CANADA AND	
	Renewal Application
Section 1	
ince your last re	enewal or recent licensure have you: (Please fill in completely)
leen diagnosed	or treated for any mental illness, including alcohol or substance abuse, o
Physical condition Your license? ○ Yes	or treated for any mental illness, including alcohol or substance abuse, o on that would impair your ability to perform the essential functions of arrested or convicted of a felony or misdemeanor in any state?
Physical condition your license? ○ Yes	on that would impair your ability to perform the essential functions of
Physical condition your license? Yes No L. Been charged, Yes No 2. Been the subj pending in any s The California	on that would impair your ability to perform the essential functions of arrested or convicted of a felony or misdemeanor in any state? Upload Supporting Doc. ect of a board citation or an administrative action whether completed or tate? Board of Pharmacy has filed an Accusation in response to a sterile
Physical condition your license? O Yes O No 1. Been charged, O Yes O No 2. Been the subj pending in any s The California	on that would impair your ability to perform the essential functions of arrested or convicted of a felony or misdemeanor in any state? Upload Supporting Doc. ect of a board citation or an administrative action whether completed or tate?

' Board of Pharmacy

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Page 2 of 4
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○ Yes ● No	Upload Supporting Doc.
If you marked YES to any of the numbered of information. If you are unsure of an answer possible.	questions (1-3) above, include the following please type unknown.Please be as complete as
<b>Board Administrative Action:</b> State:	
California	
Date:	J
10/10/2016	
Case#:	
5810	
Criminal Action: State: Date:	
Case#:	
County:	
Court:	
Section 2: 1. Are you the subject of a court order for th O Yes  No	ne support of a child?
2. IF you marked YES to the question above, O Yes O No	are you in compliance with the court order?

# Section 3:

**Continuing Education Certification:** 

Calculation=1.25 hours per month Date Range= 11/01/2015 – 10/31/2017

1. Pharmacists are exempt from completing CE for the first 2 years after graduation. Did you graduate within the last 2 years?

🔾 Yes 🖲 No

2. If you answered No to CE question 1 above, have you completed all YOUR required number of Continuing Education hours, including 1 hour in an approved NV law program if living or practicing in Nevada? (If you are a pharmacist practicing out-of-state and are currently in compliance with that state's continuing education requirements please select Yes.)

 ${\small \textcircled{\bullet}} \, {\rm Yes} \, \bigcirc \, {\rm No} \,$ 

# Section 4:

Though it is NOT required to have, SB21 required the Board to ask if you have a Nevada State Business license and if you do, please provide the number

NON-DISCIPLINARY STATE-MANDATED QUESTIONS:

1. Though it is **NOT** required to have, SB21 requires the Board to ask if you have a Nevada State Business license and if you do, please provide the

Leave blank if non-applicable.

2. Have you ever served in the military, either active, reserve or retired?

⊖ Yes ● No

State:

Military Branch:	J
Dates of Service:	J
From Date	]
To Date	

# Section 5:

It is a violation of Nevada law to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct. I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

✓ Yes, I Agree

Type your First Name and Last Name to Agree

Mimi Clayton

Save Changes

Generate License

https://nvbop.com/RenewalApplication.aspx

December 5, 2017



Nevada State Board of Pharmacy 431 W. Plumb Lane Reno Nevada 89509

Re: Mimi N. Clayton Pharmacy License No.: 19086

Dear Board of Pharmacy:

I am writing to notify you that, on November 29, 2017, the Board of Pharmacy, Department of Consumer Affairs of the State of California approved a Stipulated Settlement and Disciplinary Order ("Order") with respect to my California license (No. RHP 46784). A copy of the Order is included with this correspondence.

Pursuant to the Order, my California license is in probationary status for five (5) years. This is the result of a medication error made by an employee under my supervision. A copy of the Accusation is included with this correspondence. Among other things, it was my responsibility to immediately retrieve or provide to the California Board Inspector the employer's quality assurance policy and procedure, and quality assurance reports for all affected patients; to ensure all patients who received the wrong dose of the medication were identified within two (2) business days from the date the medication error was discovered; and to conduct an investigation in compliance with the Board's standards.

I take pride in my work and have a full appreciation for the impact it has on patients and others. This has been a very difficult situation for me, from which I have grown both personally and professionally. I view this as an opportunity to advance my knowledge, skills and service and am fully committed to fulfilling the terms of probation with respect to my California license.

In fact, one of the terms of my probation requires me to enroll in a course in ethics pharmacy law and compounding within 60 days of November 29. I enrolled and completed the course, which is endorsed by the California Board of Pharmacy, on only the third day of my probation (December 2). And, because I am committed to adhering to the highest quality of standards, I am voluntarily exploring advanced ethics courses.

Another term of probation requires me to provide at least 20 hours of community service per year during each year of probation. I am to submit to the California Board of Pharmacy, for its approval, a community service program within 60 days of November 29. Within less than seven (7) days, I have identified a program and had preliminary discussions with the organization regarding my providing community service; I have also provided preliminary notice to the California Board of Pharmacy. I have a follow-up meeting with the organization on December

15 and, will then – within approximately 15 days of November 29 – submit the community service plan to the California Board of Pharmacy for approval.

I share these examples as a demonstration of my commitment to not only fulfilling the terms of probation, but to illustrate my commitment to the profession and its standards.

I pride myself as being an honest, professional, and hard-working pharmacist who takes initiative. I have earned trust and respect from colleagues over the years. For the Board's reference, I have included several letters from current and past colleagues, which speak to my professional character.

I hope this communication with the Board is received as it was intended – as a demonstration of my transparency, genuine intent to meet the expectations of my license(s), and my ongoing efforts to grow professionally.

Please feel free to contact me with any questions.

Sincerely,

Mimi C

Mimi N. Clayton License No.: 19086

Enclosures: Stipulated Settlement and Disciplinary Order Accusation Letters of Reference (professional)

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

In the Matter of the Accusation Against:

MIMI N. CLAYTON 18300 Avenue 296 Exeter, CA 93221 Case No. 5810

OAH No. 2017010178

Pharmacist License No. RPH 46784

Respondent.

#### DECISION AND ORDER

The attached Stipulated Settlement 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 29, 2017.

It is so ORDERED on October 30, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1	XAVIER BECERRA	
2	Attorney General of California KENT D. HARRIS	
3	Supervising Deputy Attorney General DAVID E. BRICE	
4	Deputy Attorney General State Bar No. 269443	
5	1300 I Street, Suite 125 P.O. Box 944255	
6	Sacramento, CA 94244-2550	
	Telephone: (916) 324-8010 Facsimile: (916) 327-8643	
. 7	E-mail: David.Brice@doj.ca.gov Attorneys for Complainant	
8	BEFOR	ETHE
9		PHARMACY
10	STATE OF C	ALIFORNIA
11		]_
12	In the Matter of the Accusation Against:	Case No. 5810
13	MIMI N. CLAYTON 18300 Avenue 296	OAH No. 2017010178
14	Exeter, CA 93221	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER
15	Pharmacist License No. RPH 46784	DISCH LINART ORDER
16	Respondent.	
17		
18	IT IS HEREBY STIPULATED AND AGR	EED by and between the parties to the above-
19	entitled proceedings that the following matters ar	
20	PAR'	TIES
21	1. Virginia Herold (Complainant) is the	Executive Officer of the Board of Pharmacy
22	(Board). She brought this action solely in her off	
23	Xavier Becerra, Attorney General of the State of	
24	General.	
25	2. Mimi N. Clayton (Respondent) is rep	resented in this proceeding by attorney Rachele
26	Berglund, whose address is: Herr Pedersen & Be	
27	California, 93291.	,,,
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3. On or about October 15, 1993, the Board issued Pharmacist License No. RPH 46784 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 5810, and will expire on April 30, 2019, unless renewed.

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#### JURISDICTION

4. Accusation No. 5810 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 27, 2016. Respondent timely filed her Notice of Defense contesting the Accusation.

9 5. A copy of Accusation No. 5810 is attached as exhibit A and incorporated herein by
10 reference.

### ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the
charges and allegations in Accusation No. 5810. Respondent has also carefully read, fully
discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
Order.

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

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

### **CULPABILITY**

9. Respondent admits the truth of each and every charge and allegation in Accusation
No. 5810.

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

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#### **CONTINGENCY**

This stipulation shall be subject to approval by the Board of Pharmacy. Respondent 2 11. understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may 3 communicate directly with the Board regarding this stipulation and settlement, without notice to 4 or participation by Respondent or her counsel. By signing the stipulation, Respondent 5 understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation 6 prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation 7 as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or 8 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, 9 and the Board shall not be disqualified from further action by having considered this matter. 10

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

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

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

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#### **DISCIPLINARY ORDER**

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IT IS HEREBY ORDERED that Pharmacist License No. RPH 46784 issued to Respondent
Mimi N. Clayton is revoked. However, the revocation is stayed and Respondent is placed on
probation for five (5) years on the following terms and conditions.

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# 1. Obey All Laws

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1	1. Obey All Laws						
2	Respondent shall obey all state and federal laws and regulations.						
3	Respondent shall report any of the following occurrences to the board, in writing, within						
4	seventy-two (72) hours of such occurrence:						
5	• an arrest or issuance of a criminal complaint for violation of any provision of the						
6	Pharmacy Law, state and federal food and drug laws, or state and federal controlled						
7	substances laws						
8	• a plea of guilty or nolo contendere in any state or federal criminal proceeding to any						
9	criminal complaint, information or indictment	3					
10	• a conviction of any crime						
11	• discipline, citation, or other administrative action filed by any state or federal agency						
12	which involves respondent's Pharmacist License or which is related to the practice of						
13	pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging						
14	for any drug, device or controlled substance.						
15	Failure to timely report such occurrence shall be considered a violation of probation.						
16	2. Report to the Board						
17	Respondent shall report to the board quarterly, on a schedule as directed by the board or its						
18	designee. The report shall be made either in person or in writing, as directed. Among other						
19	requirements, respondent shall state in each report under penalty of perjury whether there has						
20	been compliance with all the terms and conditions of probation. Failure to submit timely reports	39					
21	in a form as directed shall be considered a violation of probation. Any period(s) of delinquency						
22	in submission of reports as directed may be added to the total period of probation. Moreover, if						
23	the final probation report is not made as directed, probation shall be automatically extended until						
24	such time as the final report is made and accepted by the board.						
25	3. Interview with the Board	1					
26	Upon receipt of reasonable prior notice, respondent shall appear in person for interviews						
27	with the board or its designee, at such intervals and locations as are determined by the board or its						
28	designee. Failure to appear for any scheduled interview without prior notification to board staff,						

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or failure to appear for two (2) or more scheduled interviews with the board or its designee during
 the period of probation, shall be considered a violation of probation.

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# 4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's
monitoring and investigation of respondent's compliance with the terms and conditions of her
probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

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

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#### 6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective
employers of the decision in case number 5810 and the terms, conditions and restrictions imposed
on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5810, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service,
respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity
licensed by the board of the terms and conditions of the decision in case number 5810 in advance
of the respondent commencing work at each licensed entity. A record of this notification must be
provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
(15) days of respondent undertaking any new employment by or through a pharmacy employment
service, respondent shall cause her direct supervisor with the pharmacy employment service to

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report to the board in writing acknowledging that she has read the decision in case number 5810 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, Supervision of Compounding, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the 13 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board, 14 supervise any compounding practice, nor serve as a consultant unless otherwise specified in this 15 order. Assumption of any such unauthorized supervision responsibilities shall be considered a 16 violation of probation. After respondent completes two (2) years of probation, the board or its 17 designee, in its discretion and without the need for respondent to petition the board, may lift the 18 19 prohibition on supervision of compounding practice as deemed appropriate; this does not 20 preclude respondent from exercising any right of petition that exists under California law.

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# 8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$11,194.50. Respondent shall make said payments according to a payment plan approved by the board.

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

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The filing of bankruptcy by respondent shall not relieve respondent of her responsibility to reimburse the board its costs of investigation and prosecution.

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# 9. Probation Monitoring Costs

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

10. Status of License

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

12 If respondent's license expires or is cancelled by operation of law or otherwise at any time 13 during the period of probation, including any extensions thereof due to tolling or otherwise, upon 14 renewal or reapplication respondent's license shall be subject to all terms and conditions of this 15 probation not previously satisfied.

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# 11. License Surrender While on Probation/Suspension

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

Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to
the board within ten (10) days of notification by the board that the surrender is accepted.

Respondent may not reapply for any license from the board for three (3) years from the effective
date of the surrender. Respondent shall meet all requirements applicable to the license sought as

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of the date the application for that license is submitted to the board, including any outstanding costs.

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12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of
employment. Said notification shall include the reasons for leaving, the address of the new
employer, the name of the supervisor and owner, and the work schedule if known. Respondent
shall further notify the board in writing within ten (10) days of a change in name, residence
address, mailing address, or phone number.

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

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# 13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of forty (40) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease
practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California,
respondent must notify the board in writing within ten (10) days of the cessation of practice, and
must further notify the board in writing within ten (10) days of the resumption of practice. Any
failure to provide such notification(s) shall be considered a violation of probation.

lt is a violation of probation for respondent's probation to remain tolled pursuant to the
provisions of this condition for a total period, counting consecutive and non-consecutive months,
exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least forty (40) hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar

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month during which respondent is practicing as a pharmacist for at least forty (40) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

# 14. Violation of Probation

5 If a respondent has not complied with any term or condition of probation, the board shall 6 have continuing jurisdiction over respondent, and probation shall automatically be extended, until 7 all terms and conditions have been satisfied or the board has taken other action as deemed 8 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and 9 to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice
and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
a petition to revoke probation or an accusation is filed against respondent during probation, the
board shall have continuing jurisdiction and the period of probation shall be automatically
extended until the petition to revoke probation or accusation is heard and decided.

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# 15. Completion of Probation

18 Upon written notice by the board or its designee indicating successful completion of19 probation, respondent's license will be fully restored.

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# 16. Community Service Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the 21 board or its designee, for prior approval, a community service program in which respondent shall 22 provide free health-care related services on a regular basis to a community or charitable facility or 23 agency for at least 20 hours per year during each year of probation. Within thirty (30) days of 24 board approval thereof, respondent shall submit documentation to the board demonstrating 25 commencement of the community service program. A record of this notification must be provided 26 to the board upon request. Respondent shall report on progress with the community service 27 111 28

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program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

### 17. Remedial Education

Within sixty (60) days of the effective date of this decision, respondent shall submit to the 4 board or its designee, for prior approval, an appropriate program of remedial education related to 5 compounding, pharmacy law, and managing/supervising a pharmacy. The program of remedial 6 education shall consist of at least ten (10) hours during each year of the period of probation. 7 which shall be completed at respondent's own expense. At least five (5) of these ten (10) units 8 shall be completed by attending "in person" C.E. All remedial education shall be in addition to, 9 and shall not be credited toward, continuing education (CE) courses used for license renewal 10 purposes. 11

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

Following the completion of each course, the board or its designee may require the respondent, at her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

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## 18. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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#### Ethics Course 19.

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Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll 2 in a course in ethlos in pharmacy law and compounding, at respondent's expense, approved in 3 advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

## ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 9 discussed it with my attorney, Rachele Berglund. I understand the stipulation and the effect it 10 will have on my Pharmaoist License. I enter into this Stipulated Settlement and Disciplinary 11 Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order 12 of the Board of Pharmacy. 13 14

DATED: 9-25-

MIMI N. CLA Respondent

I have read and fully discussed with Respondent Mimi N. Clayton the terms and conditions 16 and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve 17 18 its form and content. 19 DATED: -25-1

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RACHELE BERGLUND Attorney for Respondent

#### ENDORSEMENT

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

Dated: 9 25 20 VA

Respectfully submitted,

XAVIER BECERRA Attorney General of California KENT D. HARRIS Supervising Deputy Attorney General

DAVID E. BRICE Deputy Attorney General Attorneys for Complainant

12 SA2016101615 13 12825606.doox

# Exhibit A

Accusation No. 5810

Н						
1	Attorney General of California	81 -				
3	Supervising Deputy Attorney General					
4	Deputy Attorney General					
	1300 I Street, Suite 125					
5	Sacramento, CA 94244-2550					
6	Facsimile: (916) 327-8643					
7						
8	BOARD OF PHARMACY					
9	9 DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA					
10	0					
11	1       In the Matter of the Accusation Against:       Case No. 5810					
12	2 MIMI N. CLAYTON 18300 Avenue 296	e				
13	3 Exeter, CA 93221 A C C U S A T I O N					
14	4 Pharmacist License No. RPH 46784					
15	5 Respondent.					
16	6					
17	7 Complainant alleges:					
18	8 PARTIES					
19	9 1. Virginia Herold ("Complainant") brings this Accusation solely in her	official capacity				
20	as the Executive Officer of the Board of Pharmacy ("Board"), Department of Co	nsumer Affairs.				
21	2. On or about October 15, 1993, the Board issued Pharmacist License	Number RPH				
22	46784 to Mimi N. Clayton ("Respondent"). On or about January 31, 2015, Resp	ondent became				
23	the pharmacist-in-charge of Emanuel Medical Center ("EMC") located in Turloc	k, California.				
24	24 The pharmacist license was in full force and effect at all times relevant to the cha	urges brought				
25	herein and will expire on April 30, 2017, unless renewed.					
26	26 ///					
27	27   ///					
28	28 ///					
	1					
	(MIMI N. CLAYT	ON) ACCUSATION				

1	JURISDICTION
2	3. This Accusation is brought before the Board under the authority of the following
3	laws. All section references are to the Business and Professions Code ("Code") unless otherwise
4	indicated.
5	4. Code section 4300 states, in pertinent part:
6	(a) Every license issued may be suspended or revoked.
7 8	(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
9	(1) Suspending judgment.
10	(2) Placing him or her upon probation.
11	(3) Suspending his or her right to practice for a period not exceeding one
12	year.
13	<ul><li>(4) Revoking his or her license.</li><li>(5) Taking any other extian in relation to disciplining him on her exting</li></ul>
14	(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper
15	5. Code section 4300.1 states:
16	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
17	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
18	investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.
19	a decision suspending of revoking the neense.
20	STATUTORY AND REGULATORY PROVISIONS
21	6. Code section 4301 states, in pertinent part:
22	The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or
23	misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
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25	(c) Gross negligence.
26	
27	(o) Violating or attempting to violate, directly or indirectly, or assisting in
28	or abetting the violation of or conspiring to violate any provision or term of this
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	(MIMI N. CLAYTON) ACCUSATION

chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or 1 federal regulatory agency . . . . 2 Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be 7. 3 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining 4 to the practice of pharmacy." 5 Title 16, California Code of Regulations ("CCR"), section 1711 states, in pertinent 8. 6 7 part: (a) Each pharmacy shall establish or participate in an established quality 8 assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of 9 pharmacy service and prevent errors. 10 (b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in 11 Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent 12 or any variation allowed by law. 13 (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately 14 retrievable form. 15 (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible: 16 17 (A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the 18 error. (B) Communicate to the prescriber the fact that a medication error has 19 occurred. 20 21 (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, 22 or if the medication error resulted in a clinically significant delay in therapy. 23 24 (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication 25 errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication 26 error is discovered. All medication errors discovered shall be subject to a quality 27 assurance review. ///28 3 (MIMI N. CLAYTON) ACCUSATION

1	(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative
2	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
3	quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
4	1. the date, location, and participants in the quality assurance review;
5	2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision
7	(c); 3. the findings and determinations generated by the quality assurance review; and,
8	
9	4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.
10 11	The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.
12	(f) The record of the quality assurance review, as provided in subdivision
13	(e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created
14	9. Title 16, CCR, section 1735.2 states, in pertinent part:
15	···· · ·
16	(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
17 18	(1) Active ingredients to be used.
H	(2) Equipment to be used.
19	(3) Expiration dating requirements.
20	(4) Inactive ingredients to be used.
21	(5) Process and/or procedure used to prepare the drug.
22	(6) Quality reviews required at each step in preparation of the drug.
23 24	(7) Post-compounding process or procedures required, if any
25	COST RECOVERY
26	10. Code section 125.3 provides, in pertinent part, that a Board may request the
27	administrative law judge to direct a licentiate found to have committed a violation or violations of
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the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
 enforcement of the case.

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#### DRUG CLASSIFICATIONS

11. "Vancocin" is the brand name for vancomycin, an antibiotic. Vancocin is a dangerous drug pursuant to Code section 4022.

