	The foregoing Stipulated Surrender of Licenses and Order is hereby respectfully submitted	
9	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.	
10	DATED:	Respectfully submitted,
11		ROB BONTA
12		Attorney General of California GREGORY J. SALUTE Supervising Deputy Attorney Canada
13		Supervising Deputy Attorney General
14		
15		DESIREE I. KELLOGG Deputy Attorney General
16		Attorneys for Complainant
17		
18	DATED:	Respectfully submitted,
19		ROB BONTA Attorney General of California
20		Attorney General of California JOSHUA A. ROOM Supervising Deputy Attorney General
21		
22		MICHAEL B. FRANKLIN
23		Deputy Attorney General
24		Attorneys for Complainant
25		
26	SD2017802833 82992183.docx	
27		
28		
		13

1	I have read and fully discussed with Respondents Senior Ca.	re Pharmacy Services, Inc.,
2	2 Senior Care Pharmacy Services HB, Inc., Senior Care Pharmacy S	Services Fairfield Inc., and
3	3 Samitendu Banerjee, the terms and conditions and other matters co	ontained in this Stipulated
4	4 Surrender of Licenses and Order. I approve its form and content.	
5	5 DATED: 8/20/2021 Rac	neld. Fiset
6	RACHEL L. FISE	V-7
7	7 <u>ENDORSEMENT</u>	
8	8 The foregoing Stipulated Surrender of Licenses and Order is	hereby respectfully submitted
9	9 for consideration by the Board of Pharmacy of the Department of	Consumer Affairs.
10	10 DATED: 8 20/21 Respectfully	submitted,
11	ROB BONTA	
12	Attorney Ger GREGORY J.	neral of California
13	Supervising	Deputy Attorney General
14	14	
15	DESIREE I. K	ELLOGG
16		rney General Complainant
17	17	
18	18 DATED: 8/20/2021 Respectfully	submitted,
19		
20	20 Joshua A. R	
21	21	Deputy Attorney General
22	m/2	ml'
23	MICHAEL B. Deputy Attor	
24	Attorneys for	· Complainant
25		
26	26 SD2017802833 82992183.docx	
27		
28	28	

#### Exhibit A

Second Amended Accusation No. 6175 and Second Amended Statement of Issues Nos. 6409 and 6156

11	AVIER BECERRA torney General of California	
GI	REGORY J. SALUTE	
M	pervising Deputy Attorney General ORGAN MALEK	
	eputy Attorney General ESIREE I. KELLOGG	
	eputy Attorney General ate Bar No. 126461	
	500 West Broadway, Suite 1800 San Diego, CA 92101	
F	P.O. Box 85266 San Diego, CA 92186-5266	
]	Telephone: (619) 738-9429 Facsimile: (619) 645-2061	
	torneys for Complainant	
	BEFOR	
	BOARD OF P DEPARTMENT OF CO	ONSUMER AFFAIRS
	STATE OF CA	ALIFUKNIA
_		
Iı	n the Matter of the Accusation Against:	Case No. 6175
	ENIOR CARE PHARMACY SERVICES, NC., KIM BANERJEE AND ALPESH	SECOND AMENDED ACCUSATION
P	ATÉL OWNERS 2600-12601 Hoover Street	
11	Garden Grove, CA 92841	
	terile Compounding License No. LSC 9060	
P	Pharmacy Permit No. PHY 46000	
11	AMITENDU BANERJEE	
	P.O. Box 27638 Anaheim, CA 92809	
P	Pharmacist License No. RPH 45184	
	ALPESH PATEL	
	224 E. Marblehead Way Anaheim, CA 92808	
P	Pharmacist License No. RPH 48866	
	O-AN LU 7053 Glenford Dr.	
	Hacienda Heights, CA 91745	
P	Pharmacist License No. RPH 69811	
		1
$\parallel$ _		AND SECOND AMENDED STATEMENTS OF ISS

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:	Case No. 6409
SENIOR CARE PHARMACY SERVICES, INC.	SECOND AMENDED STATEMENT OF ISSUES
Applicant for Renewal of Sterile Compounding License	
Respondent.	
In the Matter of the Statement of Issues Against:	Case No. 6156
SENIOR CARE PHARMACY SERVICES HB, INC.	SECOND AMENDED STATEMENT OF ISSUES
Applicant for Pharmacy Permit and Sterile Compounding License	
Respondent.	
	-
Complainant alleges:	
PART	TIES .
1. Anne Sodergren (Complainant) brings	s 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 Febru	uary 15, 2006, and November 22, 2010, through
January 1, 2015, Samitendu Banerjee designated a	as the Pharmacist-in-Charge from February 15,
	2
SECOND AMENDED ACCUSATION	AND SECOND AMENDED STATEMENTS OF ISSUI

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

- 3. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding License Number LSC 99060 to Senior Care Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and expired on July 1, 2017. On or about June 9, 2017, the Board informed Senior Care Pharmacy that its Sterile Compounding License would not be renewed. The License was subsequently cancelled.
- 4. On or about January 23, 2017, the Board received an application for a pharmacy permit and sterile compounding license from Senior Care Pharmacy Services HB, Inc. with Kim Banerjee, Samitendu Banerjee and Daniel Zilafro identified as the owners of the outstanding shares (Senior Care Pharmacy Huntington Beach). On or about January 19, 2017, Kim and Samitendu Banerjee, on behalf of Senior Care Pharmacy Huntington Beach certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. On or about March 13, 2017, the Board denied Senior Care Pharmacy Huntington Beach's application.
- 5. On or about March 12, 1992, the Board of Pharmacy issued Pharmacist License Number RPH 45184 to Samitendu Banerjee (Samitendu Banerjee). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2022, unless renewed.
- 6. On or about August 14, 1996, the Board of Pharmacy issued Pharmacist License Number RPH 48866 to Alpesh Patel (Alpesh Patel). The Pharmacist License was in full force