#### STATEMENT OF FACTS

12. On or about March 9, 2015, Respondent contacted Board Inspector D. P. and 7 informed her that L. L., a staff pharmacist at EMC, had made a medication error on March 8, 8 2015. Respondent reported that L. L. had prepared vancomycin IV bags with a medication dose 9 less than the labeled dose. Respondent asked the inspector if the medication error needed to be 10 reported to the Board. The inspector told Respondent that the Board's first concern was the 11 determination of patient care issues related to the medication error; the Board's second concern 12 was that the medication error was appropriately investigated per Title 16, CCR, section 1711. 13 13. On or about March 10, 2015, Respondent called the inspector and told her that the 14 medication error had caused the death of a patient (Respondent informed the inspector later that 15 the sub-therapeutic dose of vancomycin was not a factor in the patient's death). Respondent also 16 stated that L. L. had been placed on administrative leave because she admitted she had not 17 checked the strength of the vancomycin stock bottle, but had just verified it was the right drug, 18 14. That same day (March 10, 2015), the inspector received various emails from L. L., 19 which she had sent to Respondent, including an email dated March 8, 2015. L. L. stated in the 20 email that she had discovered her medication error that day. L. L. explained that she had used a 21 stock vial containing 5 gm of vancomycin instead of 10 gm of vancomycin and that the 22 compounded vancomycin IV bags had contained one-half of the labeled strength of the drug. 23 L. L. found that 51 vancomycin IV bags had been prepared incorrectly on March 6 and 7, 2015, 24 and that 29 doses had been administered to patients. Once L. L. discovered the error, she 25 immediately pulled all of the incorrect doses from all areas of EMC. L. L. identified 14 patients, 26 who might have received the reduced doses of vancomycin, and contacted almost all of the 27 patients' physicians. On or about March 8, 2015, Respondent sent L. L. an email asking her to 28

see if patients needed to be notified of the medication error, and instructing her to review the current policy. Respondent also instructed L. L. to create a new storage bin for the vancomycin 5 gm dose and to contact "Thao" (pharmacist T. L., EMC's Clinical Pharmacy Coordinator) to create a new compound worksheet.

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15. On or about March 9, 2015, L. L. sent Respondent an email, stating that she had contacted all of the physicians whose patients may have received a reduced dose of vancomycin and that the kinetic pharmacist was following all of the patients who were currently on vancomycin. Respondent sent L. L. an email stating that she ("Respondent") would speak to the patients. Respondent again instructed L. L. to find the policy on disclosing medication errors to patients. L. L. sent Respondent a reply, stating that since she was working as a staff pharmacist, T. L. would be doing the "Verge" reporting (Verge was the in-house name for the medication error/quality assurance reports).

13 16. On or about March 11, 2015, the inspector had several telephone discussions with
14 L. L. L. L. told the inspector EMC had discovered that other pharmacists had also made the same
15 medication error; i.e., they had used a 5 gm stock bottle rather than a 10 gm stock bottle of
16 vancomycin. L. L. stated that pharmacy staff had not been informed EMC had received a
17 vancomycin 5 gm stock bottle when a vancomycin 10 gm stock bottle had been used previously,
18 which contributed to the medication error.

19 17. On or about March 12, 2015, the inspector called EMC and spoke with T. L. T. L.
20 told the inspector she was responsible for investigating and documenting medication errors and
21 that for some unknown reason, she was being excluded from the vancomycin investigation.

18. On or about March 13, 2015, the inspector went to EMC to conduct an inspection of the pharmacy. The inspector met with T. L. and obtained copies of T. L.'s email communications with Respondent and EMC's medication error policies and procedures. T. L. told the inspector that as Clinical Coordinator, she had always been in charge of investigations of medication errors and of entering the errors into EMC's "Verge" system. T. L. stated that she had come a long way in the investigation of the vancomycin error before Respondent told her to stop. The inspector reviewed the emails and found as follows:

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a. T. L. told Respondent in an email dated March 9, 2015, that she was completing the
Verge incident reports and investigation of patients affected by the vancomycin medication error.
Respondent sent T. L. a reply, asking T. L. to keep her in the loop of any updates.

b. On March 11, 2015, T. L. sent Respondent an email containing a summary of her 4 vancomycin medication error findings, including the following: 1) 25 vials of vancomycin 5 gm 5 had been delivered to EMC on February 26, 2015, and 15 vials had been delivered on March 9, 6 2015; 2) T. L. identified the 2 lot numbers involved; 3) potentially 130 bags of IV vancomycin 7 were compounded incorrectly, starting on February 26, 2015; 4) it was unknown how many bags 8 9 had reached the patients because the pharmacy department did not track which lot was dispensed to which patients; and 5) T. L. ran a Meditech report, which showed that a total of approximately 10 87 patients received IV vancomycin between February 19, 2015 and March 8, 2015. 11

c. On March 12, 2015, Respondent sent T. L. an email, stating that she (T. L.) was
"independently doing this (the investigation)" without any instructions from Respondent and that
Respondent needed her to stop.

19. During the inspection, the inspector went to the pharmacy and observed Respondent 15 and pharmacy technician A. W. digging through a pharmacy waste bin. About 15 empty glass 16 vials were laid out on the floor. The inspector asked Respondent and A. W. what they were 17 doing. A. W. told the inspector they were looking at empty vancomycin bottles to try and 18 determine all of the vancomycin lot numbers that were involved in the medication error. The 19 inspector asked Respondent why they were just now looking to identify the lot numbers of the 20 vancomycin. Respondent stated that they just found out more patients received inaccurate doses 21 of the drug. The inspector asked Respondent who was in charge of the investigation. Respondent 22 stated L. L. The inspector asked Respondent how that would work since L. L. was on 23 administrative leave. Respondent claimed that A. W. was actually in charge, then admitted that 24 she, herself, was in charge of the investigation. The inspector asked A. W. if there was a master 25 formula or compounding log worksheet for 5 gm vancomycin in the pharmacy prior to the time 26 the vancomycin 5 gm was received. A. W. said no. 27

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1	20. The inspector asked Respondent if she had written quality assurance reports on all of						
2	the affected patients. Respondent stated that medication error information on 19 patients had						
3	been input into the Verge program, but admitted that quality assurance reports were not prepared						
4	for 68 patients. The inspector asked Respondent to show her the medication error forms.						
5	Respondent stated that she did not have access to the Verge program, but would have the forms						
6	printed. Respondent left to obtain copies of the forms. Later, A. W. provided the inspector with						
7	only one of the 19 medication error forms. The inspector asked Respondent for a copy of EMC's						
8	medication error policy. Respondent began checking her computer. About 15 minutes later,						
9	Respondent found the policy and provided a copy to the inspector.						
10	FIRST CAUSE FOR DISCIPLINE						
11	(Failure to Comply with Quality Assurance Program)						
12	21. Respondent is subject to disciplinary action for unprofessional conduct pursuant to						
13	Code section 4301, subdivision (o), in that Respondent failed to comply with Title 16, CCR,						
14	section 1711, as follows:						
15	a. On or about March 13, 2015, Respondent failed to immediately retrieve or provide to						
16	Board Inspector D. P. EMC pharmacy's quality assurance policy and procedure.						
17	b. Respondent provided Board Inspector D. P. with a copy of only one quality assurance						
18	report relating to the pharmacy's vancomycin medication error when, in fact, there were a total of						
1 <b>9</b>	approximately 87 patients who could have been affected by the medication error.						
20	SECOND CAUSE FOR DISCIPLINE						
21	(Gross Negligence)						
22	22. Respondent is subject to disciplinary action for unprofessional conduct pursuant to						
23	Code section 4301, subdivision (b), in that Respondent committed acts or omissions constituting						
24	gross negligence, as follows:						
25	a. Respondent failed to identify the patients who received the wrong dose of the						
26	vancomycin within 2 business days from the date the medication error was discovered.						
27	///						
28	///						

b. Respondent made an assessment that no patient had been harmed by the pharmacy's vancomycin medication error prior to identifying all of the patients who were possibly affected by the medication error.

c. Respondent failed to concentrate on patient care issues during the initial investigation of the vancomycin medication error and instead, focused the investigation on assigning blame to the person(s) involved in the error.

d. Respondent failed to follow EMC's Administrative Policy No. 07-09-01 to promote a
non-punitive process in the investigation of the vancomycin medication error in that Respondent
initiated punitive action against L. L., who discovered and reported the medication error.

e. Respondent failed to utilize all resources available to her to investigate and determine
the cause of the vancomycin medication error, to identify the patients who could possibly have
been affected by the medication error, and to provide an appropriate response to the medication
error as part of a mission to improve the quality of EMC's pharmacy service and prevent errors.

f. Respondent failed to identify the lot numbers of the vancomycin 5 gm vials that were
obtained and used in error in the preparation of the compounded vancomycin IV bags within 5
days from the discovery of the vancomycin medication error.

g. Respondent failed to review the pharmacy's compounding records to determine the
actual number of vancomycin preparations that were compounded in error.

h. Respondent failed to immediately retrieve or provide to Board Inspector D. P. the
pharmacy's quality assurance policy and procedure, as set forth in subparagraph 21 (a) above.

i. Respondent failed to immediately identify herself to Board Inspector D. P. as the
person in charge of EMC's investigation of the vancomycin medication error.

j, Respondent failed to provide accurate medication error event data to Board Inspector
D. P.

k. Respondent subverted, or attempted to subvert, a thorough investigation of the
vancomycin medication error.

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1	THIRD CAUSE FOR DISCIPLINE						
2	(Failure to Prepare Master Formulas Prior to Compounding)						
3	23. Respondent is subject to disciplinary action for unprofessional conduct pursuant to						
4	Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, section 1735.2,						
5	subdivision (d), as follows: Respondent failed to prepare a written master formula for the use of						
6	the vancomycin 5 gm that was used in the compounding of the vancomycin IV bags, which						
7	contributed to the pharmacy's vancomycin medication error.						
8	PRAYER						
9	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,						
10	and that following the hearing, the Board of Pharmacy issue a decision:						
11	1. Revoking or suspending Pharmacist License Number RPH 46784, issued to Mimi N.						
12	Clayton;						
13	2. Ordering Mimi N. Clayton to pay the Board of Pharmacy the reasonable costs of the						
14	investigation and enforcement of this case, pursuant to Business and Professions Code section						
15	125.3; and						
16 <sup>°</sup>	3. Taking such other and further action as deemed necessary and proper.						
17	District I						
18	DATED: 10/10/16 Vegnisterdet						
19 20	Executive Officer Board of Pharmacy Department of Consumer Affairs State of California						
21	Complainant						
22	SA2016101615						
23	12423535.docx						
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	10 (MIMI N. CLAYTON) ACCUSATION						

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......DO NOT FOLD OR STAPLE ABOVE THIS LINE......

# Nevada State Board of Pharmacy - Renewal Application - PHARMACIST

431 W Plumb Lane • Reno, NV 89509 • nvbop.com

For the period of November 1, 2017 to October 31, 2019 Money Order ONLY (NO BUSINESS or PERSONAL CHECKS, NO CASH) \$180.00 (postmarked on or before 10/31/2017) OR \$320.00 (postmarked after 10/31/2017)

#### LICENSE: 16985 Kristen Rae Gorski COLFAX HWY,

Grass Valley, CA 95945

Please make any changes to name or address next to the old information

		2					
RENEW BY MAIL 1. Complete ALL sections on this for 2. Sign and date this form 3. Send MO with this form (do NO 4. Mail original form/payment to ad 5. NO COPIES 6. NO SIGNATURE STAMPS ACC	orm I staple) Idress above	<or></or>		com ructions on the pag fully completed you k to your certific	ctions on the page Ily completed your license renewal, you will receive to your certificate. We no longer mail certificates		
Section 1: Since your last renewal or recent licensure have you: (Please fill in completely) Yes No							No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?							
Board Administrative Action:	State		Date:		Cas	se #:	
	CA	01 131	0/2017	5536			
Criminal State	Date:	1	Case #:	County		Cour	t -
Action: /	1						
Section 2: Are you the subject of a court order for IF you marked YES to the question at	or the support of a bove. are you in a	child?	e with the court order	?	🗆 🧯	No S	
Section 3: (Fees apply to e	ither status)	(see co	lored insert for de	etails)			
By signing below, you certify that you have completed <u>ALL</u> required CE Hours due for the 17/19 Renewal period. ( <i>Dated from Nov. 1, 15 – Oct. 31, 17</i> , 1.25hrs per mo.). The exemption period is 2yrs after graduation <u>only</u> . <u>OR you may check the box for Inactive if you did NOT complete CE</u> You cannot renew online if you change to Inactive Inactive - D By checking this box you certify that you are <u>NOT</u> practicing in NV and do not wish to comply with the CE requirements of NV and would like your license changed to <u>inactive</u> status. Before re-activating your license it will be necessary to submit an application and to become compliant with current CE requirements (NAC 639.219). See reverse of insert for more information.							
Section 4: NON-DISCIPLINARY STATE-MANDATED QUESTIONS  1. Though it is <u>NOT</u> required to have, SB21 requires the Board to ask if you have a Nevada State Business license and if you do, please provide the #:Leave blank if non-applicable #:							
2. Have you ever served in the military, either active, reserve or retired? Yes Not Branch:							
Military Occupation/Specialty:	a construction of the second		Dates	of Service:			-
Section 5: It is a violation of Nevada law to faisify this application and sanctions will be imposed for misrepresentation. Thereby certify that Thave read this application. Tcertify that all statements made are true and correct. Tattest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate Injection practices. I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to ballave, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency. Original Signature:							

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

In the Matter of the Accusation Against:

SIERRA COMPOUNDING PHARMACY ROBERT HILBERT SEIWERT, OWNER ANGALINE MARIE WUSSTIG, PIC 1101 Maidu Drive, #200 Auburn, CA 95603 Pharmacy Permit No. PHY 49228,

ANGALINE MARIE WUSSTIG 3813 Rogue River Circle West Sacramento, CA 95691 Pharmacist License No. RPH 69944,

and

KRISTEN R. GORSKI ; Colfax Highway Grass Valley, CA 95945 Pharmacist License No. RPH 67057

Respondents.

Case No. 5534

OAH No. 2016061130

## STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

#### **DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of

Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2017.

It is so ORDERED on January 30, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

l		1	
1	KAMALA D. HARRIS Attorney General of California		
2	JANICE K. LACHMAN		
3	Supervising Deputy Attorney General ANAHITA S. CRAWFORD		
4	Deputy Attorney General State Bar No. 209545		
5	1300 I Street, Suite 125 P.O. Box 944255		
6	Sacramento, CA 94244-2550 Telephone: (916) 322-8311	N	
7	Facsimile: (916) 327-8643		
	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 5534	
12	SIERRA COMPOUNDING PHARMACY ROBERT HILBERT SEIWERT, OWNER	OAH No. 2016061130	
13	ANGALINE MARIE WUSSTIG, PIC	STIPULATED SETTLEMENT AND	
14	1101 Maidu Drive, #200 Auburn, CA 95603	DISCIPLINARY ORDER	
15	Pharmacy Permit No. PHY 49228,	ж. Э	
16	ANGALINE MARIE WUSSTIG		
17	3813 Rogue River Circle West Sacramento, CA 95691		
18	Pharmacist License No. RPH 69944,		
19	and		
20	KRISTEN R. GORSKI		
21	Colfax Highway Grass Valley, CA 95945		
22	Pharmacist License No. RPH 67057	12 1	
23	Respondents.		
24			
25			
26	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
27	entitled proceedings that the following matters are true:		
28	//	* 2	
		1	
	D	STIPULATED SETTLEMENT (5534)	

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STREET DISC

1	PARTIES	
2	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy	
3	(Board). She brought this action solely in her official capacity and is represented in this matter by	
4	Kamala D. Harris, Attorney General of the State of California, by Anahita S. Crawford, Deputy	
5	Attorney General	
6	2. Respondent Kirsten R. Gorski, PIC (Respondent) is represented in this proceeding by	
7	attorney Natalia Mazina of Kelly, Hocket, & Klein, P.C. whose address is: 44 Montgmery Street,	
8	Suite 1500, San Francisco, CA 94104.	
9	3. On or about April 19, 2012, the Board issued Pharmacist License Number RPH	
10	67057 to Kristen R. Gorski ("Respondent Gorski"). The pharmacist license was in full force and	
11	effect at all times relevant to the charges brought herein and will expire on September 30, 2017,	
12	unless renewed.	
13	JURISDICTION	
14	4. Accusation No. 5534 was filed before the Board, and is currently pending against	
15	Respondent. The Accusation and all other statutorily required documents were properly served	
16	on Respondent on May 24, 2016. Respondent timely filed her Notice of Defense contesting the	
17	Accusation.	
18	5. A copy of Accusation No. 5534 is attached as exhibit A and incorporated herein by	
19	reference.	
20	ADVISEMENT AND WAIVERS	
21	6. Respondent has carefully read, fully discussed with counsel, and understands the	
22	charges and allegations in Accusation No. 5534. Respondent has also carefully read, fully	
23	discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary	
24	Order.	
25	7. Respondent is fully aware of her legal rights in this matter, including the right to a	
26	hearing on the charges and allegations in the Accusation; the right to confront and cross-examine	
27	the witnesses against her; the right to present evidence and to testify on her own behalf; the right	
28	to the issuance of subpoenas to compel the attendance of witnesses and the production of	
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	STIPULATED SETTLEMENT (5534)	

1	documents; the right to reconsideration and court review of an adverse decision; and all other	
2	rights accorded by the California Administrative Procedure Act and other applicable laws.	
3	8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and	
4	every right set forth above.	
5	CULPABILITY	1
б	9. Respondent admits the truth of each and every charge and allegation in Accusation	
7	No. 5534.	
8	10. Respondent agrees that her Pharmacist License is subject to discipline and she agrees	
9	to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.	
10	CONTINGENCY	
11	11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent	
12	understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may	
13	communicate directly with the Board regarding this stipulation and settlement, without notice to	
14	or participation by Respondent or her counsel. By signing the stipulation, Respondent	
15	understands and agrees that he may not withdraw her agreement or seek to rescind the stipulation	
16	prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation	
17	as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or	
18	effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,	2
19	and the Board shall not be disqualified from further action by having considered this matter.	
20	12. The parties understand and agree that Portable Document Format (PDF) and facsimile	
21	copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile	
22	signatures thereto, shall have the same force and effect as the originals.	
23	13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an	
24	integrated writing representing the complete, final, and exclusive embodiment of their agreement.	
25	It supersedes any and all prior or contemporaneous agreements, understandings, discussions,	
26	negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary	
27	Order may not be altered, amended, modified, supplemented, or otherwise changed except by a	
28	writing executed by an authorized representative of each of the parties.	
	3	
	STIPULATED SETTLEMENT (5534)	

STIPULATED SETTLEMENT (5534)

1	14. In consideration of the foregoing admissions and stipulations, the parties agree that	
2	the Board may, without further notice or formal proceeding, issue and enter the following	
3	Disciplinary Order:	
4	DISCIPLINARY ORDER	
5	IT IS HEREBY ORDERED that Pharmacist License Number RPH 67057 issued to Kristen	
6	R. Gorski is revoked. However, the revocation is stayed and Respondent is placed on probation	
7	for two (2) years on the following terms and conditions.	
8	1. Obey All Laws	
9	Respondent shall obey all state and federal laws and regulations.	
10	Respondent shall report any of the following occurrences to the board, in writing, within	
11	seventy-two (72) hours of such occurrence:	
12	• an arrest or issuance of a criminal complaint for violation of any provision of the	
13	Pharmacy Law, state and federal food and drug laws, or state and federal controlled	
14	substances laws	
15	• a plea of guilty or nolo contendre in any state or federal criminal proceeding to any	
16	criminal complaint, information or indictment	
17	a conviction of any crime	
18	• discipline, citation, or other administrative action filed by any state or federal agency	
19	which involves respondent's Pharmacist License or which is related to the practice of	
20	pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging	
21	for any drug, device or controlled substance.	
22	Failure to timely report such occurrence shall be considered a violation of probation.	
23	2. Report to the Board	
24	Respondent shall report to the board quarterly, on a schedule as directed by the board or its	
25	designee. The report shall be made either in person or in writing, as directed. Among other	
26	requirements, respondent shall state in each report under penalty of perjury whether there has	
27	been compliance with all the terms and conditions of probation. Failure to submit timely reports	
28	in a form as directed shall be considered a violation of probation. Any period(s) of delinquency	
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in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

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## 3. Interview with the Board

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

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# 4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's
monitoring and investigation of respondent's compliance with the terms and conditions of her
probation. Failure to cooperate shall be considered a violation of probation.

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# 5. Continuing Education

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

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## 6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective
employers of the decision in case number 5534 and the terms, conditions and restrictions imposed
on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5534, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service,
 respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity
 licensed by the board of the terms and conditions of the decision in case number 5534 in advance
 of the respondent commencing work at each licensed entity. A record of this notification must be
 provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
(15) days of respondent undertaking any new employment by or through a pharmacy employment
service, respondent shall cause her direct supervisor with the pharmacy employment service to
report to the board in writing acknowledging that he has read the decision in case number 5534
and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the
pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
nor serve as a consultant unless otherwise specified in this order. Assumption of any such
unauthorized supervision responsibilities shall be considered a violation of probation.

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# Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the
board each and every year of probation. Such costs shall be payable to the board on a schedule as

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directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
 be considered a violation of probation.

9. Status of License

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

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

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# 10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license hertory with the board.

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

25 26 11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of
employment. Said notification shall include the reasons for leaving, the address of the new

employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

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

## 12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be
employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any
month during which this minimum is not met shall toll the period of probation, i.e., the period of
probation shall be extended by one month for each month during which this minimum is not met.
During any such period of tolling of probation, respondent must nonetheless comply with all
terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease
practicing as a pharmacist for a minimum of 40 hours per calendar month in California,
respondent must notify the board in writing within ten (10) days of the cessation of practice, and
must further notify the board in writing within ten (10) days of the resumption of practice. Any
failure to provide such notification(s) shall be considered a violation of probation.

18 It is a violation of probation for respondent's probation to remain tolled pursuant to the
19 provisions of this condition for a total period, counting consecutive and non-consecutive months,
20 exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is
not practicing as a pharmacist for at least 40 hours, as defined by Business and
Professions Code section 4000 et seq . "Resumption of practice" means any calendar
month during which respondent is practicing as a pharmacist for at least 40 hours as a
pharmacist as defined by Business and Professions Code section 4000 et seq.

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## 13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall
have continuing jurisdiction over respondent, and probation shall automatically be extended, until

all terms and conditions have been satisfied or the board has taken other action as deemed
 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
 to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

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# 14. Completion of Probation

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

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# 15. Remedial Education

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding drugs. The program of remedial education shall consist of at least 10 hours, which shall be completed within 30 months at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

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

Following the completion of each course, the board or its designee may require the respondent, at her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination,

this failure shall be considered a violation of probation. Any such examination failure shall ĭ 2 require respondent to take another course approved by the board in the same subject area. 3 ACCEPTANCE I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 4 discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will 5 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order 6 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the 7 Board of Pharmacy. 8 9 DATED; 11.17.2016 10 11 Respondent 12 I have read and fully discussed with Respondent Sierra Compounding Pharmacy; Robert 13 Hilbert Seiwert, Owner, Angaline Marie Wusstig, PIC the terms and conditions and other matters 14 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and 15 content. 16 DATED: Νον 17 2016 ALIA MAZINA 17 KELLY, HOCKEL, & KLEIN P.C. Attorney for Respondent 18 19 2021 22 23 24 25 26 Ħ 27 28 Ħ 10 STIPULATED SETTLEMENT (5534)

1	12 AV				
1	ENDORSEMENT				
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully				
3	submitted for consideration by the Board of Pharmacy.				
4	Dated: //. /7-16 Respectfully submitted,				
5	Kespectruly submitted, KAMALA D. HARRIS				
6	Attorney General of California JANICE K. LACHMAN				
7	Supervising Deputy Attorney General				
8	Ceff.				
9.	ANAHITAS. CRAWFORD				
10	Deputy Attorney General Attorneys for Complainant				
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	STIPULATED SETTLEMENT (5534)				

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# Exhibit A

Accusation No. 5534

KAMALA D. HARRIS Attorney General of California JANICE K. LACHMAN Supervising Deputy Attorney General ANAHITA S. CRAWFORD Deputy Attorney General State Bar No. 209545 1300 I Street, Suite 125 P.O. Box 944255 Sacramento, CA 94244-2550 Telephone: (916) 322-8311 Facsimile: (916) 327-8643 Attorneys for Complainant

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

Case No. 5534

ACCUSATION

In the Matter of the Accusation Against:

SIERRA COMPOUNDING PHARMACY ROBERT HILBERT SEIWERT, OWNER ANGALINE MARIE WUSSTIG, PIC 1101 Maidu Drive, #200 Auburn, CA 95603

Pharmacy Permit No. PHY 49228.

ANGALINE MARIE WUSSTIG 3813 Rogue River Circle West Sacramento, CA 95691

Pharmacist License No. RPH 69944,

and

KRISTEN R. GORSKI Colfax Highway Grass Valley, CA 95945

Pharmacist License No. RPH 67057

Respondents:

Complainant alleges: .

#### PARTIES

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

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2. On or about December 29, 2008, the Board issued Pharmacy Permit Number PHY 49228 to Robert Hilbert Seiwert ("Respondent"), owner of Sierra Compounding Pharmacy. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2016, unless renewed.

3. On or about October 3, 2013, the Board issued Pharmacist License Number RPH 69944 to Angaline Marie Wusstig ("Respondent Wusstig"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.

4. On or about April 19, 2012, the Board issued Pharmacist License Number RPH 67057 to Kristen R. Gorski ("Respondent Gorski"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

### **JURISDICTION**

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

indicated.

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6. Code section 4300.1 states:

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

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. Code section 4300 states, in pertinent part:

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

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

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(1) Suspending judgment.

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(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

#### STATUTORY PROVISIONS

#### Business and Professions Code (Disciplinary Provisions)

9. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct .... Unprofessional conduct shall include, but is not limited to, any of the following:

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

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

10. Code section 4306.5 states, in pertment part:

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

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

(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 . . .

11. Additionally, Code section 4113, subdivision (c), states that "[t]he 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."



12. Section 4013(a) of the Code states:

Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

13. Section 4169 of the Code states:

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

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

# State and Federal Drug Codes (Misbranded Drugs)

14. Health and Safety Code section 111335 states that "[a]ny drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4

(commencing with Section 110290)."

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15. Health and Safety Code section 111400 provides that a drug is misbranded if it is dangerous to "health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

16. Title 21, United States Code, section 352 states, in pertinent part:

A Drug or device shall be deemed to be misbranded --

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost...

Health and Safety Codes (Prohibition on Misbranded Drugs)

17. Health and Safety Code section 111440 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is this branded."

18. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

## **REGULATORY PROVISIONS**

19. California Code of Regulations, title 16, section 1735, subdivision (a):

states in pertinent part:

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

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

(2) Altering the strength of a drug

(3) Combining components or active ingredients

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

20. California Code of Regulations, title 16, section 1735.2 states:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

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(7) Post-compounding process or procedures required, if any.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

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## COST RECOVERY

Code section 125.3 provides, in pertinent part, that a Board may request the 21. administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

## DRUG

"Domperidone" is an anti-dopaminergic drug that acts as an antiemetic and a 10 22. prokinetic agent, and is used to relieve nausea and vomiting and to increase lactation. It is a 11 dangerous drug under Business and Professions Code section 4022. Domperidone is not 12 approved for use in humans in the United States by the Food and Drug Administration. Drug 13 products compounded using domperiodone are subject to the approval requirements of the federal 14 15 Food, Drug and Cosmetic Act.

## FACTUAL BACKGROUND

On and between October 16, 2012 and April 24, 2015, Kristen R. Gorski 23. ("Respondent Gorski") was the pharmacist-in-charge at Sierra Compounding Pharmacy. On or 18 about April 27, 2015, Angaline Marie Wusstig ("Respondent Wusstig") replaced Respondent Gorski as the pharmacist-in-charge.

24. On June 7, 2004, the U.S. Food and Drug Administration ("FDA") issued a talk 21 paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase -22 -23 Milk Production." The paper stated in pertinent part that domperidone is an "unapproved drug," and that it is not approved in the US for human use. It also warned breast-feeding women not to · 24 use the product because of safety concerns, and that FDA field personnel were alerted to be on the lookout for attempts to import domperidone so it could be detained. The talk paper indicated 26 that the FDA issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding. The paper stated, "[t]he letters

violate the Federal Food, Drug, and Cosmetic Act (the Act)<sup>1</sup> because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidonecontaining products, violates the law." Over the next several years, the FDA continued to issue and publish warning letters to laboratories and pharmacies that it identified were distributing and compounding domperidone for human use, in violation of the Act.

25. On March 18, 2011, the FDA issued an import alert for domperidone indicating the agency learned domperidone was being imported as a bulk active pharmaceutical ingredient for pharmacy compounding, which presented a public health risk and violated the Act.

26. On March 12, 2012, the FDA issued a revised import alert for domperidone. This revised import alert stated that "... domperidone is not appropriate for pharmacy compounding use because this bulk active ingredient is not a component of an FDA approved drug, or is a component of a drug that was withdrawn or removed from the market for safety reasons."

27. On or about April 14, 2015, the Board of Pharmacy issued a "subscriber alert" to pharmacies and pharmacists stating, "Domperidone is not FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the Federal Food, Drug, and Cosmetic Act."

28. Respondents did not possess any FDA approval allowing them to receive or dispense domperidone.

29. On or between April 29, 2014 and April 29, 2015, Respondents compounded 5,191 capsules of various strengths of domperidone which were dispensed on over 50 prescriptions. Respondent pharmacy stated that the pharmacy compounded domperidone pursuant to prescriptions and that the drug had been purchased from PCCA.

PCCA on and between August 19, 2014 to April 29, 2015.

<sup>1</sup> 21 U.S.C. § 301 et seq.

## FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment

## or Corresponding Responsibility)

31. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (b), in that Respondents failed to exercise or implement their best professional judgment or corresponding responsibility by compounding and dispensing domperidone, a drug that had not been approved for human use by the FDA and for which the FDA had issued a warning against its use, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

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## SECOND CAUSE FOR DISCIPLINE

# (Failing to Consult Appropriate Records)

32. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (c), in that Respondents failed to consult appropriate FDA records pertaining to the performance of pharmacy functions when they compounded and dispensed domperidone, a drug that had not been approved for human use by the FDA and for which the FDA had issued warnings against its use, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

#### THIRD CAUSE FOR DISCIPLINE

# (Received, Delivered and/or Sold Misbranded Drugs)

33. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating dangerous drugs, in that Respondents received, sold and/or delivered misbranded drugs, as defined by Health and Safety Code sections 111335, 111400, and United States Code, title 21, section 352, subdivision (f) and in violation of Health and Safety Code section 111440 and 111450, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

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### FOURTH CAUSE FOR DISCIPLINE

(Commission of Prohibited Acts)

34. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), in that Respondents violated or attempted to violate provisions of the pharmacy laws and/or of the applicable federal and state laws and regulations governing pharmacy, when Respondent's received, compounded, delivered and/or sold domperidone without FDA approval in violation of section 4169, subdivision (a)(3), and as more fully set forth in paragraphs 24-33, above, which are incorporated herein by reference.

## MATTERS IN AGGRAVATION

35. To determine the degree of discipline to be assessed against Respondents Seiwert and Gorski, if any, Complainant alleges as follows:

Respondent Seiwert/Sierra Compounding Pharmacy

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a. On or about June 30, 2011, the Board issued Citation and Fine No. CI 2010 46937 against Sierra Compounding Pharmacy for violating California Code of Regulations ("CCR"), title 16, section 1761, subdivision (a)/Health and Safety Code section 11170 (no pharmacist shall compound or dispense any prescription which contains any significant error or omission/prohibition of prescribing, etc. controlled substance for self); Health and Safety Code section 11165, subdivision (d) (for each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice); and section 4081, subdivision (a)/section 4105, subdivision (a) (records of dangerous drugs kept open for inspection/retaining records of dangerous drugs and devices on licensed premises; temporary removal; waivers; access to electronically maintained records). The Board ordered Respondent to pay a fine of \$4,500 by July 30, 2011. The citation has been paid in full and is final.

b. On or about March 24, 2014, the Board issued Citation and Fine No. CI 2013 58024 against Sierra Compounding Pharmacy for violating Title 21, Code of Federal Regulations ("CFR"), section 1304.04, subdivisions (h)(1) and (2) (inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy/Schedules III, IV, and V shall be maintained either separately from all other records of

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the pharmacy); Title 21, CFR, section 1301.75, subdivision (b) (controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet); and CCR, title 16, section 1707.5, subdivision (d) (patient-centered labels for prescription drug containers; requirements; pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label). The Board ordered Respondent to pay fines totaling \$1,250 by April 23, 2014. The citation has been paid in full and is final.

**Respondent Gorski** 

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c. On or about March 24, 2014, the Board issued Citation and Fine No. CI 2013 60613 against Respondent Gorski for violating Title 21, CFR, section 1304.04, subdivisions (h)(1) and (2) (inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy/Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy); Title 21, CFR, section 1301.75, subdivision (b) (controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet); and CCR, title 16, section 1707.5, subdivision (d) (patient-centered labels for prescription drug containers; requirements; pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label) The Board ordered Respondent to pay fines totaling \$1,250 by April 23, 2014. The citation has been paid in full and is final.

## <u>PRAYER</u>

WHERBFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit No. PHY 49228, issued to Robert Hilbert. Seiwert, owner of Sierra Compounding Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 69944, issued to Angaline Marie Wusstig;

3. Revoking or suspending Pharmacist License No. RPH 67057, issued to Kristen R. Gorski;

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4. Ordering Robert Hilbert Seiwert, owner of Sierra Compounding Pharmacy, Angaline Marie Wusstig, and Kristen R. Gorski to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

5/4/16 DATED:

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VIRGINIA HEROLD Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant

SA2015104447

(SIERRA COMPOUNDING PHARMACY) ACCUSATION

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Joegbin Clifford Esomoniu , Kngsmill Tenace Dublin, GA 94568 NV Licence 15622 The Nevads Stik Band of Phannag .. Explanation of CP Sand Alminutative Case # 4579 I had started a pharman in Oakland CA in April 2009, with my sister? The Pharmac was called Fruitvale Avenue Pharman Phy 50064. We were located in Fruitvale Avenue in Oakland were located on traitorie Wenne in Oalchard and abred to Alaneda cauto mental health depowtment. We also Filled prescription for would in patients a Mainty in 2010 al some part, of 2011 we started filling for pain patients, We had thought that we were the dayling of our community, but agreently we had also fallen victim to medicine shoppers, al foandsters. After a board inspection, in 2011 the board investigated up for a comple of years, al in 2013 filed an administrative action against our phymac, muself also Refin against our pharman myself al mysister We had stopped filling controlled substa as form a county 340B planning for HIV of Herp C. The administrative mediation went on for two years at in April 2015, I accepted to surrender my licence for a period of three years-P.T.6.

I was allowed to sell the pharman to another opecialty Hiv company, who still opera the pharmany as a DBA in some name lacept that I was negligent in n I accept that I was negligent in supprising rile as P.I.C of the pharma I had learn't all I need to know about diversion al the drug epidemic. I can no longer be folled by any one as four as controlled substance jo i am ready to become a model phannais in the state of Nevada. Since Iloeghy C. Esomonia # 15622 10.30.2017. NB. Case has been emialed +> Pherman Epherman order.

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

In the Matter of the Second Amended Accusation Against:

#### FRUITVALE AVENUE PHARMACY INC. 2693 Fruitvale Avenue Oakland, CA 94601

Pharmacy License No. PHY 50064,

IJEOMA NWAYIOCHA ESOMONU FRUITVALE AVENUE PHARMACY INC. 16 Minaret Road Oakley, CA 94561

Pharmacist License No. RPH 53516,

and

IROEGBU CLIFFORD ESOMONU FRUITVALE AVENUE PHARMACY INC. 6726 Corte Santa Maria Pleasanton, CA 94566

Pharmacist License No. RPH 53445

Respondents.

#### **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 on July 8, 2015.

It is so ORDERED on July 6, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

AMARYLIS GUTIERREZ Board President

OAH No. 2014061007

Case No. 4579

STIPULATED SURRENDER OF LICENSE AND ORDER AS TO RESPONDENT FRUITVALE AVENUE PHARMACY INC. AND RESPONDENT IROEGBU CLIFFORD ESOMONU ONLY

	H '	
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1	KAMALA D. HARRIS Attorney General of California	
2	DIANN ŠOKOLOFF	
3	Supervising Deputy Attorney General TIMOTHY J. MCDONOUGH Deputy Attorney General	
4	State Bar No. 235850 1515 Clay Street, 20th Floor	
5	P.O. Box 70550 Oakland, CA 94612-0550	
6	Telephone: (510) 622-2134	
7	Facsimile: (510) 622-2270 E-mail: Tim.McDonough@doj.ca.gov Attorneys for Complainant	
8	Anorneys for Complantant	
9	BOARD OF	RE THE PHARMACY
10	DEPARTMENT OF C STATE OF C	CONSUMER AFFAIRS CALIFORNIA
11		1
12	In the Matter of the Second Amended Accusation Against:	Case No. 4579
	_	OAH No. 2014061007
13	FRUITVALE AVENUE PHARMACY INC. 2693 Fruitvale Avenue	STIPULATED SURRENDER OF
14	Oakland, CA 94601	LICENSE AND ORDER AS TO RESPONDENT FRUITVALE AVENUE
15	Pharmacy License No. PHY 50064,	PHARMACY INC. AND RESPONDENT IROEGBU CLIFFORD ESOMONU
16	IJEOMA NWAYIOCHA ESOMONU FRUITVALE AVENUE PHARMACY INC.	
17	16 Minaret Road	
18	Oakley, CA 94561	
19	Pharmacist License No. RPH 53516,	
20	and	
21	IROEGBU CLIFFORD ESOMONU FRUITVALE AVENUE PHARMACY INC.	
22	6726 Corte Santa Maria Pleasanton, CA 94566	
23	Pharmacist License No. RPH 53445	
24	Respondents.	
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Stipulated Surrender of License (Case No. 4579)

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-1 entitled proceedings that the following matters are true: 2 3 PARTIES Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. 1. 4 She brought this action solely in her official capacity and is represented in this matter by Kamala 5 D. Harris, Attorney General of the State of California, by Timothy J. McDonough, Deputy 6 Attorney General. 7 Fruitvale Avenue Pharmacy, Inc. (Respondent Fruitvale) and Iroegbu Clifford 2. 8 Esomonu (Respondent Esomonu) are represented in this proceeding by attorney John Fleer, 9 whose address is 1850 Mt. Diablo Boulevard., Suite 120, Walnut Creek, CA 94596. 10 On or about October 21, 2009, the Board of Pharmacy issued Pharmacy Permit No. 3. 11 PHY 50064 to Fruitvale Avenue Pharmacy, Inc. The Pharmacy License was in full force and 12 effect at all times relevant to the charges brought in Second Amended Accusation No. 4579 and 13 will expire on October 1, 2015, unless renewed. 14 On or about March 28, 2002, the Board of Pharmacy issued Pharmacist License No. 4. 15 RPH 53445 to Iroegbu Clifford Esomonu. The pharmacist license was in full force and effect at 16 all times relevant to the charges brought in Second Amended Accusation No. 4579 and will 17 expire on September 30, 2015, unless renewed. 18 JURISDICTION 19 Second Amended Accusation No. 4579 was filed before the Board of Pharmacy 5. 20 (Board), Department of Consumer Affairs, and is currently pending against Respondents. The 21 Second Amended Accusation and all other statutorily required documents were properly served 22 on Respondents on May 6, 2015. A copy of Second Amended Accusation No. 4579 is attached 23 as Exhibit A and incorporated by reference. 24 ADVISEMENT AND WAIVERS 25 Respondents have carefully read, fully discussed with counsel, and understand the 6. 26 charges and allegations in Second Amended Accusation No. 4579. Respondents also have 27 28

carefully read, fully discussed with counsel, and understands the effects of this Stipulated
 Surrender of License and Order.

7. 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; the right to be
represented by counsel, at its own expense; the right to confront and cross-examine the witnesses
against them; the right to present evidence and to testify on its own behalf; the right to the
issuance of subpoenas to compel the attendance of witnesses and the production of documents;
the right to reconsideration and court review of an adverse decision; and all other rights accorded
by the California Administrative Procedure Act and other applicable laws.

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

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## **CULPABILITY**

9. Respondents admit the truth of each and every charge and allegation in Second
 Amended Accusation No. 4579, agree that cause exists for discipline and hereby surrenders their
 Pharmacy Permit No. PHY 50064 and Pharmacist License Number RPH 53445 for the Board's
 formal acceptance.

17 10. Respondents understand that by signing this stipulation, Respondent Fruitvale and
18 Respondent Esomonu enable the Board to issue an order accepting the surrender of Pharmacy
19 Permit No. PHY 50064 and Pharmacist License No. RPH 53445 without further process.

#### **RESERVATION**

11. The admissions made by Respondents in this stipulation are only for the purposes of
this proceeding, or any other proceedings in which the Board of Pharmacy or other professional
licensing agency is involved, and shall not be admissible in any other criminal or civil
proceeding.

### CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
communicate directly with the Board regarding this stipulation and surrender, without notice to or

participation by Respondent or its 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, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

#### <u>ORDER</u>

IT IS HEREBY ORDERED that Pharmacist License No. RPH 53445, issued to Respondent
Esomonu and Pharmacy Permit No. PHY 50064 issued to Respondent Fruitvale are surrendered
and accepted by the Board of Pharmacy. The effective date of the Decision as to Respondent
Fruitvale's permit surrender, however, shall be stayed until July 8, 2015, at which time the
pharmacy shall be sold or closed.