#### 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,

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 the person knew or reasonably should have known were adulterated, as set forth in	
5	Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.	
6	·	
7	(3) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.	
9	(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.	
10	(5) Fail to maintain records of acquisition or disposition of dangerous drugs or dangerous devices for at least three years.	
11	dangerous devices for at least timee years.	
12	•••	
13	22. Section 4300, subdivision (c) of the Code states, in pertinent part:	
14	The board may refuse a license to any applicant guilty of unprofessional	
15	conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure.	
16	22 Section 4201 of the Code states in neutinent neut.	
17	23. Section 4301 of the Code states in pertinent part:	
18 19	The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:	
	conduct shall include, but is not infined to, any of the following.	
20	···	
21	(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a	
22	licensee or otherwise, and whether the act is a felony or misdemeanor or not.	
23		
24	(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.	
25	cinica states regulating controlled substances and dangerous drugs.	
26	•••	
27	///	
28		

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 or of the applicable federal and state laws and regulations governing pharmacy,	
3	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 investigation of the board.	
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 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 the diabetes test device was not purchased either directly from the manufacturer or	
12		
13	us recruited in section 1700.5.	
14	24. Section 4302 of the Code states:	
15	The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where	
16	conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a	
17	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	
21	his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership,	
22	management, administration, or operation of a pharmacy or other entity licensed 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	
26	or is under suspension, or who has failed to renew his or her license while it was	

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of a pharmacy or other entity licensed by Code states that: cense or whose license has been revoked o renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly SECOND AMENDED ACCUSATION AND SECOND AMENDED STATEMENTS OF ISSUES

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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.

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

- 53. Senior Care Pharmacy was a closed door pharmacy which dispensed dangerous drugs, including controlled substances to patients who resided in assisted living and skilled nursing facilities.
- 54. Senior Care Pharmacy also compounded and dispensed sterile injectable drug products to patients who resided in assisted living and skilled nursing facilities.
- 55. On or about January 23, 2017, Senior Care Pharmacy Huntington Beach filed an application for a pharmacy permit and sterile compounding license. The outstanding shares of Senior Care Pharmacy Huntington Beach were owned by Kim and Samitendu Banerjee.

#### **Using Unlicensed Entity to Dispense Drugs**

- 56. Novasys Health Systems Private Limited (Novasys) is located in Hyderabad, India and is not licensed with the Board. From at least 2011 to July 2018, Senior Care Pharmacy utilized Novasys to dispense dangerous drugs to patients. It provided Novasys with access to confidential patient medical information in Senior Care Pharmacy's computer software systems (QS1) and its patient profiles which contained patients' medical, contact and insurance information, including patient prescription history. Novasys accessed common electronic files shared with Senior Care Pharmacy to update information relevant to the dispensing of dangerous drugs.
- 57. With Senior Care Pharmacy's knowledge and consent, Novasys processed new prescriptions to be dispensed when Senior Care Pharmacy was short-staffed. With Senior Care's knowledge and consent, Novasys also initiated the process of re-filling prescriptions for dangerous drugs.
- 58. On May 2, 2018, the Board issued a "cease and desist" order requiring Novasys to cease and desist practicing any activity under Pharmacy Law which requires licensure, including initiating the dispensing process for new prescriptions and prescription refills and the sharing of common electronic files in "QS1" and other electronic files. On May 22, 2018, the Board issued 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 Novays 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" 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

<sup>&</sup>lt;sup>1</sup> "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.

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

- 63. Senior Care Pharmacy stored the drugs returned from skilled nursing and assisted living facilities in an area with a temperature of 83 degrees Fahrenheit even though both drug manufacturers and the United States Pharmacopeia recommend that dangerous drugs be stored at 60 to 77 degrees Fahrenheit. Senior Care Pharmacy continued to store drugs in an area with a temperature above 77 degrees Fahrenheit even after being informed by the Board inspectors to cease that practice.
- 64. Controlled substances were not labeled with the name of the medication, strength, lot number, expiration dates and the initials of the verifying pharmacists in Senior Care Pharmacy's records. In 2017, drugs in bubble cards were labeled with two separate expiration dates on the front and back label.
- 65. From January 1, 2015 through June 15, 2017, more dangerous drugs, gabapentin 300mg, risperidone 1mg and metformin 500mg were dispensed than purchased. Again, there were overages in the inventory of such dangerous drugs as 10,695 capsules of gabapentin 300mg, 4,002 tablets of risperidone 1mg and 7,933.5 tablets of metformin 500mg. There were no records of acquisition and disposition for the overages of those drugs.
- 66. From September 2014 through 2017, Senior Care Pharmacy was not registered as a collector of controlled substances with the Drug Enforcement Administration. However, Senior Care Pharmacy accepted returns of controlled substances.

# <u>Failure to Retain Diabetes Test Device Records and Fraudulent Billing of Diabetes</u> <u>Test Devices</u>

- 67. From July 31, 2017 through December 6, 2017, Senior Care Pharmacy did not retain the records of acquisition and disposition for nonprescription diabetes test devices it dispensed pursuant to a prescription.
- 68. From July 31, 2017 through December 6, 2017, Senior Care Pharmacy billed more 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" 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 subpotent 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.

<sup>&</sup>lt;sup>2</sup> 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.

- 73. Senior Care Pharmacy continued to compound sterile drug preparations after being told by a Board inspector to stop their practices and they promised under penalty of perjury to do so).
- 74. Senior Care Pharmacy did not possess written policies and procedures for compounded sterile preparation stability and beyond use dating and temperature variations.
- 75. Senior Care Pharmacy compounded sterile drug products (i.e., vancomycin 750mg/NS 250ml and vancomycin 1gm/NS/NS 250ml) without first preparing master formulas which specified a laminar flow hood as equipment, an appropriate beyond use date, sterile water for injection as an active ingredient and instructions for storage and handling.
- 76. Senior Care Pharmacy compounded and dispensed vancomycin 750mg/NS 250ml and vancomycin 1gm/NS 250ml without documenting the quantity, manufacturer, expiration date and lot number of the sterile water for injection used as a component in a compounding log.
- 77. In April 2017, Senior Care Pharmacy did not use a germicidal detergent to clean the laminar flow hood in the compounding area.
- 78. Between January 1, 2017 and May 9, 2017, Senior Care Pharmacy did not perform viable air sampling by volumetric sampling procedures.
- 79. Between October 12, 2016 to March 10, 2017, Senior Care Pharmacy performed media fill validation by incubating for seven days rather than fourteen days.
- 80. On May 15, 2017, the Board issued a Cease and Desist Order to halt Senior Care Pharmacy's sterile compounding operations. Senior Care Pharmacy agreed to an extension of that cease and desist order until after the date of the expiration of its Sterile Compounding License. In June 2017, the Board informed Senior Care Pharmacy that the Board would not renew Senior Care Pharmacy's sterile compounding license.

#### **Lack of Drug Security and Reporting**

- 81. In 2016 through 2017, pharmacy technicians possessed keys to the areas where dangerous drugs were stored at Senior Care Pharmacy.
- 82. On February 8, 2016, Senior Care Pharmacy did not possess self-assessments for 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.*, redispensed dangerous drugs), that were adulterated within the meaning of Health and Safety Code

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

#### SECOND CAUSE FOR DISCIPLINE

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

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

#### THIRD CAUSE FOR DISCIPLINE

# (Received Returns of Controlled Substances Without Proper Registration Against All Respondents)

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

#### FOURTH CAUSE FOR DISCIPLINE

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

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

#### FIFTH CAUSE FOR DISCIPLINE

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

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

#### SIXTH CAUSE FOR DISCIPLINE

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

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

#### SEVENTH CAUSE FOR DISCIPLINE

#### (Sharing Common Files with Unlicensed Entity Against All Respondents)

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

#### **EIGHTH CAUSE FOR DISCIPLINE**

# (Processing Requests for Refill of Prescriptions Received by Unlicensed Entity Against All Respondents)

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

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.
26	
27	<i>///</i>
28	<i>///</i>

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#### FIFTEENTH CAUSE FOR DISCIPLINE

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

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

#### SIXTEENTH CAUSE FOR DISCIPLINE

# (Compounded with Incomplete Master Formulas Against Senior Care Pharmacy and Banerjee)

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

#### SEVENTEENTH CAUSE FOR DISCIPLINE

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

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

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

#### EIGHTEENTH CAUSE FOR DISCIPLINE

## (Failure to Properly Clean Compounding Facility and Equipment Against Senior Care Pharmacy and Banerjee)

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

#### NINETEENTH CAUSE FOR DISCIPLINE

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

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

#### TWENTIETH CAUSE FOR DISCIPLINE

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

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

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#### TWENTY-FIRST CAUSE FOR DISCIPLINE

## (Failure to Complete Compounding Self-Assessment Against Senior Care Pharmacy and Banerjee)

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

#### TWENTY-SECOND CAUSE FOR DISCIPLINE

# (Failure to Complete Pharmacy Self-Assessment Against Senior Care Pharmacy and Banerjee)

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

#### TWENTY-THIRD CAUSE FOR DISCIPLINE

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

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

#### TWENTY-FOURTH CAUSE FOR DISCIPLINE

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

112. Respondents Senior Care Pharmacy, Kenny Tran and Po-An Lu are subject to disciplinary action under Code section 4301, subdivision (q), for subverting an investigation of 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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#### TWENTY-EIGHTH CAUSE FOR DISCIPLINE

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

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

#### **OTHER MATTERS**

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

- 120. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 48866 issued to Alpesh Patel, Alpesh Patel shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 48866 is placed on probation or until Pharmacist License Number RPH 48866 is reinstated if it is revoked.
- 121. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 45184 issued to Samitendu Banerjee, Samitendu Banerjee shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45184 is placed on probation or until Pharmacist License Number RPH 45184 is reinstated if it is revoked.
- 122. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 69811 issued to Po-An Lu, Po-An Lu shall be prohibited 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 it is revoked.
- 123. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Technician Registration No. TCH 57643 issued to Kenny Tran, Kenny Tran shall be prohibited 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 it is revoked.

#### **DISCIPLINARY CONSIDERATIONS**

- 124. To determine the degree of discipline, if any, to be imposed on Alpesh Patel, Complainant alleges that on June 17, 2017, the Board issued Citation number CI 2014 65695 against Alpesh Patel for violating California Code of Regulations, section 1716 for deviating from the requirements of a prescription. The Board issued a fine which Alpesh Patel paid.
- 125. To determine the degree of discipline, if any to be imposed on Respondents,
  Complainant alleges that the Executive Office of the Board issued a Cease and Desist on May 2,
  2018 that was upheld in the Decision After Hearing to Contest Cease and Desist Order, effective

1	May 22, 2018. On May 15, 2017, the Executive Officer of the Board also issued a Cease and
2	Desist Order that was extended by stipulation.
3	SECOND AMENDED STATEMENT OF ISSUES AGAINST:
4	SENIOR CARE PHARMACY HUNTINGTON BEACH
5	CAUSE FOR DENIAL
6	(Various)
7	126. Respondent Senior Care Pharmacy Huntington Beach's applications are subject to
8	denial under Code sections 480, subdivision (a)(2), 480, subdivision (a)(3)(A), 4300, subdivision
9	(c), 4301, subdivisions (f), (j), (o), (q), (t) and (u) and 4302 for violating the statutes and
10	regulations referenced in the Second Amended Accusation, which are incorporated herein by
11	reference.
12	SECOND AMENDED STATEMENT OF ISSUES AGAINST:
13	SENIOR CARE PHARMACY-
14	RENEWAL OF STERILE COMPOUNDING LICENSE
15	CAUSE FOR DENIAL
16	(Various)
17	127. Respondent Senior Care Pharmacy's application to renew its sterile compounding
18	license is subject to denial under Code sections 480, subdivision (a)(2), 480, subdivision
19	(a)(3)(A), 4300, subdivision (c), 4301, subdivisions (f), (j), (o), (q), (t) and (u) and 4302 for
20	violating the statutes and regulations referenced in the Second Amended Accusation, which are
21	incorporated herein by reference.
22	PRAYER
23	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
24	and that following the hearing, the Board of Pharmacy issue a decision:
25	1. Revoking or suspending Pharmacy Permit Number PHY 46000, issued to Senior Care
26	Pharmacy Services, Inc.;
27	2. Revoking or suspending Sterile Compounding License Number LSC 99060, issued to
28	Senior Care Pharmacy Services, Inc.;
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3.	Prohibiting Senior Care Pharmacy Services, Inc., from serving as a manager,
adminis	ator, owner, member, officer, director, associate, or partner of a licensee for five years i
Pharma	Permit Number PHY 46000 is placed on probation or until Pharmacy Permit Number
PHY 46	00 is reinstated if Pharmacy Permit Number PHY 46000 issued to Senior Care
Pharma	Services, Inc. is revoked;