The surrender of Respondents' Pharmacy Permit and Pharmacist License and the
 acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline
 against Respondents. This stipulation constitutes a record of the discipline and shall become a
 part of Respondents' license history with the Board of Pharmacy.

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Stipulated Surrender of License (Case No. 4579)

2. In the event that Fruitvale Avenue Pharmacy, Inc. is sold and an application for a new permit is submitted to the Board, the Board shall expedite the processing of that application.

3 3. Respondent Fruitvale shall lose all rights and privileges as a pharmacy in California
4 as of the effective date of the Board's Decision and Order.

4. Respondent Esomonu shall lose all rights and privileges as a pharmacist in California
as of the effective date of the Board's Decision and Order.

7 5. Respondent Esomonu shall cause to be delivered to the Board its pocket license and,
8 if one was issued, its wall certificate, on or before the effective date of the Decision and Order.

6. If Respondent 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. 4579 shall be deemed to be true, correct and admitted by Respondent when the Board
determines whether to grant or deny the application or petition.

15 7. Respondent shall pay the agency its costs of investigation and enforcement in the
16 amount of \$50,973.50 prior to issuance of a new or reinstated license.

If Respondent should ever apply or reapply for a new license or certification, or
 petition for reinstatement of a license, by any other health care licensing agency in the State of
 California, all of the charges and allegations contained in Second Amended Accusation, No. 4579
 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any
 Statement of Issues or any other proceeding seeking to deny or restrict licensure.

9. In the event that Fruitvale Avenue Pharmacy, Inc. is not sold by July 8, 2015,
Respondent Fruitvale shall, within ten (10) days of the stayed effective date of the Board's order,
arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the Board
of all controlled substances and dangerous drugs and devices. Respondent Fruitvale shall further
provide written proof of such disposition and submit a completed Discontinuance of Business
form according to Board guidelines.

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1	Respondent owner shall also, by the effective date of this decision, arrange for the
2	continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written
3	notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that
4	identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating
5	as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five
6	days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy
7	of the written notice to the board. For the purposes of this provision, "ongoing patients" means
8	those patients for whom the pharmacy has on file a prescription with one or more refills
9	outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)
10	days.
11	10. Respondent may not apply, reapply, or petition for any licensure or registration of the
12	Board for three (3) years from the effective date of the Decision and Order.
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	Stipulated Surrender of License (Case No. 4579)

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1 ACCEPTANCE I have carefully read the above Stipulated Surrender of License and Order and have fully 2 discussed it with my attorney, John Fleer. I understand the stipulation and the effect it will have 3 on my Pharmacy License. I enter into this Stipulated Surrender of License and Order voluntarily, 4 knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of 5 Pharmacy. б 7 06.19.12 DATED: 8 **IROEGBU CLIFFORD ESOMON** 9 FRUITVALE AVENUE PHARMACY, INC. Respondent 10 11 I have carefully read the above Stipulated Surrender of License and Order and have fully 12 discussed it with my attorney, John Fleer. I understand the stipulation and the effect it will have 13 on my Pharmacist License. I enter into this Stipulated Surrender of License and Order 14 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the 15 Board of Pharmacy. 16 17 DATED: 061915 **IROEGBU CLIFFORD ESOMONU** 18 Respondent 19 I have read and fully discussed with Respondent Fruitvale Avenue Pharmacy, Inc. and 20 Respondent Iroegbu Clifford Esomonu the terms and conditions and other matters contained in 21 this Stipulated Surrender of License and Order. I approve its form and content. 22 DATED: 23 6-22-15 **IOHN FLEER** 24 Attorney for Respondent 25 26 27 28

1	ENDORSEMENT			
2	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted			
3	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.			
4	Dated: $(-2)^{-20/5}$ Respectfully submitted,			
5	KAMALA D. HARRIS Attorney General of California			
6	DIANN SOKOLOFF Supervising Deputy Attorney General			
7				
8	Add			
9	TIMOTHY L-MCDONOUGH Deputy Attorney General Attorneys for Complainant			
10	Adiorneys for Complainant			
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	8 Stipulated Surrender of License (Case No. 4579)	Ļ		

1	ACCEPTANCE				
2	I have carefully read the above Stipulated Surrender of License and Order and have fully				
3	discussed it with my attorney, John Fleer. I understand the stipulation and the effect it will have				
4					
5	on my Pharmacy License. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of				
6	Pharmacy.				
7					
8	DATED:				
9	IROEGBU CLIFFORD ESOMONU				
10	FRUITVALE AVENUE PHARMACY, INC. Respondent				
11					
12	I have carefully read the above Stipulated Surrender of License and Order and have fully				
13	discussed it with my attorney, John Fleer. I understand the stipulation and the effect it will have				
14	on my Pharmacist License. I enter into this Stipulated Surrender of License and Order				
15	voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the				
16	Board of Pharmacy.				
17					
18	DATED: IROEGBU CLIFFORD ESOMONU				
19	Respondent				
20	I have read and fully discussed with Respondent Fruitvale Avenue Pharmacy, Inc. and				
21	Respondent Iroegbu Clifford Esomonu the terms and conditions and other matters contained in				
22	this Stipulated Surrender of License and Order. I approve its form and content.				
23	DATED:				
24	JOHN FLEER Attorney for Respondent				
25	Automey for Respondent				
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Stipulated Surrender of License (Case No. 4579)

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# Exhibit A

Second Amended Accusation No. 4579

.1	Kamala D. Harris	
2	Attorney General of California DIANN SOKOLOFF	
3	Supervising Deputy Attorney General TIMOTHY J. MCDONOUGH	
4	Deputy Attorney General State Bar No. 235850	
5	1515 Clay Street, 20th Floor	
	P.O. Box 70550 Oakland, CA 94612-0550	
6	Telephone: (510) 622-2134 Facsimile: (510) 622-2270	
7	E-mail: Tim.McDonough@doj.ca.gov Attorneys for Complainant	
8	BEFOI	RE THE
9	BOARD OF	PHARMACY CONSUMER AFFAIRS
10		CALIFORNIA
11	In the Matter of the Second Amended	Case No. 4579
12	Accusation Against:	Case 110. 4577
13	FRUITVALE AVENUE PHARMACY INC.	SECOND AMENDED ACCURATION
14	2693 Fruitvale Avenue Oakland, CA 94601	SECOND AMENDED ACCUSATION
15	Pharmacy License No. PHY 50064,	
16	IJEOMA NWAYIOCHA ESOMONU	
17	FRUITVALE AVENUE PHARMACY INC. 16 Minaret Road	
18	Oakley, CA 94561	
19	Pharmacist License No. RPH 53516,	
20	and	
21	IROEGBU CLIFFORD ESOMONU FRUITVALE AVENUE PHARMACY INC.	
22	6726 Corte Santa Maria Pleasanton, CA 94566	
23	Pharmacist No. RPH 53445	
24	Respondents.	
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		Second Amended Accusat

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Second Amended Accusation

Complainant alleges: 1 PARTIES 2 1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in her 3 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer 4 Affairs. 5 2, On or about October 21, 2009, the Board of Pharmacy issued Pharmacy License 6 Number PHY 50064 to Fruitvale Avenue Pharmacy Inc. (Respondent FAP). The Pharmacy 7 License was in full force and effect at all times relevant to the charges brought in this Second 8 Amended Accusation and will expire on October 1, 2015, unless renewed. 9 On or about April 23, 2002, the Board of Pharmacy issued Pharmacist License 3. 10 Number RPH 53516 to Ijeoma Nwanyiocha Esomonu (Respondent INE). The Pharmacist 11 License was in full force and effect at all times relevant to the charges brought in this Second 12 Amended Accusation and will expire on April 30, 2017, unless renewed. 13 On or about March 28, 2002, the Board of Pharmacy issued Pharmacist License 4. 14 Number RPH 53445 to Iroegbu Clifford Esomonu (Respondent ICE). The Pharmacist License 15 was in full force and effect at all times relevant to the charges brought in this Second Amended 16 Accusation and will expire on September 30, 2015, unless renewed. 17 JURISDICTION 18 This Accusation is brought before the Board of Pharmacy (Board), Department of 5. 19 Consumer Affairs, under the authority of the following laws. All section references are to the 20 Business and Professions Code unless otherwise indicated. 21 Section 4011 of the Code provides that the Board shall administer and enforce both 6. 22 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances 23 Act [Health & Safety Code, § 11000 et seq.]. 24 Section 4300 of the Code states, in relevant part: 7. 25 "(a) Every license issued may be suspended or revoked. 26 27 28 2

Second Amended Accusation

"(b) The board shall discipline the holder of any license issued by the board, whose default 1 has been entered or whose case has been heard by the board and found guilty, by any of the 2 3 following methods: "(1) Suspending judgment. 4 "(2) Placing him or her upon probation. 5 "(3) Suspending his or her right to practice for a period not exceeding one year. 6 "(4) Revoking his or her license. 7 "(5) Taking any other action in relation to disciplining him or her as the board in its 8 9 discretion may deem proper. 10 "(e) The proceedings under this article shall be conducted in accordance with Chapter 5 11 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board 12 shall have all the powers granted therein. The action shall be final, except that the propriety of 13 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of 14 Civil Procedure." 15 8. Section 4300.1 of the Code provides that "[t]he expiration, cancellation, forfeiture, or 16 suspension of a board-issued license by operation of law or by order or decision of the board or a 17 court of law, the placement of a license on a retired status, or the voluntary surrender of a license 18 19 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 20 suspending or revoking the license." 21 22 STATUTORY/REGULATORY PROVISIONS 9. 23 Section 4301 of the Code states, in relevant part: "The board shall take action against any holder of a license who is guilty of unprofessional 24 25 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following: 26 27 "(a) Gross immorality. 28 . . . 3

Second Amended Accusation

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a)
 of Section 11153 of the Health and Safety Code.

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

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

10. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 12 or dangerous devices shall be at all times during business hours open to inspection by authorized 13 officers of the law, and shall be preserved for at least three years from the date of making. A 14 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary 15 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 16 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 17 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 18 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 19 Institutions Code who maintains a stock of dangerous drugs or dangerous devices. 20

"(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.

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

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Section 4113, subdivision (c), of the Code provides that "[t]he 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."

4 12. Section 4333 of the Code states, in relevant part, that all prescriptions filled by a
5 pharmacy and all other records required by Section 4081 shall be maintained on the premises and
6 available for inspection by authorized officers of the law for a period of at least three years. In
7 cases where the pharmacy discontinues business, these records shall be maintained in a
8 board-licensed facility for at least three years.

9 13. Health and Safety Code section 11165, subdivision (d), states:
"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as
defined in the controlled substances schedules in federal law and regulations, specifically
Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal
Regulations, the dispensing pharmacy or clinic shall provide the following information to the
Department of Justice on a weekly basis and in a format specified by the Department of Justice:

15 "(1) Full name, address, and the telephone number of the ultimate user or research subject,
16 or contact information as determined by the Secretary of the United States Department of Health
17 and Human Services, and the gender, and date of birth of the ultimate user.

"(2) The prescriber's category of licensure and license number; federal controlled
substance registration number; and the state medical license number of any prescriber using the
federal controlled substance registration number of a government-exempt facility.

21 "(3) Pharmacy prescription number, license number, and federal controlled substance
22 registration number.

"(4) NDC (National Drug Code) number of the controlled substance dispensed,

"(5) Quantity of the controlled substance dispensed.

"(6) ICD-9 (diagnosis code), if available.

"(7) Number of refills ordered.

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"(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request."(9) Date of origin of the prescription.

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1	"(10) Date of dispensing of the prescription."
2	14. Health and Safety Code section 11164 states, in relevant part:
3	"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall
4	any person fill, compound, or dispense a prescription for a controlled substance, unless it
5	complies with the requirements of this section."
6	"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V,
7	except as authorized by subdivision (b), shall be made on a controlled substance prescription form
8	as specified in Section 11162.1"
9	15. Health and Safety Code section 11162.1 states, in relevant part:
10	"(a) The prescription forms for controlled substances shall be printed with the following
11	features:
12	· · · ·
13	"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber
14	may indicate the quantity by checking the applicable box where the following quantities shall
15	appear:
16	= 1-2-4 = 25-49 = 50-74
17	• 75-100 • 101-150
18	<ul> <li>151 and over.</li> </ul>
19	•••
20	"(8) Prescription blanks shall contain a statement printed on the bottom of the
21	prescription blank that the 'Prescription is void if the number of drugs prescribed is not noted."
22	
23	"(b) Each batch of controlled substance prescription forms shall have the lot number printed
24	on the form and each form within that batch shall be numbered sequentially beginning with the
25	numeral one."
26	16. Health and Safety Code section 11153, subdivision (a), states:
27	"A prescription for a controlled substance shall only be issued for a legitimate medical
28	purpose by an individual practitioner acting in the usual course of his or her professional
	6 Second Amended Accusation
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practice. The responsibility for the proper prescribing and dispensing of controlled substances is 1 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist 2 who fills the prescription. Except as authorized by this division, the following are not legal 3 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 4 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or 5 habitual user of controlled substances, which is issued not in the course of professional treatment 6 or as part of an authorized narcotic treatment program, for the purpose of providing the user with 7 controlled substances, sufficient to keep him or her comfortable by maintaining customary use." 8

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17. 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."

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18. California Code of Regulations, title 16, section 1761, states:

13 "(a) No pharmacist shall compound or dispense any prescription which contains any 14 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any 15 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to 16 validate the prescription.

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense
a controlled substance prescription where the pharmacist knows or has objective reason to know
that said prescription was not issued for a legitimate medical purpose."

20 19. California Code of Regulations, title 16, section 1707.2, states, in relevant part:
 21 "(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent
 22 in all care settings:

23 "(1) upon request; or

24 "(2) whenever the pharmacist deems it warranted in the exercise of his or her professional
25 judgment.

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall
provide oral consultation to his or her patient or the patient's agent in any care setting in which the
patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or 1 "(B) whenever a prescription drug not previously dispensed to a patient in the same dosage 2 form, strength or with the same written directions, is dispensed by the pharmacy." 3 20. California Code of Regulations, title 16, section 1716, states: 4 "Pharmacists shall not deviate from the requirements of a prescription except upon the 5 prior consent of the prescriber or to select the drug product in accordance with Section 4073 of 6 the Business and Professions Code. 7 "Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-8 accepted pharmaceutical practice in the compounding or dispensing of a prescription." 9 California Code of Regulations, title 16, section 1718, states: 21. 10 "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions 11 Code shall be considered to include complete accountability for all dangerous drugs handled by 12 every licensee enumerated in Sections 4081 and 4332. 13 The controlled substances inventories required by Title 21, CFR, Section 1304 shall be 14 available for inspection upon request for at least 3 years after the date of the inventory." 15 22. Code section 4306.5, states: 16 "Unprofessional conduct for a pharmacist may include any of the following: 17 "(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or 18 her education, training, or experience as a pharmacist, whether or not the act or omission arises in 19 the course of the practice of pharmacy or the ownership, management, administration, or 20 operation of a pharmacy or other entity licensed by the board. 21 "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement 22 his or her best professional judgment or corresponding responsibility with regard to the 23 dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with 24 regard to the provision of services. 25 "(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate 26 patient, prescription, and other records pertaining to the performance of any pharmacy function. 27 "(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and 28 8

retain appropriate patient-specific information pertaining to the performance of any pharmacy function."

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23. Section 4307 of the Code states, in relevant part:

"(a) Any person who has been denied a license or whose license has been revoked or is 4 5 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 6 any partnership, corporation, firm, or association whose application for a license has been denied 7 or revoked, is under suspension or has been placed on probation, and while acting as the manger, 8 9 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 10 placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, 11 officer, director, associate, or partner of a licensee as follows: 12

"(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.

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

24. Code section 4022, states:

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

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

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

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

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1	CONTROLLED SUBSTANCES	
2	25. Section 4021 of the Code states:	
3	"Controlled substance' means any substance listed in Chapter 2 (commencing with Section	
4	11053) of Division 10 of the Health and Safety Code."	
5	26. Oxycodone is a Schedule II controlled substance as designated by Health and Safety	
6	Code section 11055, subdivision (b)(1)(M).	
7	27. Hydrocodone with acetaminophen is a Schedule III controlled substance as	
8	designated by Health and Safety Code section 11056, subdivision (e)(4).	
9	28. Promethazine with codeine is a Schedule V controlled substance as designated by	
10	Health and Safety Code section 11058.	
11	COST RECOVERY	
12	29. Section 125.3 of the Code provides, in relevant part, that the Board may request the	
13	administrative law judge to direct a licentiate found to have committed a violation or violations of	
14	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and	
15	enforcement of the case, with failure of the licentiate to comply subjecting the license to not being	
16	renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be	
17	included in a stipulated settlement.	
1.8	FACTUAL BACKGROUND	
19	30. From about October 21, 2009, to the present, Respondent Fruitvale Avenue Pharmacy	
20	(FAP) has been operating as a pharmacy in Oakland, California. From on or about October 21,	
21	2009, until about May 19, 2011, Respondent Ijeoma Nwanyiocha Esomonu (INE), the owner of	
22	FAP, was also the pharmacist-in-charge (PIC) at FAP. From on or about October 21, 2009, to the	
23	present, Respondent Iroegbu Clifford Esomonu (ICE) worked as a pharmacist at FAP. From	
24	about May 19, 2011, to the present, Respondent ICE worked as the PIC at FAP.	
25	May 17, 2011 Inspection	
26	31. On May 17, 2011, a Board inspector (Inspector 1) conducted an inspection at FAP	
27	because the Board identified FAP as a pharmacy that failed to report any Controlled Substances	
28	Utilization Review and Evaluation System (CURES) data to the Department of Justice (DOJ).	
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	Second Amended Accusation	

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During the inspection, Inspector 1 observed several pharmacy law violations, including, but not
 limited to, never transmitting any CURES data to the DOJ.

While at FAP, Inspector 1 reviewed prescription documents from Bay Internal 3 32. Medicine (BIM). The prescriptions appeared legitimate but, upon further investigation, Inspector 4 1 found that none of the prescribers' contact information on the prescriptions contained a valid 5 working phone number. Inspector 1 asked Respondent ICE to verify the BIM prescribers on the 6 Medical Board of California's website. The web search revealed that none of the BIM 7 prescribers' listed addresses on the Medical Board's website matched the addresses on the 8 9 prescriptions. Significantly, Respondent ICE admitted to Inspector 1 that he had never before verified a prescriber using the Medical Board's website. In addition, Inspector 1 observed 10 numerous other violations of pharmacy laws. During his inspection, Inspector 1 obtained several 11 materials including prescription documents, dispensing detail reports, and Cardinal Health 12 Narcotic Sales Reports. Inspector 1 also requested FAP to provide additional documents and 13 explanations regarding pharmacy law violations indicated in the report. At the conclusion of the 14 inspection, Inspector 1 prepared an inspection report documenting various pharmacy law 15 violations. Inspector I gave a copy of the report to Respondent ICE, and then had Respondent 16 ICE review and sign off on it. 17

33. On or about May 30, 2011, Inspector 1 received and reviewed faxed responses from 18 FAP. Subsequently, Inspector 1 contacted 15 different prescribers listed as the supposed 19 prescriber on the prescription documents. Inspector 1 sent each prescriber a list of prescriptions 20 from FAP to verify the legitimacy of the prescriptions. Each of the prescribers responded with a 21 written statement that they did not authorize the prescriptions from FAP. In fact, one prescriber 22 23 from Kaiser stated he did not authorize any of the prescriptions and that they were written on 24 prescriptions that were stolen from his locker at the hospital. Additionally, one prescriber from BIM stated BIM's practice had been closed since June 2009. All the BIM prescription documents 25 26 that Inspector 1 sent to the BIM prescribers to review were dated and filled by FAP in 2011,

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Physician Assistant G. P.<sup>1</sup> (G.P.) was one of the 15 prescribers that Inspector 1 1 34. contacted to verify the legitimacy of the prescription documents he got from FAP. On or about 2 June 7, 2011, Inspector 1 received a response from G.P., indicating that he did not authorize the 3 prescriptions and the documents were forgeries. In addition, G.P. noted that several of the 4 prescription documents were not written on proper controlled substances prescription forms. 5 Significantly, during the May 17, 2012 visit to FAP, Inspector 1 made the same observation; that 6 FAP had improperly dispensed controlled substances on five invalid prescription documents. 7 These five prescription documents were invalid because they lacked several required security 8 features such as quantity check off boxes, the required statement of "Prescription is void if the 9 number of drugs prescribed is not noted," and the prescriptions were not sequentially numbered. 10 Inspector 1's investigation revealed that from October 2009, to about April 2011, 35. 11 FAP failed to transmit CURES data to the DOJ. The investigation further showed that from about 12 July 2010, to May 2011, Respondent INE and Respondent ICE had filled approximately 350 13 fraudulent prescriptions. Many of these prescription documents contained significant 14 irregularities that should have prompted Respondent INE and Respondent ICE to verify the 15 legitimacy of the prescription before dispensing the controlled substances. In addition, a review 16 of FAP's dispensing printouts obtained during the investigation showed Respondent ICE's initials 17 on most, if not all, of the printouts' "filled by" section. Furthermore, in a written statement, 18 Respondent ICE admitted that he was the pharmacist on duty everyday since the opening of FAP. 19 September 17, 2014 Inspection 20 On or about July 7, 2014, the Board opened an investigation for pharmacies filing 36. 21 prescriptions written by Dr. Tan Nguyen based on news articles stating the prescriber was 22 charged with excessive prescribing of controlled substances. The subsequent review of 23 pharmacies filling those prescriptions revealed that 44.59 percent of written prescriptions by 24 another prescriber, Dr. Hai Nguyen, were being filled at Fruitvale Avenue Pharmacy (FAP). That 25 information led to an investigation of FAP and its dispensing practices regarding several 26 27 <sup>1</sup> G.P. is used in this document rather than the actual name of the Physician Assistant. 28 12

prescribers, Dr. Hai Nguyen, Dr. Collin Leong, Dr. Tan Nguyen, and Dr. Daniel Shin (the
 Prescribers).