- 4. Prohibiting Kim Banerjee from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46000 is placed on probation or until Pharmacy Permit Number PHY 46000 is reinstated if Pharmacy Permit Number 46000 issued to Senior Care Pharmacy Services, Inc. is revoked;
- 5. Revoking or suspending Pharmacist License Number RPH 45184, issued to Samitendu Banerjee;
- 6. Prohibiting Samitendu Banerjee from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45184 is placed on probation or until Pharmacist License Number RPH 45184 is reinstated if Pharmacist License Number RPH 45111 issued to Samitendu Banerjee is revoked;
- 7. Revoking or suspending Pharmacist License Number RPH 48866, issued to Alpesh Patel:
- 8. Prohibiting Alpesh Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46000 is placed on probation or until Pharmacy Permit Number PHY 46000 is reinstated if Pharmacy Permit Number PHY 46000 issued to Senior Care Pharmacy Services, Inc. is revoked
- 9. Prohibiting Alpesh Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 48866 is placed on probation or until Pharmacist License Number RPH 48866 is reinstated if Pharmacist License Number RPH 48866 issued to Alpesh Patel is revoked;
- 10. Revoking or suspending Pharmacist License Number RPH 69811, issued to Po-An Lu;

#### **Exhibit B**

First Amended Accusation No. 6161

1	XAVIER BECERRA								
2	Attorney General of California JOSHUA A. ROOM								
3	Supervising Deputy Attorney General MICHAEL B. FRANKLIN								
4	Deputy Attorney General State Bar No. 136524								
5	455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004								
6	Telephone: (415) 510-3455 Facsimile: (415) 703-5480								
7	E-mail: Michael.franklin@doj.ca.gov  Attorneys for Complainant								
8	BEFORE								
9	BOARD OF PH DEPARTMENT OF CO								
10	STATE OF CA	LIFORNIA							
11	In the Matter of the Accusation Against:	Case No. 6161							
12	SENIOR CARE PHARMACY SERVICES								
13	FAIRFIELD INC., KIM E. BANERJEE, SAMITENDU BANERJEE, ANTONY P.	FIRST AMENDED ACCUSATION							
14	THEKKEK, and PREMA P. THEKKEK, OWNERS AND OFFICERS								
15	4950 Fulton Avenue, Suites A & B Fairfield, CA 94534,								
16	Pharmacy License No. PHY 50619,								
17	SAMITENDU BANERJEE								
18	P.O. Box 27638 Anaheim, CA 92809,								
19	Pharmacist License No. RPH 45184,								
20	VAN THAO MY NGUYEN 2044 Malden Avenue								
21	San Jose, CA 95122,								
22	Pharmacist License No. RPH 66472,								
23	<b>KALI WONG</b> 3046 Bradshaw Drive								
24	San Jose, CA 95148,								
25	Pharmacist License No. RPH 73152,								
26	Respondents. <sup>1</sup>								
27	The Accusation in this matter named addit	ional Respondents Xiao Zhao (RPH 78051),							
28	Jenny Dinh (RPH 69736), Jennifer Chan (RPH 673 (RPH 73324), and Caroline Nguyen (RPH 71478).								
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#### **PARTIES**

- 1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.
- 2. On or about April 28, 2011, the Board issued Original Permit (Pharmacy License) Number PHY 50619 to Senior Care Pharmacy Services Fairfield Inc., Kim E. Banerjee, President and 50% shareholder, Samitendu Banerjee, Chief Executive Officer and 5% shareholder, Antony P. Thekkek, Vice President and 22% shareholder, Prema P. Thekkek, Vice President and 22% shareholder (Respondent SCPS Fairfield). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2021, unless renewed.
- 3. On or about March 12, 1992, the Board issued Pharmacist License Number RPH 45184 to Samitendu Banerjee (Respondent Banerjee). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2022, unless renewed. Between on or about April 28, 2011 and on or about March 1, 2015, Respondent Banerjee served as Pharmacist in Charge (PIC) for Respondent SCPS Fairfield.
- 4. On or about October 27, 2011, the Board issued Pharmacist License Number RPH 66472 to Van Thao My Nguyen (Respondent Van Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2021, unless renewed. Between on or about March 1, 2015 and on or about July 28, 2016, Respondent Van Nguyen served as PIC for Respondent SCPS Fairfield.
- 5. On or about August 27, 2015, the Board issued Pharmacist License Number RPH 73152 to Kali Wong (Respondent Wong). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2020, unless renewed. Between on or about August 15, 2016 and on or about February 2, 2018, Respondent Wong served as PIC for Respondent SCPS Fairfield.

#### **JURISDICTION**

6. This Accusation is brought before the Board of Pharmacy, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

- 7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 8. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.
- 9. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, 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 PROVISIONS**

- 10. Section 733, subdivision (a), of the Code states:
- (a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.
  - 11. 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.

- 12. Section 4076, subdivision (a)(2), of the Code states:
- (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
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(2) The directions for the use of the drug.

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13.	Section 4081,	subdivisions	(a).	(b)	and	(d)	of the	Code state.	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-incharge, 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 . . .
  - 14. Section 4113, subdivision (c), of the Code states:
- (c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
  - Section 4169, subdivisions (a)(2)-(a)(5), of the Code state: 15.
  - (a) A person or entity shall not do any of the following:

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

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- (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 device's manufacturer or the manufacturer's authorized distributors as identified in Section 4160.5.
- (u) The submission of a reimbursement claim for a nonprescription diabetes test 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 the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in section 4160.5.
  - 17. Section 4306.5, subdivisions (a) and (c), of the Code state:

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

...