3 37. On July 25, 2014, a Board inspector (Inspector 2) began an investigation which
4 included gathering information and conducting an inspection of FAP. Documents and
5 information were requested from FAP and information was obtained regarding the prescription
6 patterns of the Prescribers. These documents and information included, but were not limited to,
7 CURES reports, prescriptions, and drug usage reports.

On September 17, 2014, Inspector 2 reviewed the Medical Board of California's 38. 8 website and checked the license status of the Prescribers. That same day, Inspector 2 and other 9 board inspectors went to FAP, conducted an inspection, and reviewed pharmacy operations and 10 various documents, including pharmacy self-assessment data, policy and procedures on 11 preventing medication diversion and controlled substances, DEA biennial inventory for CIII-V 12 controlled substances report, dispensing reports, sample prescription labels, the current inventory 13 including a large box filled with approximately 80-100 prescription vials returned by patients for 14 destruction, and prescription hard copies for controlled substances. 15

39. During the inspection, Inspector 2 interviewed the Pharmacist-in-Charge (PIC), 16 Respondent ICE, and asked about prescription dispensing and filling processes in general, and 17 specifically regarding the Prescribers. Inspector 2 requested additional documents including, 18 multiple dispensing histories for various prescribers, some drug usage reports, on-hand quantity 19 of selected drugs, the DEA biennial inventory, total prescriptions dispensed from September 17, 20 2011, to September 17, 2014, prescription hard copies for Dr. Tan Nguyen, purchase history for 21 selected drugs, policy and procedure for theft/diversion, interpretive services and quality 22 assurance, and patient centered labeling corrections (font and clustering information). FAP failed 23 to provide the current DEA biennial inventory for inspection. 24

40. On October 21, 2014, Inspector 2 sent survey letters to numerous patients listed on
FAP's dispensing records for prescriptions written by the Prescribers. The surveys were sent to
gather information from the patients who used FAP to have their prescriptions filled.

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The evaluation of dispensing practices of FAP demonstrates that the Prescribers aided 41. 1 the medically illegitimate dispensing of controlled substances, and that FAP and Respondent ICE 2 filled and dispensed medically illegitimate prescriptions. The data showed that FAP dispensed 3 excessive amounts of controlled substances for irregular or uncertain prescriptions and ignored 4 key objective factors suggesting the medical illegitimacy of the prescriptions. Some of these 5 objective factors were: (1) payment methods for controlled substances were in excess of normal 6 distribution between cash and insurance; (2) there was an irregular pattern of patients willing to 7 pay cash for expensive medication (100% cash payment method for 2 of the 4 Prescribers); (3) 8 there was an irregular pattern of patients willing to drive well over 50 miles to obtain controlled 9 substance prescriptions from the Prescribers and to fill prescriptions at FAP (average distance 10 travelled was 165.55 miles); (4) sequential or near sequential numbering of prescriptions filled for 11 patients of the Prescribers; (5) excessive filling of controlled substances in comparison to 12 competitor pharmacies in proximity to FAP; (6) failing to assess "narcotic naïve" patients to 13 determine if large doses of highly abused drugs were written for a legitimate medical purpose; (7) 14 failing to exercise professional judgment when filling prescriptions for large quantities of 15 controlled substances for highly abused drugs; and (8) failing to exercise education, training and 16 experience as a pharmacist when assessing prescriptions written for highly abused controlled 17 substances. Additionally, FAP and its PIC (Respondent ICE) did not assume their corresponding 18 responsibility when they failed to appropriately scrutinize patients' drug therapy with readily 19 available tools such as CURES reports and industry "red flags" to verify prescriptions, so they 20 repeatedly prescribed controlled substances to pharmacy and doctor shoppers. Some of the "red 21 flags" that existed but were not heeded were: prescribers and patients from outside the pharmacy 22 service area, prescriptions for highly abused drugs, prescriptions paid for in cash (or debit or 23 credit card), large quantities outside the normal scope of dispensing, early dispensing, and 24 sequential filling of prescriptions from a single prescriber for multiple patients for "drug 25 cocktails"2 26

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<sup>2</sup> "Drug cocktails" are typically a combination of hydrocodone/APAP 10/325 mg, promethazine with codeine, oxycodone 30 mg, diazepam 10 mg, carisoprodol 350 mg and other (continued...)

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During the inspection, Inspector 2 interviewed Respondent ICE regarding FAP's 42. 1 controlled substance filling and dispensing practices. Respondent ICE explained that FAP is 2 registered for the CURES PDMP program<sup>3</sup> but he does not utilize it much because he knows the doctors are checking the CURES, so he does not do it.

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From September 17, 2011, to September 17, 2014, FAP dispensed controlled 5 43. substances with an established history of high potential for abuse despite multiple cues of 6 irregularity and uncertainty based on the patients and prescribers. In general, FAP dispensed 7 32,553 prescriptions and 19,502 prescriptions for various controlled substances from 4 specific 8 prescribers. FAP dispensed a total of 598,928 doses of hydrocodone/APAP 10/32mg, 312,680 9 tablets of oxycodone 30mg, and 5,336 pints of promethazine with codeine. Specifically, FAP 10 dispensed 15,926 controlled substance prescriptions written by Dr. Hai Nguyen, 2,822 by Dr. 11 Collin Leong, 704 by Dr. Daniel Shin, and 50 by Dr. Tan Nguyen with disregard or negligence to 12 the following factors: distance from FAP to the prescriber's office, distance from FAP to patient's 13 home, percentage of cash patients in relation to specific prescribers, same or similar prescribing 14 patterns for individual patients, and filling controlled substance prescriptions in groups. Also, 15 FAP did not scrutinize patients' drug therapy with readily available tools, like the CURES PDMP 16 program, and industry "red flags" to verify prescriptions.<sup>4</sup> These omissions resulted in repeated 17 dispensing of controlled substances to patients who engaged in doctor and pharmacy shopping 18 activity, and filling prescriptions for large quantities of narcotics for patients who used multiple 19 20 controlled substances prescribed all together or in other combinations of 2 or 3 of these drugs. 21 The CURES PDMP program allows the pharmacist to look up a patient's prescription fill history. 22 A pharmacist must be alert to see potential "red flags" that will suggest that the prescriptions are not for a legitimate medical purposes some of these "red flags include, but are 23 not limited to: prescriptions written by prescribers from outside the pharmacy service area; a. 24 patients are from outside the pharmacy service area; b. prescriptions for highly abused drugs; c. 25 d. prescriptions paid for in cash; large quantities of medicine prescribed outside the normal scope of dispensing; ę, 26 f. early dispensing; sequential filling of prescriptions from a single prescriber for multiple patients for g. seque "drug cocktails." 27 28

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prescribers and without confirming the prescriptions and that the quantities of narcotics
 prescribed were for a legitimate medical purpose.

44. Inspector 2's review of the prescription hard copies revealed: 39 prescription hard
copies were not provided; 18 prescriptions were in scanned image form, not hard copies; and
several prescriptions were processed with the wrong prescriber. Also, FAP could not account for
140.8 pints of promethazine with codeine syrup that it purchased between September 17, 2011
and September 17, 2014.

8 45. During the September 17, 2014, board inspector 2 spoke with two FAP clerks who 9 stated that when a "new" prescription is picked up, they review the patient's profile to see if the 10 patient was previously on the medication and ask the patients if they have any questions for the 11 pharmacists. During the inspection on September 17, 2014, the inspector observed that there 12 were no requests for consultation from the pharmacist.

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Prescriber Information

46. Dr. Collin Leung surrendered his California Medical License with an effective date of
February 4, 2014. Dr. Leung's surrender of his license was a disciplinary resolution to
Accusation No. 03-2012-220574 brought against his medical license by the Medical Board of
California. There were numerous causes for discipline alleged in the Accusation including causes
based on excessive prescribing.

47. On October 3, 2014, Dr. Tan Nguyen surrendered his California Medical License.
 Dr. Tan Nguyen's surrender of his license was a disciplinary resolution to Accusation No.
 5002014000107 brought against his medical license.

48. On March 20, 2014, the Medical Board of California filed Accusation No. 12 2011
216564 against Dr. Hai Van Nguyen' medical license. The Accusation alleges numerous causes
for discipline including several causes for discipline for prescribing dangerous drugs without
appropriate prior examination and indication. The Accusation is currently pending against Dr.
Hai Van Nguyen.

49. On March 25, 2014, Judge Longoria of the Los Angeles County Superior Court
issued an order in the case of *State of California v. Daniel Shin*, Case No. BA421892, that as a

condition of his bail, Dr. Daniel Shin shall cease and desist from the practice of medicine, and 1 immediately surrender any and all controlled substance prescription forms. Previously, on 2 January 13, 2012, the Medical Board of California filed Accusation No. 19-2010-208332 against 3 Dr. Daniel Shin's medical license. On August 31, 2012, the Medical Board of California placed 4 Dr. Shinn's medical license on probation for 5 years. 5 **CAUSES OF DISCIPLINE AGAINST RESPONDENT FAP** 6 7 FIRST CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301, subd. (j), & Health and Safety Code § 11165, subd. (d)) 8 9 50. Respondent Fruitvale Avenue Pharmacy's (FAP) Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (j), because FAP violated Health and 10 Safety Code section 11165, subdivision (d), in that from on or about October 21, 2009, until 11 approximately April 2011, FAP failed to transmit dispensing data for Schedule II, Schedule III, 12 and Schedule IV controlled substances to the Department of Justice for the Controlled Substances 13 Utilization Review and Evaluation System (CURES) on a weekly basis. The circumstances are 14 further explained in paragraphs 30 through 35, above. 15 SECOND CAUSE FOR DISCIPLINE 16 (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) 17 (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a)) Respondent FAP's Pharmacy License is subject to disciplinary action under Code 51. 18 section 4301, subdivision (o), because FAP violated California Code of Regulations, title 16, 19 section 1761, subdivision (a), in that pharmacists and staff at FAP filled approximately 350 20 21 irregular prescriptions. Many of these prescriptions reflect orders for an unusually large amount of controlled substances for "as-needed" purposes. The circumstances are further explained in 22 paragraphs 30 through 35, above. 23 24 THIRD CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) 25 (Bus. & Prof. § 4301, subd. (i), and Health and Safety Code § 11153, subd. (a)) 52. Respondent FAP's Pharmacy License is subject to disciplinary action under Code 26 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11153. 27 subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding 28 17

1	responsibility of verifying the patient's legitimate medical purposes for controlled substances.
2	The pharmacists and staff at FAP breached their corresponding responsibility by furnishing
3	unusually large quantities of controlled substances to patients without confirming the legitimacy
4	of the prescriptions with the supposed prescribers. In fact, the pharmacists and staff at FAP filled
5	approximately 350 fraudulent prescriptions, many of which were for unusually large quantities of
6	controlled substances. The circumstances are further explained in paragraphs 30-35, above.
7	FOURTH CAUSE FOR DISCIPLINE
8	(Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164)
9	53. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
10	section 4301, subdivision (j), because FAP violated Health and Safety Code section 11164, in that
11	the pharmacists and staff at FAP furnished controlled substances to patients based on invalid
12	controlled substances prescription forms. Specifically, during May 2011, FAP filled five
13	prescription documents that lacked several required security measures. The circumstances are
14	further explained in paragraph 34, above.
15 16	<u>FIFTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Maintain Records of Disposition) (Bus. & Prof. §§ 4301, subd. (j), & 4333)
17	54. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
18	section 4301, subd. (j), because it violated Code section 4081, in that it did not maintain on its
19	premises and have available for inspection all records of disposition for three years. Specifically,
20	on September 17, 2014, Inspector 2 obtained prescription hard copies and requested additional
21	documents after the inspection. During the inspection, 39 prescription hard copies-which were
22	filled between September 17, 2011 and September 17, 2014-were missing and FAP only
23	provided scan images of 18 prescriptions filled by the pharmacy during this three year period for
24	patients of Dr. Tan Nguyen.
25	SIXTH CAUSE FOR DISCIPLINE
26	(Unprofessional Conduct-Possessing Adulterated Drugs) (Bus. & Prof. § 4301, subd. (j), and Health and Safety Code § 111295)
27	55. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
28	sections 4301, subd. (j), in that FAP violated Health and Safety Code section 111295, in that the
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	Second Amended Accusation

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1	pharmacists and staff at FAP possessed dangerous drugs that had been adulterated. Specifically,
2	on September 17, 2014, during an inspection at FAP, a board inspector discovered a large box fill
3	with approximately 80 prescription vials returned by patients for destruction in the pharmacy.
4	SEVENTH CAUSE FOR DISCIPLINE
5	(Unprofessional Conduct-Failure to Provide Record of DEA Biennial Inventory) (Bus. & Prof. § 4301, subd. (0), & 16 CCR § 1718)
6	56. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
7	section 4301, subdivision (0), because it failed to comply with title 16 section 1718 of the
8	California Code of Regulations. Specifically, on September 17, 2104, during an inspection, a
9	Board inspector requested the record of the DEA biennial inventory for inspection. Respondent
10	FAP failed to provide the record for inspection. <sup>5</sup>
11	EIGHTH CAUSE FOR DISCIPLINE
12	(Unprofessional Conduct-Failure to Consult with Patient) (Bus. & Prof. § 4301, subd. (0), and 16 CCR § 1707.2, subd. (b)(1)(A))
13	57. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
14	section 4301, subdivision (0), because FAP violated California Code of Regulations, title 16,
15	section 1707.2, subdivision (b)(1)(A), in that FAP failed to consult with patients regarding new
16	medications. The circumstances are further explained in paragraph 45, above.
17	NINTH CAUSE FOR DISCIPLINE
18	(Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (d), & Health and Safety Code § 11153, subd. (a))
19	58. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
20	section 4301, subdivision (d), because FAP engaged in the excessive furnishing of controlled
21	substances in violation of Health and Safety Code section 11153, subdivision (a), in that
22	pharmacists and staff at FAP failed to uphold their corresponding responsibility of verifying the
23	patient's legitimate medical purposes for controlled substances. Specifically, the pharmacists and
24 .	staff at FAP breached their corresponding responsibility by furnishing unusually large quantities
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27 28	<sup>5</sup> Under title 21 of the Code of Federal Regulations (CFR) section 1304, the DEA biennial inventory shall be available for inspection upon request for at least 3 years after the date of the inventory.
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1	of controlled substances to patients from September 17, 2011 to September 17, 2014. The	
2	circumstances are further explained in paragraphs 36-49, above.	
3	TENTH CAUSE FOR DISCIPLINE	
4	(Unprofessional Conduct-Variation from Prescription) (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1716)	
5	59. Respondent FAP's Pharmacy License is subject to disciplinary action under Code	
6	section 4301, subdivision (o), because FAP violated California Code of Regulations, title 16,	
7	section 1716, in that FAP deviated from the requirements of a prescription without prior consent	
8	of the prescriber on several occasions. During the inspection of FAP on September 17, 2014,	
9	Inspector 2 reviewed prescription hard copies which were processed with the wrong prescriber,	
10	The circumstances are further explained in paragraph 44, above.	
11	ELEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Maintain Records of Disposition)	
12	(Unprofessional Conduct-Fanure to Maintain Records of Disposition) (Bus, & Prof. § 4301, subd. (o), and 4081)	
13	60. Respondent FAP's Pharmacy License is subject to disciplinary action under Code	
14	section 4301, subdivision (o), because FAP violated Code section 4081, in that Respondent FAP	
15	did not have all records of manufacturer and of sale, acquisition, or disposition of dangerous	
16	drugs or dangerous devices at all times during business hours open to inspection by an authorized	Č.
17	officer of the law, for at least three years. Specifically, between the dates of September 17, 2011	
18	and September 17, 2014, FAP could not account for 140.8 pints of promethazine with codeine	
19	syrup. The circumstances are further explained in paragraphs 36 through 44, above.	
20	CAUSES OF DISCIPLINE AGAINST RESPONDENT INE	
21	TWELFTH CAUSE FOR DISCIPLINE	
22	(Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d))	
23	61. Respondent Ijeoma Nwanyiocha Esomonu (INE), as Pharmacist-in-Charge of FAP,	
24	has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision	
25	(j), by violating Health and Safety Code sections 11165, subdivision (d), in that from on or about	
26	October 21, 2009, until approximately May 19, 2011, INE failed to insure that FAP transmit to	
27	the Department of Justice for the Controlled Substances Utilization Review and Evaluation	
28	System (CURES) dispensing data for Schedule II, Schedule III, and Schedule IV controlled	
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substances on a weekly basis. The circumstances are further explained in paragraphs 30-35, 1 2 above. 3 THIRTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) 4 (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a)) Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 5 62. License to disciplinary action under Code section 4301, subdivision (o), because she violated 6 California Code of Regulations, title 16, section 1761, subdivision (a), in that pharmacists and 7 staff at FAP filled approximately 350 irregular prescriptions. Many of these prescriptions order 8 9 an unusually large amount of controlled substances for "as-needed" purposes. The circumstances 10 are further explained in paragraphs 30-35, above. 11 FOURTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) 12 (Bus. & Prof. § 4301, subd. (j), & Health and Safety Code § 11153, subd. (a)) 63. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 13 License to disciplinary action under Code section 4301, subdivision (j), because she violated 14 Health and Safety Code section 11153, subdivision (a), in that pharmacists and staff at FAP failed 15 16 to uphold their corresponding responsibility of verifying the patient's legitimate medical purposes for controlled substances. The pharmacists and staff at FAP breached their corresponding 17 responsibility by furnishing unusually large quantities of controlled substances to patients without 18 confirming with the supposed prescribers the legitimacy of the prescriptions. In fact, the 19 pharmacists and staff at FAP filled approximately 350 fraudulent prescriptions, many of which 20 21 were for unusually large quantities of controlled substances. The circumstances are further explained in paragraphs 30-35, above. 22 23 FIFTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) 24 (Bus. & Prof. § 4301, subd. (j), & Health and Safety Code § 11164) 25 64. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision (j), because she violated 26 27 Health and Safety Code section 11164, in that the pharmacists and staff at FAP furnished controlled substances to patients based on invalid controlled substances prescription forms. 28 21

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1	Specifically, during May 2011, FAP filled five prescription documents that lacked several
2	required security measures. The circumstances are further explained in paragraph 34, above.
3	CAUSES OF DISCIPLINE AGAINST RESPONDENT ICE
4	SIXTEENTH CAUSE FOR DISCIPLINE
5	(Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (0), & 16 CCR § 1761, subd. (a))
6	65. Respondent Iroegbu Clifford Esomonu (ICE), as a pharmacist of FAP, has subjected
7	his Pharmacist License to disciplinary action under Code section 4301, subdivision (0), because
8	he violated California Code of Regulations, title 16, section 1761, subdivision (a), in that
9	Respondent ICE filled prescriptions with significant irregularity. Many of the prescriptions
10	ordered unusually large quantities of controlled substances including oxycodone, hydrocodone
11	with acetaminophen, alprazolam and promethazine with codeine. The circumstances are further
12	explained in paragraphs 30-35, above.
13	SEVENTEENTH CAUSE FOR DISCIPLINE
14	(Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j), & Health and Safety Code § 11153, subd. (a))
15	66. Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to
16	disciplinary action under Code section 4301, subdivision (j), because he violated Health and
17	Safety Code section 11153, subdivision (a), in that, on numerous occasions, Respondent ICE
18	failed to verify the legitimate medical purpose for prescribing an unusually large quantity of
19	controlled substances. In fact, FAP's drug dispensing printouts show that Respondent ICE filled
20	approximately 350 fraudulent prescriptions, many which were for unusually large quantities of
21	controlled substances. The circumstances are further explained in paragraphs 30-35, above.
22	EIGHTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions)
23	(Unprofessional Conduct-Dispensed Controlled Substances on Invania 1164) (Bus. & Prof. § 4301, subd. (j), & Health and Safety Code § 11164)
24	67. Respondent ICE has subjected his Pharmacist License to disciplinary action under
25	Code section 4301, subdivision (j), in that Respondent ICE dispensed controlled substances based
26	on invalid prescription documents. Specifically, Respondent ICE's initials were on the pharmacy
27	dispensing printouts for five invalid prescription documents. The circumstances are further
28	explained in paragraph 34, above.
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1	<u>NINETEENTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Maintain Records of Disposition) (Bus. & Prof. §§ 4301, subd. (j), & 4081)
3	68. Respondent ICE, as the pharmacist-in-charge of FAP <sup>6</sup> , has subjected his Pharmacist
4	License to disciplinary action under Code section 4301, subd. (j), because he violated Code
5	section 4081, in that he did not maintain on FAP's premises and have available for inspection all
6	records of disposition for inspection for 3 years. Specifically, on September 17, 2014, inspector 2
7	obtained prescription hard copies and requested additional documents after the inspection,
8	During the inspection, 39 prescription hard copies—which were filled between September 17,
9	2011 and September 17, 2014—were missing and FAP provided scan images of 18 prescriptions
10	filled by the pharmacy during this three year period for patients of Dr. Tan Nguyen.
11 12	<u>TWENTIETH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Possessing Adulterated Drugs) (Bus. & Prof. § 4301, subd. (j), and Health and Safety Code § 111295)
13	69. Respondent ICE, as pharmacist-in-charge of FAP, has subjected his Pharmacist
14	License to disciplinary action under Code sections 4031, subd. (j) because FAP violated Health
15	and Safety Code section 111295, in that the pharmacists and staff at FAP possessed dangerous
16	drugs that had been adulterated. Specifically, on September 17, 2014, during an inspection at
17	FAP, a board inspector discovered a large box fill with approximately 80 prescription vials
18	returned by patients for destruction in the pharmacy.
19 20	<u>TWENTY-FIRST CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Provide Record of DEA Biennial Inventory) (Bus. & Prof. § 4031, subd. (0), & 16 CCR § 1718)
21	70. Respondent ICE, as pharmacist-in-charge of FAP, has subjected his Pharmacist
22	License to disciplinary action under Code Section 4301, subdivision (o), because he failed to
23	comply with title 16 section 1718 of the California Code of Regulations. Specifically, on
24	September 17, 2104, during an inspection, a Board inspector requested the record of the DEA
25	biennial inventory for inspection. Respondent FAP failed to provide the record for inspection. <sup>7</sup>
26 27	<sup>6</sup> On or about September 19, 2011, Respondent ICE became the PIC at Fruitvale Avenue Pharmacy. <sup>7</sup> Under title 21 of the CFR section 1304, the DEA biennial inventory shall be available
28	for inspection upon request for at least 3 years after the date of the inventory.
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1 2	<u>TWENTY-SECOND CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Consult with Patient) (Bus, & Prof. § 4301, subd. (0) and 16 CCR § 1767.2, subd. (b)(1)(A))
3	71. Respondent ICE, as pharmacist-in-charge of FAP, has subjected his Pharmacist
4	License to disciplinary action under Code section 4301, subdivision (o), because he violated
5	California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(A), in that pharmacists
6	and staff at FAP failed to consult with patients regarding new medications. The circumstances
7	are further explained in paragraph 45, above.
8	TWENTY-THIRD CAUSE FOR DISCIPLINE
9	(Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (d), & Health and Safety Code § 11153, subd. (a))
10	72. Respondent ICE, as pharmacist-in-charge of FAP, has subjected his Pharmacist
11	License to disciplinary action under Code section 4301, subdivision (d), because FAP engaged in
12	the excessive furnishing of controlled substances in violation of Health and Safety Code section
13	11153, subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding
14	responsibility of verifying the patient's legitimate medical purposes for controlled substances.
15	Specifically, the pharmacists and staff at FAP breached their corresponding responsibility by
16	furnishing unusually large quantities of controlled substances to patients from September 17,
17	2011 to September 17, 2014. The circumstances are further explained in paragraphs 36-49,
18	above.
19 20	<u>TWENTY-FOURTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Variation from Prescription) (Bus. & Prof. § 4301, subd. (0), & 16 CCR § 1716)
21	73. Respondent ICE, as the pharmacist-in-charge of FAP, has subjected his
22	Pharmacist License to disciplinary action under Code section 4301, subdivision (o), because FAP
23	violated California Code of Regulations, title 16, section 1716, in that FAP deviated from the
24	requirements of a prescription without prior consent of the prescriber on several occasions.
25	During the inspection of FAP on September 17, 2014, Inspector 2 reviewed prescription hard
26	copies which were processed with the wrong prescriber. The circumstances are further explained
27	in paragraph 44, above.
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1 2	<u>TWENTY-FIFTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Maintain Records of Disposition) (Bus. & Prof. § 4301, subd. (0), & 4081)
3	74. Respondent ICE, as the pharmacist-in-charge of FAP, has subjected his Pharmacist
4	License to disciplinary action under Code section 4301, subdivision (o), because FAP violated
5	Code section 4081, in that Respondent FAP did not have all records of manufacturer and of sale,
6	acquisition, or disposition of dangerous drugs or dangerous devices at all times during business
7	hours open to inspection by an authorized officer of the law, for at least three years. Specifically,
8	between the dates of September 17, 2011 and September 17, 2014, FAP could not account for
9	140.8 pints of promethazine and codeine syrup. The circumstances are further explained in
10	paragraphs 36 through 44, above.
11	TWENTY-SIXTH CAUSE FOR DISCIPLINE
12	(Unprofessional Conduct-Misuse of Education by Pharmacist) (Bus. & Prof. §§ 4301, subd. (0), & 4306.5)
13	75. Respondent ICE, as the pharmacist-in-charge of FAP, has subjected his Pharmacist
14	License to disciplinary action under Code sections 4301, subdivision (o), and 4306 in that
15	between September 17, 2011 and September 17, 2014, Respondent ICE failed to use his
16	education, training, and experience when he filled prescriptions for large quantities of narcotics
17	for patients who used multiple prescribers without confirming the prescriptions and the quantities
18	of narcotics prescribed were for a legitimate medical purpose. The circumstances are further
19	explained in paragraphs 36 through 49, above.
20	OTHER MATTERS
21	76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
22	PHY 50064 issued to Fruitvale Avenue Pharmacy Inc., it shall be prohibited from serving as a
23	manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
24	five years if Pharmacy Permit Number PHY 50064 is placed on probation or until Pharmacy
25	Permit Number PHY 50064 are reinstated if they are revoked.
26	77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
27	PHY 50064 issued to Fruitvale Avenue Pharmacy, Inc., while Respondent Iroegbu Clifford
28	Esomonu had been an officer and owner and had knowledge of or knowingly participated in any
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1	Second Amended Accusation

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conduct for which the licensee was disciplined, Respondent Iroegbu Clifford Esomonu 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 50064 are placed on
 probation or until Pharmacy Permit Number PHY 50064 are reinstated if they are revoked.
 78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
RPH 53445 issued to Respondent Iroegbu Clifford Esomonu, Respondent Iroegbu Clifford
Esomonu, 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
53445 is placed on probation or until Pharmacist License Number RPH 53445 is reinstated if it is
revoked.

## DISCIPLINE CONSIDERATIONS

To determine the degree of discipline, if any, to be imposed on Respondent ICE,
Complainant alleges that on or about December 28, 2010, in a prior action, the Board of
Pharmacy issued Citation Number CI 2010 45230 and ordered Respondent ICE to pay a \$2,500
fine for violating sections 4301, subdivisions (h) and (l) (arrest for driving under the influence
and conviction on the lesser charge of wet/reckless). That Citation is now final and is
incorporated by reference as if fully set forth.

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### PRAYER

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

Revoking or suspending Pharmacy License Number PHY 50064, issued to
 Fruitvale Avenue Pharmacy Inc.;

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2. Revoking or suspending Pharmacist License Number RPH 53516, issued to
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Revoking or suspending Pharmacist License Number RPH 53445, issued to
 Iroegbu Clifford Esomonu, Fruitvale Avenue Pharmacy Inc.;

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4. Prohibiting Fruitvale Avenue Pharmacy, Inc. from serving as a manager, 1 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if 2 Pharmacy Permit Number PHY 50064 are placed on probation or until Pharmacy Permit Number PHY 50064 are reinstated if Pharmacy Permit Number PHY 50064 issued to Fruitvale Avenue Pharmacy, Inc. are revoked;

5. Prohibiting Respondent Iroegbu Clifford Esomonu from serving as a manager, 6 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if 7 Pharmacy Permit Number PHY 50064 is placed on probation or until Pharmacy Permit Numbers 8 PHY 50064 are reinstated if Pharmacy Permit Number PHY 50064 issued to Fruitvale Avenue . 9 Pharmacy, Inc. is revoked; 10

6. Prohibiting Respondent Iroegbu Clifford Esomonu from serving as a manager, 11 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if 12 Pharmacist License Number RPH 53445 is placed on probation or until Pharmacist License 13 Number RPH 53445 is reinstated if Pharmacist License Number RPH 53445 issued to 14 15 Respondent Iroegbu Clifford Esomonu is revoked;

7. Ordering Fruitvale Avenue Pharmacy Inc., Ijeoma Nwanyiocha Esomonu and 16 Iroegbu Clifford Esomonu to pay the Board of Pharmacy the reasonable costs of the investigation 17 and enforcement of this case, pursuant to Business and Professions Code section 125.3; 18

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

DATED:

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VIRGINIA HEROLD Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant

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Attorneys for Complainant	· · · · ·
BEFO	RETHE
BOARD OF	PHARMACY CONSUMER AFFAIRS
	CALIFORNIA
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In the Matter of the Accusation Against:	Case No. 4579
FRUITVALE AVENUE PHARMACY INC.	
2693 Fruitvale Avenue	
Oakland, CA 94601	AMENDED ACCUSATION
Pharmacy License No. PHY 50064,	4) 20
IJEOMA NWAYIOCHA ESOMONU	2014
FRUITVALE AVENUE PHARMACY INC.	
16 Minaret Road Oakley, CA 94561	27. <sup>-</sup>
Pharmacist License No. RPH 53516,	
and	
IROEGBU CLIFFORD ESOMONU	-A. C.
FRUITVALE AVENUE PHARMACY INC.	5
6726 Corte Santa Maria Pleasanton, CA 94566	
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Respondents.	
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	1	Complainant alleges:
	2	PARTIES
	3	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
	4	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
	5	2. On or about October 21, 2009, the Board of Pharmacy issued Pharmacy License
	6	Number PHY 50064 to Fruitvale Avenue Pharmacy Inc. (Respondent FAP). The Pharmacy
	7	License was in full force and effect at all times relevant to the charges brought in this Accusation
	- 8	and will expire on October 1, 2013, unless renewed.
	9	3. On or about April 23, 2002, the Board of Pharmacy issued Pharmacist License
	10	Number RPH 53516 to Ijeoma Nwanyiocha Esomonu (Respondent INE). The Pharmacist
	11	License was in full force and effect at all times relevant to the charges brought in this Accusation
	12	and will expire on April 30, 2015, unless renewed.
	13	4. On or about March 28, 2002, the Board of Pharmacy issued Pharmacist Number RPH
•	14	53445 to Iroegbu Clifford Esomonu (Respondent ICE). The Pharmacist License was in full force
	15	and effect at all times relevant to the charges brought in this Accusation and will expire on
	16	September 30, 2013, unless renewed.
	17	JURISDICTION
	18	5. This Accusation is brought before the Board of Pharmacy (Board), Department of
	19	Consumer Affairs, under the authority of the following laws. All section references are to the
	20	Business and Professions Code unless otherwise indicated.
	21	6. Section 4011 of the Code provides that the Board shall administer and enforce both
	22	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
	23	Act [Health & Safety Code, § 11000 et seq.].
,	24	7. Section 4300 of the Code states:
	25	"(a) Every license issued may be suspended or revoked.
	26	"(b) The board shall discipline the holder of any license issued by the board, whose default
	27	has been entered or whose case has been heard by the board and found guilty, by any of the
·	28	following methods:
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"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

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"(e) The proceedings under this article shall be conducted in accordance with Chapter 5
(commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
shall have all the powers granted therein. The action shall be final, except that the propriety of
the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
Civil Procedure."

8. Section 4300.1 of the Code provides that "[t]he 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."

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### STATUTORY/REGULATORY PROVISIONS

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9. Section 4301 of the Code states, in relevant part:

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

"(a) Gross immortality.

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"(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or

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to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

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

"(I) The conviction of a crime substantially related to the qualifications, functions, and 7 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 8 (commencing with Section 801) of Title 21 of the United States Code regulating controlled 9 substances or of a violation of the statutes of this state regulating controlled substances or 10 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the 11 record of conviction shall be conclusive evidence only of the fact that the conviction occurred. 12 The board may inquire into the circumstances surrounding the commission of the crime, in order 13 to fix the degree of discipline or, in the case of a conviction not involving controlled substances 14 15 or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or 16 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning 17 of this provision. The board may take action when the time for appeal has elapsed, or the 18 judgment of conviction has been affirmed on appeal or when an order granting probation is made 19 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of 20 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not 21 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or 22 23 indictment.

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25 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 26 violation of or conspiring to violate any provision or term of this chapter or of the applicable 27 federal and state laws and regulations governing pharmacy, including regulations established by 28 the board or by any other state or federal regulatory agency."

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10. Section 4113, subdivision (c), of the Code provides that "[t]he 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."

4 11. Section 490 of the Code provides, in relevant part, that the Board may suspend or
5. revoke a license when it finds that the licensee has been convicted of a crime substantially related
6 to the qualifications, functions or duties of the license.

12. Section 493 of the Code states:

"Notwithstanding any other provision of law, in a proceeding conducted by a board within 8 the department pursuant to law to deny an application for a license or to suspend or revoke a 9 license or otherwise take disciplinary action against a person who holds a license, upon the 10 ground that the applicant or the licensee has been convicted of a crime substantially related to the 11 qualifications, functions, and duties of the licensee in question, the record of conviction of the 12 crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, 13 and the board may inquire into the circumstances surrounding the commission of the crime in 14 order to fix the degree of discipline or to determine if the conviction is substantially related to the 15 qualifications, functions, and duties of the licensee in question. 16

17 "As used in this section, 'license' includes 'certificate,' 'permit,' 'authority,' and
18 'registration.'"

13. Health and Safety Code section 11165, subdivision (d), states:

"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as
defined in the controlled substances schedules in federal law and regulations, specifically
Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal
Regulations, the dispensing pharmacy or clinic shall provide the following information to the
Department of Justice on a weekly basis and in a format specified by the Department of Justice:
"(1) Full name, address, and the telephone number of the ultimate user or research subject,

"(1) Full name, address, and the telephone number of the ultimate user of rescaled subject
or contact information as determined by the Secretary of the United States Department of Health
and Human Services, and the gender, and date of birth of the ultimate user.

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"(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

"(3) Pharmacy prescription number, license number, and federal controlled substance 4 registration number. 5

"(4) NDC (National Drug Code) number of the controlled substance dispensed.

"(5) Quantity of the controlled substance dispensed.

"(6) ICD-9 (diagnosis code), if available.

"(7) Number of refills ordered.

"(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request. "(9) Date of origin of the prescription.

"(10) Date of dispensing of the prescription."

14. Health and Safety Code section 11164 states, in relevant part:

14 "Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it 15 complies with the requirements of this section." 16

17 "(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form 18 as specified in Section 11162.1,...." 19

15. Health and Safety Code section 11162.1 states, in relevant part:

"(a) The prescription forms for controlled substances shall be printed with the following features:

"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall

25 appear:

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"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the 'Prescription is void if the number of drugs prescribed is not noted."

"(b) Each batch of controlled substance prescription forms shall have the lot number printed on 5 the form and each form within that batch shall be numbered sequentially beginning with the 6 numeral one." 7

16. Health and Safety Code section 11153, subdivision (a), states:

"A prescription for a controlled substance shall only be issued for a legitimate medical 9 purpose by an individual practitioner acting in the usual course of his or her professional 10 practice. The responsibility for the proper prescribing and dispensing of controlled substances is 11 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist 12 who fills the prescription. Except as authorized by this division, the following are not legal 13 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 14 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or 15 habitual user of controlled substances, which is issued not in the course of professional treatment 16 or as part of an authorized narcotic treatment program, for the purpose of providing the user with 17 controlled substances, sufficient to keep him or her comfortable by maintaining customary use." 18

17. California Code of Regulations, title 16, section 1761, states:

"(a) No pharmacist shall compound or dispense any prescription which contains any 20 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to 22 validate the prescription. 23

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense 24 a controlled substance prescription where the pharmacist knows or has objective reason to know 25 that said prescription was not issued for a legitimate medical purpose." 26

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18. California Code of Regulations, title 16, section 1770, states:

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"For the purpose of denial, suspension, or revocation of a personal or facility license

pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions, or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

## CONTROLLED SUBSTANCES

19. Section 4021 of the Code states:

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"Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

20. Oxycodone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M).

12 21. Hydrocodone with acetaminophen is a Schedule III controlled substance as
13 designated by Health and Safety Code section 11056, subdivision (e)(4).

Alprazolam is a Schedule IV controlled substance as designated by Health and Safety
Code section 11057, subdivision (d)(1).

Promethazine with codeine is a Schedule V controlled substance as designated by
Health and Safety Code section 11058.

#### COST RECOVERY

19 24. Section 125.3 of the Code provides, in relevant part, that the Board may request the 20 administrative law judge to direct a licentiate found to have committed a violation or violations of 21 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and 22 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being 23 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be 24 included in a stipulated settlement.

### FACTUAL BACKGROUND

25. From about October 21, 2009, to the present, Respondent Fruitvale Avenue Pharmacy
(FAP) has been operating as a pharmacy in Oakland, California. From on or about October 21,
2009, until May 19 2011, Respondent Ijeoma Nwanyiocha Esomonu (INE), the owner of FAP,

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was also the pharmacist-in-charge (PIC) at FAP. From on or about October 21, 2009, until May
19, 2011, Respondent Iroegbu Clifford Esomonu (ICE) worked as a pharmacist at FAP. From
May 19, 2011, to the present, Respondent ICE took over as the PIC at FAP.

26. On May 17, 2011, a Board inspector (inspector) conducted an inspection at FAP
because the Board had identified FAP as a pharmacy that failed to report any Controlled
Substances Utilization Review and Evaluation System (CURES) data to the Department of
Justice (DOJ). During the inspection at FAP, the inspector observed several pharmacy law
violations. Specifically, the inspector noted that FAP had never transmitted any CURES data to
the DOJ.

27. While at FAP, the inspector looked into prescription documents from Bay Internal 10 Medicine (BIM). The prescriptions appeared legitimate but, upon further investigation, the 11 inspector found that none of prescribers' contact information on the prescriptions contained a 12 valid working phone number. The inspector asked Respondent ICE to verify the BIM prescribers 13 on the Medical Board of California's website. The web search revealed that none of the BIM 14 prescribers' listed addresses on the Medical Board's website matched the addresses on the 15 prescriptions. Significantly, Respondent ICE admitted to the inspector that he had never before 16 verified a prescriber using the Medical Board's website. In addition, the inspector observed 17 numerous other violations of pharmacy laws. At the conclusion of the inspection, the inspector 18 prepared an inspection report documenting various pharmacy law violations. The inspector gave 19 a copy of the report to Respondent ICE, and then had Respondent ICE review and sign off on it. 20 During his inspection, the inspector obtained certain documents including prescription 21

documents, dispensing detail reports, and Cardinal Health Narcotic Sales Reports. The inspector
also requested FAP to provide additional documents and explanations regarding pharmacy law
violations indicated in the report.

25 28. On or about May 30, 2011, the inspector received and reviewed faxed responses from
FAP. Subsequently, the inspector contacted 15 different prescribers listed as the supposed
prescriber on the prescription documents. The inspector sent each prescriber a list of
prescriptions from FAP to verify the legitimacy of the prescriptions. Each of the prescribers

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Amended Accusation

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responded with a written statement that they did not authorize the prescriptions from FAP. In
 fact, one prescriber from Kaiser stated he did not authorize any of the prescriptions and that they
 were written on prescriptions that were stolen from his locker at the hospital. Additionally, one
 prescriber from BIM stated their practice had been closed since June 2009. All the BIM
 prescription documents that the inspector sent to the BIM prescribers to review were dated and
 filled by FAP in 2011.