- (c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.
  - 18. Section 4307, subdivision (a), of the Code states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

- (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

#### 19. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

#### 20. Health and Safety Code section 111260 states:

Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

#### 21. Health and Safety Code section 111295 states:

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

22. Health and Safety Code section 111330 states:

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

23. Health and Safety Code section 111335 states:

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

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

Any drug is misbranded in any of the following cases:

. . .

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

25. Health and Safety Code section 111440 states:

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

26. 21 U.S.C. § 352, subdivision (g), states:

A drug or device shall be deemed to be misbranded –

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

#### **REGULATORY PROVISIONS**

- 27. California Code of Regulations, title 16, section 1707.4, states:
- (a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:
- (1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
  - (2) The prescription container:
- (A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and
- (B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

- (3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
  - (4) Both pharmacies maintain complete and accurate records of the refill, including:
  - (A) the name of the pharmacist who refilled the prescription;
  - (B) the name of the pharmacy refilling the prescription; and
  - (C) the name of the pharmacy that received the refill request.
- (5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.
- (6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.
- (b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or patient's agent or transmitted to it by a prescriber.
  - 28. California Code of Regulations, title 16, section 1711, subdivision (e), states:
- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
  - 1. the date, location, and participants in the quality assurance review;
- 2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
  - 3. the findings and determinations generated by the quality assurance review; and,
  - 4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.
  - 29. California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), state:
- (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed.

The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

. . .

- (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.
- 30. California Code of Regulations, title 16, section 1716, states:

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

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

- 31. California Code of Regulations, title 16, section 1717.1, subdivision (a), states:
- (a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required 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.
  - 32. California Code of Regulations, title 16, section 1718, states:

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

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

- 33. California Code of Regulations, title 16, section 1793.3, subdivision (a), states:
- (a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise

enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

- 34. California Code of Regulations, title 22, section 72353, subdivision (d), states:
- (d) Arrangements shall be made to assure that pharmaceutical services are available to provide patients with prescribed drugs and biologicals.
- 35. California Code of Regulations, title 22, section 72355, subdivision (a)(1), states: (a) Pharmaceutical service shall include, but is not limited to, the following:
- (1) Obtaining necessary drugs including the availability of 24-hour prescription service on a prompt and timely basis . . .
  - 36. 21 C.F.R. § 1301.75, subdivision (b), states:
- (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

#### **COST RECOVERY**

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

#### **FACTUAL ALLEGATIONS**

- 38. Respondent SCPS Fairfield is one of three pharmacies licensed with the Board which include the words "Senior Care" in their names, and which share some or all owners or officers. The other Senior Care pharmacies are located in Sun Valley, CA and Garden Grove, CA.
- 39. At all times relevant herein, Respondent SCPS Fairfield was a closed-door pharmacy that contracted to provide pharmacy services to long-term-care facilities including skilled nursing facilities (SNFs) and assisted living facilities (ALFs) in the San Francisco Bay Area. At least

some of these facilities were subject to regulations promulgated under Title 22 of the California Code of Regulations, relating to circumstances and timelines for provision of patient care, and by contracting to perform pharmacy services for these facilities, Respondent SCPS Fairfield shared the responsibility to comply with Title 22 regulations governing delivery of pharmacy services.

40. Between 2016 and 2018, Respondent SCPS Fairfield and its operations were the subjects of several inspections and investigations. These inspections and investigations found numerous violations of state and federal laws and regulations governing pharmacies. These violations are grouped by type under the following sub-headings. Under each sub-heading are the causes for discipline alleged on the basis of those alleged facts, and the alleged respondents.

#### **Using Unlicensed Entity to Dispense Drugs**

- 41. Novasys Health Systems Private Limited (Novasys) is located in Hyderabad, India and is not licensed with the Board. In or about May 2018, and for an unknown period of time prior to this date, Respondent SCPS Fairfield utilized Novasys to dispense dangerous drugs to patients. It provided Novasys with access to confidential patient medical information in Respondent SCPS Fairfield's computer software systems (QS1) and its patient profiles which contained patients' medical, contact and insurance information, including patient prescription history. Novasys accessed common electronic files shared with Respondent SCPS Fairfield to update information relevant to the dispensing of dangerous drugs.
- 42. With Respondent SCPS Fairfield's knowledge and consent, Novasys processed new prescriptions to be dispensed when Respondent SCPS Fairfield was short-staffed. With Respondent SCPS Fairfield's knowledge and consent, Novasys also initiated the process of refilling prescriptions for dangerous drugs.

#### FIRST CAUSE FOR DISCIPLINE

# (Aiding and Abetting Unlicensed Practice of Pharmacy Against Respondents SCPS Fairfield and Banerjee)

43. Respondents SCPS Fairfield and Banerjee are subject to disciplinary action under Code section 4301, subdivision (o), Code section 4037, subdivision (a), and/or California Code of Regulations, title 16, section 1707.4, subdivision (a), section 1717.1, subdivision (a), and/or

section 1793.3 subdivision (a), in that Respondents aided and abetted Novasys, an entity not licensed by the Board, to act as a pharmacy licensed by the Board, by allowing Novasys to access Respondent SCPS Fairfield's electronic files, to process prescription refills and to allow non-licensed individuals to enter prescription information as set forth above in paragraphs 41-42.

#### **Inadequate Records of Diabetic Test Strips**

- 44. On or about December 6, 2017, Board Inspectors conducted an audit of all records of acquisition and disposition of all Respondent SCPS Fairfield's FreeStyle Lite diabetic test strips from April 1, 2015 to December 6, 2017. Records showed that Respondent SCPS Fairfield dispensed a total of 726,600 test strips, but only purchased a total of 4,750 test strips from wholesale dealers. This resulted in a negative variance of 721,850 test strips.
- 45. Between April 1, 2015 and July 28, 2016, when Respondent Van Nguyen was the PIC of Respondent SCPS Fairfield, the audit of all records of acquisition and disposition of all Respondent SCPS Fairfield's FreeStyle Lite diabetic test strips that Respondent SCPS Fairfield dispensed a total of 512,850, but only purchased a total of 750 test strip from wholesale dealers. A total of 750 test strips were returned during this time period. This resulted in a negative variance of 512,850 test strips.
- 46. Between August 15, 2016 and December 6, 2017, when Respondent Wong was the PIC of Respondent SCPS Fairfield, the audit of all records of acquisition and disposition of all Respondent SCPS Fairfield's FreeStyle Lite diabetic test strips showed that Respondent SCPS Fairfield dispensed a total of 197,450 but only purchased a total of 4,000 test strips from wholesale dealers. A total of 3,900 test strips were returned during this time period. This resulted in a negative variance of 197,400 test strips.
- 47. On July 17, 2017, an amendment of Code section 4081, subdivision (d), required pharmacies to retain records of acquisition and sale of nonprescription diabetes test devices and to have those records available at all times during business hours. Records reviewed by Board investigators established that from July 17, 2017 to December 6, 2017, Respondent SCPS Fairfield dispensed a total of 63,250 test strips and had an inventory of 50 test strips on December

6, 2017. Respondent SCPS Fairfield provided no records of purchasing any test strips from any wholesale dealer during this time period.

#### **SECOND CAUSE FOR DISCIPLINE**

# (Failure to Maintain Diabetes Test Device Records

#### **Against Respondents SCPS Fairfield and Wong)**

48. Respondents SCPS Fairfield and Wong are subject to disciplinary action under Code section 4301, subdivision (o), and/or Code section 4081, subdivision (d), in that Respondent SCPS Fairfield failed to maintain records for nonprescription diabetes test devices dispensed pursuant to prescriptions, as set forth above in paragraphs 44-47.

#### THIRD CAUSE FOR DISCIPLINE

# (Acts Involving Dishonesty, Fraud, Deceit, or Corruption Against Respondents SCPS Fairfield, Van Nguyen, Wong and Banerjee)

49. Respondents SCPS Fairfield, Van Nguyen, Wong and Banerjee are subject to disciplinary action under Code section 4301, subdivision (f), in that Respondents dispensed more diabetic test strips than were purchased from wholesale dealers. Respondents billed and dispensed test strips without inventory, as set forth above in paragraphs 44-47.

#### **Inconsistent Expiration Dates – Misbranded Products**

- 50. On December 6, 2017, Board Inspectors conducted an inspection of Respondent SCPS Fairfield. Inspectors observed prepacked medications ready to be dispensed and found:
- a. Labeling for 29 packages of Proponol 10mg had two different expiration dates. The expiration date on the patient labels was June 3, 2018, but the pharmacy's own labels listed December 31, 2018 as the expiration date. Inclusion of two different expiration dates on each of the 29 packages could cause confusion for patients and could lead to the continued use of the medication longer than the appropriate expiration date.
- b. Labeling for 68 packages of Clozapine ODT 100mg had two different expiration dates. The expiration date on the patient labels was June 5, 2019, but the pharmacy's own labels listed May 31, 2018 as the expiration date. Inclusion of two different expiration dates on each of the 68

14, 2017, overages of 48,874 capsules of gabapentin 300mg, 4,417.5 tablets of metformin 500mg and 6,238.5 tablets of risperidone 1mg as set forth in paragraph 52 above.

#### Security, Inventory, Misbranding, Insurance - February 3 and 11, 2016 Inspections

- 54. During inspections on February 3, 2016, and again on February 11, 2016, Board Inspectors found cabinets that stored controlled medications, ranging from Schedule II to Schedule V. These cabinets had no locking mechanism to adequately secure the cabinets.
- 55. On February 3, 2016, Board Inspectors observed medication waste disposal bins, containing partially used and expired medications, located throughout the pharmacy, accessible to unlicensed personnel. Controlled and non-controlled drugs were commingled. No records were located or provided regarding any of the medications found in the waste containers.
- 56. During the inspections on February 3 and February 11, 2016, Board Inspectors found various medication tablets cut in half. Medications that were halved included: meloxicam 15mg; Uloric 80mg; Fanapt 10mg; Crestor 20mg; and Crestor 5mg. Cutting these tablets could alter the intended delivery system, and Inspectors observed uneven splitting of tablets, which would alter the intended doses of the medications.
- 57. During the inspections on February 3 and February 11, 2016, Board Inspectors observed multiple stock bottles which contained a greater quantity than indicated on the bottle. There were no records or documentation kept or provided that indicated lot numbers or expiration dates were checked prior to overfilling the bottles. Specific examples included:
  - a. Uloric 80mg, 2 containers, bottle indicated 30 each (60 total), total 84 tablets/capsules.
  - b. Fanapt 10mg, 1 container, bottle indicated 60, total 109 tablets/capsules.
  - c. Fanapt 8mg, 1 container, bottle indicated 60, total 90 tablets/capsules.
  - d. Valproic Acid 250mg, 2 containers, bottle indicated 200 each (400 total), total 276.
  - e. Geodon 60mg, 1 container, bottle indicated 60, total 73.
  - f. Geodon 20mg, bottle indicated 60, total 121.
  - g. Toviaz 8mg, bottle indicated 30, total 84.
  - h. Viread 300mg, bottle indicated 30, total 35.

54-55 above, cabinets and bins used to store / dispose of controlled substances were not secured.  SEVENTH CAUSE FOR DISCIPLINE  (Failure to Maintain Current Inventory and Records
(Failure to Maintain Current Inventory and Records
·
Against Respondents SCPS Fairfield and Van Nguyen)
61. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
Code section 4301, subdivision (j) and/or (o), Code section 4081, subdivision (a), and/or
California Code of Regulations, title 16, section 1718, in that multiple waste bins were observed
without records of the disposed medications, as set forth in paragraph 55 above.
EIGHTH CAUSE FOR DISCIPLINE
(Adulterated and/or Misbranded Drugs
Against Respondents SCPS Fairfield and Van Nguyen)
62. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
Code section 4301, subdivisions (j) and (o), Health and Safety Code sections 111260, 111295,
111330, and/or 111440, and/or Code section 4169, subdivision (a)(2) and/or (a)(3), in that they
sold, delivered, held or offered for sale dangerous drugs that were not intended to be halved that
were cut in half. Medications identified include: meloxicam 15mg; Uloric 80mg; Fanapt 10mg;
Crestor 20mg; and Crestor 5mg, as set forth in paragraph 56 above.
NINTH CAUSE FOR DISCIPLINE
(Adulterated and/or Misbranded Drugs
Against Respondents SCPS Fairfield and Van Nguyen)
63. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
Code section 4301, subdivisions (j) and (o), Health and Safety Code sections 111260, 111295,
111330, and/or 111440, and/or Code section 4169, subdivision (a)(2) and/or (a)(3), in that they
sold, delivered, held or offered for sale dangerous drugs that were adulterated and/or misbranded
when medication stock bottles were found with a greater amount of medication than was
indicated on the manufacturer labels, as set forth in paragraph 57 above.
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(SENIOR CARE PHARMACY SERVICES FAIRFIELD INC., et al.) ACCUSATION