29. Physician Assistant G. P.<sup>1</sup> (G. P.) was one of the 15 prescribers that the inspector 7 contacted to verify the legitimacy of the prescription documents he got from FAP. On or about 8 June 7, 2011, the inspector received a response from G. P., indicating that he did not authorize the 9 prescriptions and the documents were forgeries. In addition, G. P. noted that several of the 10 prescription documents were not written on proper controlled substances prescription forms. 11 Significantly, during the May 17, 2011 visit to FAP, the inspector had made the same observation 12 that FAP had improperly dispensed controlled substances on five invalid prescription documents, 13 These five prescription documents were invalid because they lacked several required security 14 features such as quantity check off boxes, the required statement of "Prescription is void if the 15 number of drugs prescribed is not noted," and the prescriptions were not sequentially numbered. 16 17 30. The inspector's investigation revealed that, from October 2009, to about April 2011, FAP failed to transmit CURES data to the DOJ. The investigation further showed that, from 18 about July 2010, to May 2011, Respondent INE, and Respondent ICE had filled over 350 19 fraudulent prescriptions. Many of these prescription documents contained significant 20 21 irregularities that should have prompted Respondent INE and Respondent ICE to verify the 22 legitimacy of the prescription before dispensing the controlled substances. In addition, a review of FAP's dispensing printouts obtained during the investigation showed Respondent Ice's initials 23 on most, if not all, of the printouts' "filled by" section. Furthermore, in a written statement, 24 Respondent ICE admitted that he was the pharmacist on duty everyday since the opening of FAP, 25 26 111 27 <sup>1</sup> G. P. is used in this document rather than the actual name of the Physician Assistant. 28

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### CAUSES OF DISCIPLINE AGAINST RESPONDENT FAP

#### FIRST CAUSE FOR DISCIPLINE

### (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d))

31. Respondent Fruitvale Avenue Pharmacy's (FAP) Pharmacy License is subject to
disciplinary action under Code section 4301, subdivision (j), because FAP violated Health and
Safety Code section 11165, subdivision (d), in that from on or about October 21, 2009, until
approximately April 2011, FAP failed to transmit dispensing data for Schedule II, Schedule III,
and Schedule IV controlled substances to the Department of Justice for the Controlled Substances
Utilization Review and Evaluation System (CURES) on a weekly basis. The circumstances are
further explained in paragraphs 25-30, above.

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### SECOND CAUSE FOR DISCIPLINE

# (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus, & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a))

32. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
section 4301, subdivision (o), because FAP violated California Code of Regulations, title 16,
section 1761, subdivision (a), in that pharmacists and staff at FAP filled over 350 irregular
prescriptions. Many of these prescription documents order an unusually large amount of
controlled substances for "as-needed" purposes. The circumstances are further explained in
paragraphs 25-30, above.

#### THIRD CAUSE FOR DISCIPLINE

 (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a))
 33. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11153,

23 subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding

24 responsibility of verifying the patient's legitimate medical purposes for controlled substances.

25 The pharmacists and staff at FAP breached their corresponding responsibility by furnishing

26 unusually large quantities of controlled substances to patients without confirming with the

27 supposed prescribers the legitimacy of the prescriptions. In fact, the pharmacists and staff at FAP

28 filled approximately 350 fraudulent prescriptions, many of which were for unusually large

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quantities of controlled substances. The circumstances are further explained in paragraphs 25-30, 1 2 above. 3 FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164) 4 Respondent FAP's Pharmacy License is subject to disciplinary action under Code 34. 5 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11164, in that 6 the pharmacists and staff at FAP furnished controlled substances to patients based on invalid 7 controlled substances prescription forms. Specifically, during May 2011, FAP filled five 8 prescription documents that lacked several required security measures. The circumstances are 9 further explained in paragraphs 25-30, above. 10 CAUSES OF DISCIPLINE AGAINST RESPONDENT INE 11 12 FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) 13 (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d)) 35. Respondent Ijeoma Nwanyiocha Esomonu (INE), as Pharmacist-in-Charge of FAP, 14 has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision 15 (j), by violating Health and Safety Code sections 11165, subdivision (d), in that from on or about 16 October 21, 2009, until approximately April 2011, INE failed to insure that FAP transmit to the 17 Department of Justice for the Controlled Substances Utilization Review and Evaluation System 18 (CURES) dispensing data for Schedule II, Schedule III, and Schedule IV controlled substances on 19 a weekly basis. The circumstances are further explained in paragraphs 25-30, above. 20 21 SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a)) 22 36. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 23 License to disciplinary action under Code section 4301, subdivision (o), because she violated 24 California Code of Regulations, title 16, section 1761, subdivision (a), in that pharmacists and 25 staff at FAP filled over 350 irregular prescriptions. Many of these prescription documents order 26 an unusually large amount of controlled substances for "as-needed" purposes. The circumstances 27 28 are further explained in paragraphs 25-30, above. 12

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1 SEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 2 37. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 3 License to disciplinary action under Code section 4301, subdivision (j), because she violated 4 Health and Safety Code section 11153, subdivision (a), in that pharmacists and staff at FAP failed 5 to uphold their corresponding responsibility of verifying the patient's legitimate medical purposes 6 for controlled substances. The pharmacists and staff at FAP breached their corresponding 7 responsibility by furnishing unusually large quantities of controlled substances to patients without 8 confirming with the supposed prescribers the legitimacy of the prescriptions. In fact, the 9 pharmacists and staff at FAP filled approximately 350 fraudulent prescriptions, many of which 10 were for unusually large quantities of controlled substances. The circumstances are further 11 explained in paragraphs 25-30, above. 12

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EIGHTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164) 14 Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 38. 15 License to disciplinary action under Code section 4301, subdivision (j), because she violated 16 Health and Safety Code section 11164, in that the pharmacists and staff at FAP furnished 17 controlled substances to patients based on invalid controlled substances prescription forms. 18 Specifically, during May 2011, FAP filled five prescription documents that lacked several 19 required security measures. The circumstances are further explained in paragraphs 25-30, above. 20

# CAUSES OF DISCIPLINE AGAINST RESPONDENT ICE

# NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a))

39. Respondent Iroegbu Clifford Esomonu (ICE), as a pharmacist of FAP, has subjected 24 his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), because 25 he violated California Code of Regulations, title 16, section 1761, subdivision (a), in that 26 Respondent ICE filled prescriptions with significant irregularity. Many of the prescriptions order 27 unusually large quantities of controlled substances including oxycodone, hydrocodone with

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Amended Accusation

acetaminophen, alprazolam and promethazine with codeine. The circumstances are further explained in paragraphs 25-30, above.

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<u>TENTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a))

40. Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (j), because he violated Health and Safety Code section 11153, subdivision (a), in that, on numerous occasions, Respondent ICE failed to verify the legitimate medical purpose for prescribing an unusually large quantity of controlled substances. In fact, FAP's drug dispensing printouts show that Respondent ICE filled approximately 350 fraudulent prescriptions, many which were for unusually large quantities of controlled substances. The circumstances are further explained in paragraphs 25-30, above.

ELEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164)

Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to 14 41. disciplinary action under Code section 4301, subdivision (j), in that Respondent ICE dispensed 15 controlled substances based on invalid prescription documents. Specifically, Respondent ICE's 16 initials were on the pharmacy dispensing printouts for those five invalid prescription documents. 17 The circumstances are further explained in paragraphs 25-30 above. 18

### TWELFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Use of Alcohol in a Dangerous Manner) (Bus. & Prof. § 4301, subd. (h))

42. Respondent ICE has subjected his Pharmacist License to disciplinary action under 21 Code section 4301, subdivision (h), in that on or about April 23, 2012, Respondent ICE was 22 arrested by a San Leandro police officer for driving under the influence of alcohol. The 23 circumstances are as follows: 24

43. 25 On or about 12:25 a.m. on April 23, 2012, a San Leandro police officer stopped Respondent's vehicle for a violation of Vehicle Code section 21650 (a vehicle on the highway 26 must be driven on the right side of the road). The officer approached Respondent's vehicle and 27 observed symptoms of intoxication including red watery eyes, alcoholic odor emitting from 28

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Amended Accusation

Respondent's breath and slurred speech. Respondent failed a series of field sobriety tests. Two
 breath tests from Respondent at approximately 1:19 a.m. and 1:22 a.m. revealed a blood alcohol
 concentration (BAC) of .13.

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### THIRTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Conviction) (Bus. & Prof. §§ 490 & 4301, subd. (I))

6 44. Respondent ICE has subjected his Pharmacist License to disciplinary action under
7 Code section 4301, subdivision (1), and section 490, in that Respondent ICE was convicted of a
8 crime substantially related to the qualifications, functions and duties of a pharmacist. The
9 circumstances are as follows:

45. On or about December 13, 2012, in a criminal matter entitled *People of the State of California v. Iroegbu Clifford Esomonu*, in the Alameda County Superior Court, Respondent ICE
was convicted upon plea of no contest to the violation of Vehicle Code section 23152,

subdivision (b) (driving with a blood alcohol level of .08 or more), a misdemeanor. Respondent
ICE was ordered to serve 15 days in county jail. Respondent was placed on probation for 3 years
with various conditions including completing a Drinking Driver Program and paying various fees
and fines.

# DISCIPLINE CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondent ICE,
Complainant alleges that on or about December 28, 2010, in a prior action, the Board of
Pharmacy issued Citation Number CI 2010 45230 and ordered Respondent ICE to pay a \$2,500
fine for violating sections 4301, subdivisions (h) and (l) [arrest for driving under the influence
and conviction on the lesser charge of wet/reckless]. That Citation is now final and is
incorporated by reference as if fully set forth.

### PRAYER

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

 Revoking or suspending Pharmacy License Number PHY 50064, issued to Fruitvale Avenue Pharmacy Inc.;

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Amended Accusation

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. 1	2. Revoking or suspending Pharmacist License Number RPH 53516, issued to	{
2	Ijeoma Nwanyiocha Esomonu, Fruitvale Avenue Pharmacy Inc.;	
3	3. Revoking or suspending Pharmacist License Number RPH 53445, issued to	
4	Iroegbu Clifford Esomonu, Fruitvale Avenue Pharmacy Inc.;	
5	4. Ordering Fruitvale Avenue Pharmacy Inc., Ijeoma Nwanyiocha Esomonu and	
6	Iroegbu Clifford Esomonu to pay the Board of Pharmacy the reasonable costs of the investigation	
7	and enforcement of this case, pursuant to Business and Professions Code section 125.3;	
8	5. Taking such other and further action as deemed necessary and proper.	
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-11	DATED: 12/17/13 ()11001 No. 1	
12	VIRGINIA HEROLD	
13	Executive Officer Board of Pharmacy	
14	Department of Consumer Affairs State of California	
15	Complainant SF2013901373	
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1	KAMALA D. HARRIS	}
2	Attorney General of California DIANN SOKOLOFF	· · · · · ·
3	Supervising Deputy Attorney General TIMOTHY J. MCDONOUGH	
4	Deputy Attorney General	× *
	State Bar No. 235850 1515 Clay Street, 20th Floor	· · · · ·
5	P.O. Box 70550 Oakland, CA 94612-0550	
6	Telephone: (510) 622-2134	
7	Facsimile: (510) 622-2270 E-mail: Tim.McDonough@doj.ca.gov Attorneys for Complainant	
8		
9	BOARD OF	RE THE PHARMACY
10	DEPARTMENT OF C STATE OF C	CONSUMER AFFAIRS CALIFORNIA
11		1
12	In the Matter of the Accusation Against:	Case No. 4579
3	FRUITVALE AVENUE PHARMACY INC. 2693 Fruitvale Avenue	
14	Oakland, CA 94601	ACCUSATION
15	Pharmacy License No. PHY 50064,	
16	IJEOMA NWAYIOCHA ESOMONU	
17	FRUITVALE AVENUE PHARMACY INC. 16 Minaret Road	
18	Oakley, CA 94561	
- 3	Pharmacist License No. RPH 53516,	
19	and	
20	IROEGBU CLIFFORD ESOMONU FRUITVALE AVENUE PHARMACY INC.	
21	6726 Corte Santa Maria Pleasanton, CA 94566	
22	Pharmacist No. RPH 53445	a
23		*
24	Respondents.	
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Complainant alleges:

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# PARTIES

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

2. On or about October 21, 2009, the Board of Pharmacy issued Pharmacy License
Number PHY 50064 to Fruitvale Avenue Pharmacy Inc. (Respondent FAP). The Pharmacy
License was in full force and effect at all times relevant to the charges brought in this Accusation
and will expire on October 1, 2013, unless renewed.

9 3. On or about April 23, 2002, the Board of Pharmacy issued Pharmacist License
Number RPH 53516 to Ijeoma Nwanyiocha Esomonu (Respondent INE). The Pharmacist
11- License was in full force and effect at all times relevant to the charges brought in this Accusation
12 and will expire on April 30, 2015, unless renewed.

4. On or about March 28, 2002, the Board of Pharmacy issued Pharmacist Number RPH
 53445 to Iroegbu Clifford Esomonu (Respondent ICE). The Pharmacist License was in full force
 and effect at all times relevant to the charges brought in this Accusation and will expire on
 September 30, 2013, unless renewed.

# JURISDICTION

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

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.].

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Section 4300 of the Code states:

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

"(b) The board shall discipline the holder of any license issued by the board, whose default
has been entered or whose case has been heard by the board and found guilty, by any of the
following methods:

. . . 2

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

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"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

8. Section 4300.1 of the Code provides that "[t]he 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."

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# STATUTORY/REGULATORY PROVISIONS

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9. Section 4301 of the Code states, in relevant part:

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

"(a) Gross immortality.

26 "(h) The administering to oneself, of any controlled substance, or the use of any dangerous
27 drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to
28 oneself, to a person holding a license under this chapter, or to any other person or to the public, or

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to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license. 2

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. . .

"(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.

"(1) The conviction of a crime substantially related to the qualifications, functions, and 7 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 8 9 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or 10 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the 41record of conviction shall be conclusive evidence only of the fact that the conviction occurred. 12 13 The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances 14 15 or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or 16 17 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the 18 judgment of conviction has been affirmed on appeal or when an order granting probation is made 19 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of 20 21 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or 22 23 indictment.

25 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable 26 federal and state laws and regulations governing pharmacy, including regulations established by 27 the board or by any other state or federal regulatory agency." 28

10. Section 4113, subdivision (c), of the Code provides that "[t]he 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 490 of the Code provides, in relevant part, that the Board may suspend or
revoke a license when it finds that the licensee has been convicted of a crime substantially related
to the qualifications, functions or duties of the license.

12. Section 493 of the Code states:

(....

"Notwithstanding any other provision of law, in a proceeding conducted by a board within 8 the department pursuant to law to deny an application for a license or to suspend or revoke a 9 license or otherwise take disciplinary action against a person who holds a license, upon the 10 ground that the applicant or the licensee has been convicted of a crime substantially related to the 11 qualifications, functions, and duties of the licensee in question, the record of conviction of the 12 crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, 13 and the board may inquire into the circumstances surrounding the commission of the crime in 14 order to fix the degree of discipline or to determine if the conviction is substantially related to the 15 qualifications, functions, and duties of the licensee in question. 16

"As used in this section, 'license' includes 'certificate,' 'permit,' 'authority,' and
'registration.'"

13. Health and Safety Code section 11165, subdivision (d), states:

and Human Services, and the gender, and date of birth of the ultimate user.

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"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as
defined in the controlled substances schedules in federal law and regulations, specifically
Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal
Regulations, the dispensing pharmacy or clinic shall provide the following information to the
Department of Justice on a weekly basis and in a format specified by the Department of Justice:
"(1) Full name, address, and the telephone number of the ultimate user or research subject,
or contact information as determined by the Secretary of the United States Department of Health

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1	"(2) The prescriber's category of licensure and license number; federal controlled
2	substance registration number; and the state medical license number of any prescriber using the
3	federal controlled substance registration number of a government-exempt facility.
4	"(3) Pharmacy prescription number, license number, and federal controlled substance
5	registration number.
6	"(4) NDC (National Drug Code) number of the controlled substance dispensed.
7	"(5) Quantity of the controlled substance dispensed.
8	"(6) ICD-9 (diagnosis code), if available.
9	"(7) Number of refills ordered.
10	"(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
11	"(9) Date of origin of the prescription.
12	"(10) Date of dispensing of the prescription."
13	14. Health and Safety Code section 11164 states, in relevant part:
14	"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall
15	any person fill, compound, or dispense a prescription for a controlled substance, unless it
16	complies with the requirements of this section."
17	"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V,
18	except as authorized by subdivision (b), shall be made on a controlled substance prescription form
19	as specified in Section 11162.1"
20	15. Health and Safety Code section 11162.1 states, in relevant part:
21	"(a) The prescription forms for controlled substances shall be printed with the following features:
22	•••
23	"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber
24	may indicate the quantity by checking the applicable box where the following quantities shall
25	appear:
26	<ul> <li>1-24</li> <li>25-49</li> <li>50-74</li> </ul>
27	- 75-100 - 101-150
28	<ul> <li>151 and over.</li> </ul>
	6 · Accusation

"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the 'Prescription is void if the number of drugs prescribed is not noted."

"(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one."

16. Health and Safety Code section 11153, subdivision (a), states:

"A prescription for a controlled substance shall only be issued for a legitimate medical 9 purpose by an individual practitioner acting in the usual course of his or her professional 10 practice. The responsibility for the proper prescribing and dispensing of controlled substances is 11 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist 12 who fills the prescription. Except as authorized by this division, the following are not legal 13 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 14 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or 15 habitual user of controlled substances, which is issued not in the course of professional treatment 16 or as part of an authorized narcotic treatment program, for the purpose of providing the user with 17 controlled substances, sufficient to keep him or her comfortable by maintaining customary use." 18 19

17. California Code of Regulations, title 16, section 1761, states:

"(a) No pharmacist shall compound or dispense any prescription which contains any 20 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any 21 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to 22 23 validate the prescription.

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense 24 a controlled substance prescription where the pharmacist knows or has objective reason to know 25 that said prescription was not issued for a legitimate medical purpose." 26

18. California Code of Regulations, title 16, section 1770, states:

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"For the purpose of denial, suspension, or revocation of a personal or facility license

pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a 1 crime or act shall be considered substantially related to the qualifications, functions, or duties of a 2 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a 3 licensee or registrant to perform the functions authorized by his license or registration in a manner 4 consistent with the public health, safety, or welfare." 5 CONTROLLED SUBSTANCES 6 19. 7 Section 4021 of the Code states: "Controlled substance' means any substance listed in Chapter 2 (commencing with Section 8 11053) of Division 10 of the Health and Safety Code." 9 Oxycodone is a Schedule II controlled substance as designated by Health and Safety 10 20. Code section 11055, subdivision (b)(1)(M).... 11 12 21. Hydrocodone with acetaminophen is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(4). 13 14 22. Alprazolam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1). 15 23. Promethazine with codeine is a Schedule V controlled substance as designated by 16 Health and Safety Code section 11058. 17 18 COST RECOVERY 19 24, Section 125.3 of the Code provides, in relevant part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of 20 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and 21 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being 22 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be 23 included in a stipulated settlement. 24 25 FACTUAL BACKGROUND 26 25, From about October 21, 2009, to the present, Respondent Fruitvale Avenue Pharmacy (FAP) has been operating as a pharmacy in Oakland, California. From on or about October 21, 27 28 2009, until May 19 2011, Respondent Ijeoma Nwanyiocha Esomonu (INE), the owner of FAP, Accusation was also the pharmacist-in-charge (PIC) at FAP. From on or about October 21, 2009, until May
 19, 2011, Respondent Iroegbu Clifford Esomonu (ICE) worked as a pharmacist at FAP. From
 May 19, 2011, to the present, Respondent ICE took over as the PIC at FAP.

26. On May 17, 2011, Board Inspector conducted an inspection at FAP
because the Board had identified FAP as a pharmacy that failed to report any Controlled
Substances Utilization Review and Evaluation System (CURES) data to the Department of
Justice (DOJ). During the inspection at FAP, Inspector conducted several pharmacy law
violations. Specifically, Inspector conducted that FAP had never transmitted any CURES
data to the DOJ.