#### TENTH CAUSE FOR DISCIPLINE

#### (Failure to Maintain Current Inventory and Records

#### **Against Respondents SCPS Fairfield and Van Nguyen)**

64. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), Code section 4081, subdivision (a), and/or California Code of Regulations, title 16, section 1718, in that, as set forth in paragraph 58 above, between January 15, 2015 and February 11, 2016, an audit revealed inventory overages of 42 tablets of Fanapt 8mg, 125 tablets of Fanapt 10mg, 3408 tablets of Valproic Acid 250mg, 231 tablets of Geodone 20mg, and 62 tablets of Geodone 60mg.

#### **ELEVENTH CAUSE FOR DISCIPLINE**

# (Failure to Reverse Insurance Claims for Medications Refused Upon Delivery Against Respondents SCPS Fairfield, Van Nguyen and Banerjee)

65. Respondents SCPS Fairfield, Van Nguyen and Banerjee are subject to disciplinary action under Code section 4301, subdivision (f), for acts involving dishonesty, fraud, deceit, or corruption, in that Respondents failed to reverse insurance claims for medications refused upon delivery and returned to the pharmacy, as set forth in paragraph 59 above.

#### **Medication Error and Quality Assurance**

- 66. The Board received a complaint that Respondent SCPS Fairfield had filled a prescription that was supposed to be valproic acid 250mg/5 ml syrup with metoclopramide 5mg/5 ml syrup. Evidence obtained established that on June 9, 2016, prescription Rx#26241298 for patient LF<sup>2</sup> was entered into the pharmacy system correctly as valproic acid 250mg/5ml syrup but was incorrectly dispensed with metoclopramide 5mg/5ml syrup on June 14, 2016.
- 67. During the course of the investigation, the Board Inspector requested a quality assurance report pertaining to the acknowledged medication error on October 12, October 20, October 28 and November 4, 2016. Respondent SCPS Fairfield finally provided the quality assurance report on November 8, 2016, 27 days after it was first requested.

<sup>&</sup>lt;sup>2</sup> Full names will be revealed to Respondents, if requested, during discovery.

#### TWELFTH CAUSE FOR DISCIPLINE

#### (Variation from a Prescription

#### **Against Respondent SCPS Fairfield)**

68. Respondent SCPS Fairfield is subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or California Code of Regulations, title 16, section 1716, in that on or about June 9, 2016, a prescription was entered into the pharmacy system as valproic acid 250mg/5ml syrup but was incorrectly dispensed with metoclopramide 5mg/5ml syrup on June 14, 2016, as set forth in paragraph 66 above.

#### THIRTEENTH CAUSE FOR DISCIPLINE

# (Failure to Comply with Quality Assurance Requirements Against Respondent SCPS Fairfield)

69. Respondent SCPS Fairfield is subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or California Code of Regulations, title 16, section 1711, subdivision (e), in that, as set forth in paragraph 67 above, Respondent failed to maintain an immediately retrievable quality assurance report in the pharmacy, as required.

#### Medication Errors; Delays in Delivery; and Withholding Narcotic Medications

- 70. Between January 25, 2016 and July 20, 2016, the Board received several complaints against Respondent SCPS Fairfield regarding providing the wrong medications and/or the wrong dosages, delays in the delivery of medications, and withholding narcotic medications. Following an investigation of all complaint items, the Board Inspectors found the following.
- 71. On or about June 30, 2015, zolpidem 5mg was ordered for patient MC. Respondent SCPS Fairfield incorrectly filled with zolpidem 10mg (RX#24018142). MC ingested eight (8) days of the wrong dose.
- 72. On or about August 15, 2015, Respondent SCPS Fairfield dispensed Depakote DR [divalproex] 500mg tablets without prescriber authorization for patient SSa. On July 8, 2015, SSa was prescribed Depakote DR 500mg tablets, which were properly filled by Respondent SCPS Fairfield. On July 22, 2015, SSa was admitted to a hospital, then discharged back to Creekside

Behavioral Health on August 6, 2015, with new orders, but no new orders for Depakote DR 500mg tablets. The orders from the previous stay at Creekside should have been removed when the new orders were entered. In addition, the blister packs for divalproex dispensed October 4, 2015, October 29, 2015 and November 24, 2015, were each misbranded with an incorrect expiration date. The expiration date for repackaged bubble cards should either be one year from the date of fill or the actual expiration date of the stock bottle, whichever is less. For the divalproex dispensed October 4, 2015, the expiration date was December 31, 2017. For the divalproex dispensed October 29, 2015, the expiration date was January 31, 2018. For the divalproex dispensed November 24, 2015, the expiration date was December 31, 2017.

- 73. On or about December 23, 2015, Respondent SCPS Fairfield received a refill request for Ativan 2mg for patient SSm at Creekside. Respondent SCPS Fairfield did not deliver the drug until January 28, 2016. Patient SSm missed one dose of medication as a result.
- 74. On or about February 8, 2016, Respondent SCPS Fairfield received a prescription order for Pristiq for patient AAP. Respondent SCPS Fairfield contacted the prescriber late in the evening at home and made a recommendation to change the prescriber's order from Pristiq to Effexor because the insurance required AAP to have tried and failed Effexor before Pristiq. AAP's patient profile indicated that AAP had already tried and failed Effexor from November 2014 to August 2015.
- 75. On or about May 9, 2013, Respondent SCPS Fairfield dispensed a partial fill for carbamazepine ER 300mg for patient IS because Respondent SCPS Fairfield did not have enough of the product on hand to fill the entire prescription. Respondent SCPS Fairfield failed to deliver the balance of the drug until May 14, 2013, causing patient IS to miss three doses.
- 76. On or about June 5, 2013, Respondent SCPS Fairfield dispensed a partial fill for diazepam 2mg tablets [9 tablets out of 84] for patient RT. Respondent SCPS Fairfield failed to timely order diazepam 2mg tablets from its wholesaler on June 5 or June 6, 2013, which would have arrived before RT ran out of medication. Respondent SCPS Fairfield failed to deliver the balance of the drug until June 10, 2013, causing patient RT to miss five doses.

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1	FIFTEENTH CAUSE FOR DISCIPLINE
2	(Variation from a Prescription
3	Against Respondents SCPS Fairfield and Van Nguyen)
4	83. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
5	Code section 4301, subdivision (j) and/or (o), and/or California Code of Regulations, title 16,
6	section 1716, in that on or about August 15, 2015, as set forth in paragraph 72 above, Respondent
7	SCPS Fairfield dispensed Depakote DR 500mg tablets without authorization from the prescriber.
8	SIXTEENTH CAUSE FOR DISCIPLINE
9	(Misbranded and/or Expired Products
10	Against Respondents SCPS Fairfield and Van Nguyen)
11	84. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
12	Code section 4301, subdivision (j) and/or (o), Health and Safety Code section 111330 and/or
13	111440, Code section 4169, subdivisions (a)(3) and/or (a)(4), and/or 21 U.S.C. § 352, in that, as
14	set forth in paragraph 72 above, they sold, delivered, held or offered for sale dangerous drugs
15	with incorrect expiration dates; blister packs for divalproex dispensed October 4, 2015, October
16	29, 2015, and November 24, 2015, for patient SSa, each bore an incorrect expiration date.
17	SEVENTEENTH CAUSE FOR DISCIPLINE
18	(Failure to Timely Dispense Prescription Drugs
19	Against Respondents SCPS Fairfield and Van Nguyen)
20	85. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
21	Code section 733, subdivision (a), 4301, subdivisions (j) and (o), and/or California Code of
22	Regulations, title 22, section 72353, subdivision (a), and/or 72355, subdivision (a)(1), in that they
23	failed to timely provide Ativan 2mg for patient SSm as set forth in paragraph 73 above.
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1	EIGHTEENTH CAUSE FOR DISCIPLINE
2	(Failure to Consult Appropriate Patient Records
3	Against Respondent SCPS Fairfield)
4	86. Respondent SCPS Fairfield is subject to disciplinary action under Code section
5	4306.5, subdivision (c), in that, as set forth in paragraph 74 above, it failed to review patient
6	AAP's patient profile prior to making a recommendation to change a medication.
7	NINETEENTH CAUSE FOR DISCIPLINE
8	(Failure to Timely Dispense Prescription Drugs
9	Against Respondents SCPS Fairfield and Banerjee)
10	87. Respondents SCPS Fairfield and Banerjee are subject to disciplinary action under
11	Code section 733, subdivision (a), 4301, subdivisions (j) and (o), and/or California Code of
12	Regulations, title 22, section 72353, subdivision (a), and/or 72355, subdivision (a)(1), in that, as
13	set forth in paragraph 75 above, they failed to timely provide carbamazepine to patient IS.
14	TWENTIETH CAUSE FOR DISCIPLINE
15	(Failure to Timely Dispense Prescription Drugs
16	Against Respondents SCPS Fairfield and Banerjee)
17	88. Respondents SCPS Fairfield and Banerjee are subject to disciplinary action under
18	Code section 733, subdivision (a), 4301, subdivisions (j) and (o), and/or California Code of
19	Regulations, title 22, section 72353, subdivision (a), and/or 72355, subdivision (a)(1), in that, as
20	set forth in paragraph 76 above, they failed to timely provide diazepam 2mg tablets to patient RT.
21	TWENTY-FIRST CAUSE FOR DISCIPLINE
22	(Improperly Labeled Prescription Container
23	Against Respondents SCPS Fairfield and Van Nguyen)
24	89. Respondents SCPS Fairfield and Van Nguyen are subject to disciplinary action under
25	Code section 4301, subdivisions (j) and/or (o), and/or Code section 4076(a)(2), in that they failed
26	to properly label prescriptions dispensed to patient GA from January 20, 2015 to March 16, 2016,
27	as set forth in paragraph 77 above.
28	///

1714, subdivision (b) and/or (d), in that, as set forth in paragraph 81 above, on or about January 11, 2016, transporters contracted by Respondent SCPS Fairfield left a 30 gallon bag of medications unattended in the hallway of the lockdown Behavior Health Unit.

#### **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 50619, issued to Senior Care Pharmacy Services Fairfield, Inc.;
- 2. Prohibiting Senior Care Pharmacy Services Fairfield, Inc., from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50619 is placed on probation or until Pharmacy Permit Number PHY 50619 is reinstated if Pharmacy Permit Number PHY 50619 issued to Senior Care Pharmacy Services Fairfield, Inc. is revoked;
- 3. Revoking or suspending Original Pharmacist License Number RPH 45184, issued to Samitendu Banerjee;
- 4. Prohibiting Samitendu Banerjee from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45184 is placed on probation or until Pharmacist License Number RPH 45184 is reinstated if Pharmacist License Number RPH 45184 issued to Samitendu Banerjee is revoked;
- Revoking or suspending Original Pharmacist License Number RPH 66472, issued to
   Van Thao My Nguyen;
- 6. Prohibiting Van Thao My Nguyen from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 66472 is placed on probation or until Pharmacist License Number RPH 66472 is reinstated if Pharmacist License Number RPH 66472 issued to Van Thao My Nguyen is revoked;
- 7. Revoking or suspending Original Pharmacist License Number RPH 73152, issued to Kali Wong;

(SENIOR CARE PHARMACY SERVICES FAIRFIELD INC., et al.) ACCUSATION