27. While at FAP, Inspector looked into prescription documents from Bay 10 Internal Medicine (BIM). The prescriptions appeared legitimate but, upon further investigation, . 11 found that none of prescribers' contact information on the prescriptions Inspector 12 contained a valid working phone number. Inspector asked Respondent ICE to verify the 13 BIM prescribers on the Medical Board of California's website. The web search revealed that 14 none of the BIM prescribers' listed addresses on the Medical Board's website matched the 15 addresses on the prescriptions. Significantly, Respondent ICE admitted to Inspector that 16 he had never before verified a prescriber using the Medical Board's website. In addition, 17 observed numerous other violations of pharmacy laws. At the conclusion of Inspector 18 prepared an inspection report documenting various pharmacy the inspection, Inspector 19 law violations. Inspector gave a copy of the report to Respondent ICE, and then had 20 obtained Respondent ICE review and sign off on it. During his inspection, Inspector 21 certain documents including prescription documents, dispensing detail-reports, and Cardinal 22 Health Narcotic Sales Reports. Inspector also requested FAP to provide additional 23 documents and explanations regarding pharmacy law violations indicated in the report. 24 On or about May 30, 2011, Inspector received and reviewed faxed responses 28. 25 from FAP. Subsequently, Inspector contacted 15 different prescribers listed as the 26 supposed prescriber on the prescription documents. Inspector sent each prescriber a list 27 of prescriptions from FAP to verify the legitimacy of the prescriptions. Each of the prescribers 28 9

responded with a written statement that they did not authorize the prescriptions from FAP. In fact, one prescriber from Kaiser stated he did not authorize any of the prescriptions and that they 2 were written on prescriptions that were stolen from his locker at the hospital. Additionally, one .3 prescriber from BIM stated their practice had been closed since June 2009. All the BIM prescription documents that Inspector sent to the BIM prescribers to review were dated 5 and filled by FAP in 2011. 6

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7 29. Physician Assistant George Pearson was one of the 15 prescribers that Inspector contacted to verify the legitimacy of the prescription documents he got from FAP. On or 8 about June 7, 2011, Inspector Treceived a response from Mr. Pearson, indicating that he 9 did not authorize the prescriptions and the documents were forgeries. In addition, Mr. Pearson 10 noted that several of the prescription documents were not written on proper controlled substances 11 prescription forms. Significantly, during the May 17, 2011 visit to FAP, Inspector 12 l had made the same observation that FAP had improperly dispensed controlled substances on five 13 invalid prescription documents. These five prescription documents were invalid because they 14 lacked several required security features such as quantity check off boxes, the required statement 15 of "Prescription is void if the number of drugs prescribed is not noted," and the prescriptions were 16 17 not sequentially numbered.

18 30, Inspector 's investigation revealed that, from October 2009, to about April 19 2011, FAP failed to transmit CURES data to the DOJ. The investigation further showed that, from about July 2010, to May 2011, Respondent INE, and Respondent ICE had filled over 350 20 21 fraudulent prescriptions. Many of these prescription documents contained significant irregularities that should have prompted Respondent INE and Respondent ICE to verify the 22 legitimacy of the prescription before dispensing the controlled substances. In addition, a review 23 of FAP's dispensing printouts obtained during the investigation showed Respondent Ice's initials 24 on most, if not all, of the printouts' "filled by" section. Furthermore, in a written statement, 25 26 Respondent ICE admitted that he was the pharmacist on duty everyday since the opening of FAP. 27 III111

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# CAUSES OF DISCIPLINE AGAINST RESPONDENT FAP

# FIRST CAUSE FOR DISCIPLINE

# (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus, & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d))

31. Respondent Fruitvale Avenue Pharmacy's (FAP) Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (j), because FAP violated Health and Safety Code section 11165, subdivision (d), in that from on or about October 21, 2009, until approximately April 2011, FAP failed to transmit dispensing data for Schedule II, Schedule III, and Schedule IV controlled substances to the Department of Justice for the Controlled Substances Utilization Review and Evaluation System (CURES) on a weekly basis. The circumstances are further explained in paragraphs 25-30, above.

# (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a))

32. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
section 4301, subdivision (o), because FAP violated California Code of Regulations, title 16,
section 1761, subdivision (a), in that pharmacists and staff at FAP filled over 350 irregular
prescriptions. Many of these prescription documents order an unusually large amount of
controlled substances for "as-needed" purposes. The circumstances are further explained in
paragraphs 25-30, above.

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# THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 20 33. Respondent FAP's Pharmacy License is subject to disciplinary action under Code 21 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11153, 22 subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding 23 responsibility of verifying the patient's legitimate medical purposes for controlled substances. 24 The pharmacists and staff at FAP breached their corresponding responsibility by furnishing 25 unusually large quantities of controlled substances to patients without confirming with the 26 supposed prescribers the legitimacy of the prescriptions. In fact, the pharmacists and staff at FAP 27 filled approximately 350 fraudulent prescriptions, many of which were for unusually large 28 11

quantities of controlled substances. The circumstances are further explained in paragraphs 25-30, 1 above. 2 3 FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164) 4 Respondent FAP's Pharmacy License is subject to disciplinary action under Code 34. 5 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11164, in that 6 the pharmacists and staff at FAP furnished controlled substances to patients based on invalid 7 controlled substances prescription forms. Specifically, during May 2011, FAP filled five 8 prescription documents that lacked several required security measures. The circumstances are 9 further explained in paragraphs 25-30, above. 10 CAUSES OF DISCIPLINE AGAINST RESPONDENT INE -11 12 FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) 13 (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d)) Respondent Ijeoma Nwanyiocha Esomonu (INE), as Pharmacist-in-Charge of FAP, 35. 14 has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision 15 (j), by violating Health and Safety Code sections 11165, subdivision (d), in that from on or about 16 October 21, 2009, until approximately April 2011, INE failed to insure that FAP transmit to the 17 Department of Justice for the Controlled Substances Utilization Review and Evaluation System 18 (CURES) dispensing data for Schedule II, Schedule III, and Schedule IV controlled substances on 19 a weekly basis. The circumstances are further explained in paragraphs 25-30, above. 20 21 SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) 22 (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a)) Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 23 36. License to disciplinary action under Code section 4301, subdivision (o), because she violated 24 California Code of Regulations, title 16, section 1761, subdivision (a), in that pharmacists and 25 staff at FAP filled over 350 irregular prescriptions. Many of these prescription documents order 26 an unusually large amount of controlled substances for "as-needed" purposes. The circumstances 27 are further explained in paragraphs 25-30, above. 28 ; 12

SEVENTH CAUSE FOR DISCIPLINE

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(Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 37. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision (j), because she violated Health and Safety Code section 11153, subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding responsibility of verifying the patient's legitimate medical purposes for controlled substances. The pharmacists and staff at FAP breached their corresponding responsibility by furnishing unusually large quantities of controlled substances to patients without 8 confirming with the supposed prescribers the legitimacy of the prescriptions. In fact, the 9 pharmacists and staff at FAP filled approximately 350 fraudulent prescriptions, many of which 10 were for unusually large quantities of controlled substances. The circumstances are further ..... explained in paragraphs 25-30, above 12

# EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164)

38. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 15 License to disciplinary action under Code section 4301, subdivision (j), because she violated 16 Health and Safety Code section 11164, in that the pharmacists and staff at FAP furnished 17 controlled substances to patients based on invalid controlled substances prescription forms. 18 Specifically, during May 2011, FAP filled five prescription documents that lacked several 19 required security measures. The circumstances are further explained in paragraphs 25-30, above. 20

# CAUSES OF DISCIPLINE AGAINST RESPONDENT ICE

# NINTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity)

(Bus. & Prof. §.4301, subd. (o) and 16 CCR § 1761, subd. (a))

39. Respondent Iroegbu Clifford Esomonu (ICE), as a pharmacist of FAP, has subjected

his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), because 25

he violated California Code of Regulations, title 16, section 1761, subdivision (a), in that 26

Respondent ICE filled prescriptions with significant irregularity. Many of the prescriptions order 27

unusually large quantities of controlled substances including oxycodone, hydrocodone with 28

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acetaminophen, alprazolam and promethazine with codeine. The circumstances are further 1 2 explained in paragraphs 25-30, above, 3 TENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 4

40. Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (j), because he violated Health and Safety Code section 11153, subdivision (a), in that, on numerous occasions, Respondent ICE failed to verify the legitimate medical purpose for prescribing an unusually large quantity of controlled substances. In fact, FAP's drug dispensing printouts show that Respondent ICE filled approximately 350 fraudulent prescriptions, many which were for unusually large quantities of controlled substances. The circumstances are further explained in paragraphs 25-30, above....

# <u>ELEVENTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164)

Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to 14 41. disciplinary action under Code section 4301, subdivision (j), in that Respondent ICE dispensed 15 controlled substances based on invalid prescription documents. Specifically, Respondent ICE's 16 initials were on the pharmacy dispensing printouts for those five invalid prescription documents, 17 The circumstances are further explained in paragraphs 25-30 above. 18

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# <u>TWELFTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Use of Alcohol in a Dangerous Manner) (Bus. & Prof. § 4301, subd. (h))

42. Respondent ICE has subjected his Pharmacist License to disciplinary action under 21 22 Code section 4301, subdivision (h), in that on or about April 23, 2012, Respondent ICE was arrested by a San Leandro police officer for driving under the influence of alcohol. The 23 circumstances are as follows: 24

25 43. On or about 12:25 a.m. on April 23, 2012, a San Leandro police officer stopped Respondent's vehicle for a violation of Vehicle Code section 21650 (a vehicle on the highway 26 must be driven on the right side of the road). The officer approached Respondent's vehicle and 27 28 observed symptoms of intoxication including red watery eyes, alcoholic odor emitting from

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Respondent's breath and slurred speech. Respondent failed a series of field sobriety tests. Two breath tests from Respondent at approximately 1:19 a.m. and 1:22 a.m. revealed a blood alcohol concentration (BAC) of .13.

# THIRTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Conviction) (Bus. & Prof. §§ 490 & 4301, subd. (l))

44. Respondent ICE has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (l), and section 490, in that Respondent ICE was convicted of a crime substantially related to the qualifications, functions and duties of a pharmacist. The circumstances are as follows:

45. On or about December 13, 2012, in a criminal matter entitled *People of the State of California v. Iroegbu Clifford Esomoriu*, in the Alameda County-Superior Court, Respondent ICE
was convicted upon plea of no contest to the violation of Vehicle Code section 23152,
subdivision (b) (driving with a blood alcohol level of .08 or more), a misdemeanor. Respondent
ICE was ordered to serve 15 days in county jail. Respondent was placed on probation for 3 years
with various conditions including completing a Drinking Driver Program and paying various fees

# 16 and fines.

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# DISCIPLINE CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondent ICE,
Complainant alleges that on or about December 28, 2010, in a prior action, the Board of
Pharmacy issued Citation Number CI 2010 45230 and ordered Respondent ICE to pay a \$2,500
fine for violating sections 4301, subdivisions (h) and (l) [arrest for driving under the influence
and conviction on the lesser charge of wet/reckless]. That Citation is now final and is
incorporated by reference as if fully set forth.

# PRAYER

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

Revoking or suspending Pharmacy License Number PHY 50064, issued to
 Fruitvale Avenue Pharmacy Inc.;

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(:)Revoking or suspending Pharmacist License Number RPH 53516, issued to 2, 1 Ijeoma Nwanyiocha Esomonu, Fruitvale Avenue Pharmacy Inc.; 2 Revoking or suspending Pharmacist License Number RPH 53445, issued to 3 3. Iroegbu Clifford Esomonu, Fruitvale Avenue Pharmacy Inc.; 4 Ordering Fruitvale Avenue Pharmacy Inc., Ijeoma Nwanyiocha Esomonu and 5 4, Iroegbu Clifford Esomonu to pay the Board of Pharmacy the reasonable costs of the investigation 6 and enforcement of this case, pursuant to Business and Professions Code section 125.3; 7 Taking such other and further action as deemed necessary and proper. 8 5. 9 10 11 DATED: 12 VIRGINIA HEROLD Executive Officer 13 Board of Pharmacy Department of Consumer Affairs 14 State of California 15 Complationt SF2013901373 16 90329994.docx 17 18 19 20 21 22 23 24 25 26 27 28 16 Accusation

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1 KAMALA D. HARRIS Attorney General of California 2 DIANN ŠOKOLOFF Supervising Deputy Attorney General TIMOTHY J. MCDONOUGH 3 Deputy Attorney General State Bar No. 235850 1515 Clay Street, 20th Floor P.O. Box 70550 4 5 Oakland, CA 94612-0550 б Telephone: (510) 622-2134 Facsimile: (510) 622-2270 7 E-mail: Tim.McDonough@doj.ca.gov Attorneys for Complainant 8 **BEFORE THE** 9 **BOARD OF PHARMACY** DEPARTMENT OF CONSUMER AFFAIRS 10 STATE OF CALIFORNIA 11 In the Matter of the Accusation Against: Case No. 4579 12 FRUITVALE AVENUE PHARMACY INC. 13 2693 Fruityale Avenue Oakland, CA 94601 ACCUSATION 14 Pharmacy License No. PHY 50064, 15 IJEOMA NWAYIOCHA ESOMONU 16 FRUITVALE AVENUE PHARMACY INC. 16 Minaret Road 17 Oakley, CA 94561 18 Pharmacist License No. RPH 53516, 19 and 20 **IROEGBU CLIFFORD ESOMONU** FRUITVALE AVENUE PHARMACY INC. 21 6726 Corte Santa Maria Pleasanton, CA 94566 22 Pharmacist No. RPH 53445 23 Respondents. 24 25 26 27 28 1

Comp	lainant	alleges:
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# <u>PARTIES</u>

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

2. On or about October 21, 2009, the Board of Pharmacy issued Pharmacy License Number PHY 50064 to Fruitvale Avenue Pharmacy Inc. (Respondent FAP). The Pharmacy License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on October 1, 2013, unless renewed.

9 3. On or about April 23, 2002, the Board of Pharmacy issued Pharmacist License
10 Number RPH 53516 to Ijeoma Nwanyiocha Esomonu (Respondent INE). The Pharmacist
11- License was in full force and effect at all times relevant to the charges brought in this Accusation
12 and will expire on April 30, 2015, unless renewed.

4. On or about March 28, 2002, the Board of Pharmacy issued Pharmacist Number RPH
 53445 to Iroegbu Clifford Esomonu (Respondent ICE). The Pharmacist License was in full force
 and effect at all times relevant to the charges brought in this Accusation and will expire on
 September 30, 2013, unless renewed.

# JURISDICTION

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

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

7. Section 4300 of the Code states:

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

"(b) The board shall discipline the holder of any license issued by the board, whose default
has been entered or whose case has been heard by the board and found guilty, by any of the
following methods:

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"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding.one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

8 "(e) The proceedings under this article shall be conducted in accordance with Chapter 5
9 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
10 shall have all the powers granted therein. The action shall be final, except that the propriety of
11 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
12 Civil Procedure."

8. Section 4300.1 of the Code provides that "[t]he 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."

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# STATUTORY/REGULATORY PROVISIONS

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9. Section 4301 of the Code states, in relevant part:

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

"(a) Gross immortality.

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"(h) The administering to oneself, of any controlled substance, or the use of any dangerous
drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to
oneself, to a person holding a license under this chapter, or to any other person or to the public, or

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to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

"(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.

7 "(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 8 (commencing with Section 801) of Title 21 of the United States Code regulating controlled 9 substances or of a violation of the statutes of this state regulating controlled substances or 10 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the 41 record of conviction shall be conclusive evidence only of the fact that the conviction occurred. 12 13 The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances 14 or dangerous drugs, to determine if the conviction is of an offense substantially related to the 15 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or 16 17 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the 18 judgment of conviction has been affirmed on appeal or when an order granting probation is made 19 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of 20 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not 21 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or 22 23 indictment.

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25 "(0) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 26 violation of or conspiring to violate any provision or term of this chapter or of the applicable 27 federal and state laws and regulations governing pharmacy, including regulations established by 28 the board or by any other state or federal regulatory agency."

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Section 4113, subdivision (c), of the Code provides that "[t]he 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."

11. Section 490 of the Code provides, in relevant part, that the Board may suspend or
revoke a license when it finds that the licensee has been convicted of a crime substantially related
to the qualifications, functions or duties of the license.

12. Section 493 of the Code states:

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"Notwithstanding any other provision of law, in a proceeding conducted by a board within 8 the department pursuant to law to deny an application for a license or to suspend or revoke a 9 license or otherwise take disciplinary action against a person who holds a license, upon the 10 ground that the applicant or the licensee has been convicted of a crime substantially related to the 11 qualifications, functions, and duties of the licensee in question, the record of conviction of the 12 crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, 13 and the board may inquire into the circumstances surrounding the commission of the crime in 14 order to fix the degree of discipline or to determine if the conviction is substantially related to the 15 qualifications, functions, and duties of the licensee in question. 16 "As used in this section, 'license' includes 'certificate,' 'permit,' 'authority,' and 17

18 "registration."

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13. Health and Safety Code section 11165, subdivision (d), states:

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"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as 20 defined in the controlled substances schedules in federal law and regulations, specifically 21 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal 22 Regulations, the dispensing pharmacy or clinic shall provide the following information to the 23 Department of Justice on a weekly basis and in a format specified by the Department of Justice: 24 "(1) Full name, address, and the telephone number of the ultimate user or research subject, 25 or contact information as determined by the Secretary of the United States Department of Health 26 and Human Services, and the gender, and date of birth of the ultimate user. 27

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1	"(2) The prescriber's category of licensure and license number; federal controlled
2	substance registration number; and the state medical license number of any prescriber using the
3	federal controlled substance registration number of a government-exempt facility.
4	"(3) Pharmacy prescription number, license number, and federal controlled substance
5	registration number.
6	"(4) NDC (National Drug Code) number of the controlled substance dispensed.
7	"(5) Quantity of the controlled substance dispensed.
8	"(6) ICD-9 (diagnosis code), if available.
9	"(7) Number of refills ordered.
0	"(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request,
1	"(9) Date of origin of the prescription.
2	"(10) Date of dispensing of the prescription."
3	14. Health and Safety Code section 11164 states, in relevant part:
4	"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall
5	any person fill, compound, or dispense a prescription for a controlled substance, unless it
6	complies with the requirements of this section."
7	"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V,
8	except as authorized by subdivision (b), shall be made on a controlled substance prescription form
9	as specified in Section 11162.1"
20	15. Health and Safety Code section 11162.1 states, in relevant part:
21	"(a) The prescription forms for controlled substances shall be printed with the following features:
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23	"(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber
24	may indicate the quantity by checking the applicable box where the following quantities shall
25	appear: • 1-24
26	• 1724 • 25-49 • 50-74
27	• 75-100 • 101-150
28	<ul> <li>151 and over.</li> </ul>
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"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the 'Prescription is void if the number of drugs prescribed is not noted."

"(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one."

16. Health and Safety Code section 11153, subdivision (a), states:

"A prescription for a controlled substance shall only be issued for a legitimate medical 9 purpose by an individual practitioner acting in the usual course of his or her professional 10 practice. The responsibility for the proper prescribing and dispensing of controlled substances is 11 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist 12 who fills the prescription. Except as authorized by this division, the following are not legal 13 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 14 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or 15 habitual user of controlled substances, which is issued not in the course of professional treatment 16 or as part of an authorized narcotic treatment program, for the purpose of providing the user with 17 controlled substances, sufficient to keep him or her comfortable by maintaining customary use." 18 17. California Code of Regulations, title 16, section 1761, states: 19

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

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense
a controlled substance prescription where the pharmacist knows or has objective reason to know
that said prescription was not issued for a legitimate medical purpose."

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18. California Code of Regulations, title 16, section 1770, states:"For the purpose of denial, suspension, or revocation of a personal or facility license

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pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions, or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

# CONTROLLED SUBSTANCES

19. Section 4021 of the Code states:

8 "Controlled substance' means any substance listed in Chapter 2 (commencing with Section
9 11053) of Division 10 of the Health and Safety Code."

12 21. Hydrocodone with acetaminophen is a Schedule III controlled substance as

designated by Health and Safety Code section 11056, subdivision (e)(4).

14 22. Alprazolam is a Schedule IV controlled substance as designated by Health and Safety
15 Code section 11057, subdivision (d)(1).

Promethazine with codeine is a Schedule V controlled substance as designated by
Health and Safety Code section 11058. ...

# COST RECOVERY

19 24. Section 125.3 of the Code provides, in relevant part, that the Board may request the 20 administrative law judge to direct a licentiate found to have committed a violation or violations of 21 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and 22 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being 23 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be 24 included in a stipulated settlement.

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# FACTUAL BACKGROUND

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Accusation

25. From about October 21, 2009, to the present, Respondent Fruitvale Avenue Pharmacy
(FAP) has been operating as a pharmacy in Oakland, California. From on or about October 21,
2009, until May 19 2011, Respondent Ijeoma Nwanyiocha Esomonu (INE), the owner of FAP,

was also the pharmacist-in-charge (PIC) at FAP. From on or about October 21, 2009, until May 2 19, 2011, Respondent Iroegbu Clifford Esomonu (ICE) worked as a pharmacist at FAP. From May 19, 2011, to the present, Respondent ICB took over as the PIC at FAP.

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26. On May 17, 2011, Board Inspector conducted an inspection at FAP because the Board had identified FAP as a pharmacy that failed to report any Controlled Substances Utilization Review and Evaluation System (CURES) data to the Department of 6 Justice (DOJ). During the inspection at FAP, Inspector observed several pharmacy law 7 violations. Specifically, Inspector noted that FAP had never transmitted any CURES 8 data to the DOJ. 9

27. While at FAP, Inspector **Example** looked into prescription documents from Bay 10 Internal Medicine (BIM). The prescriptions appeared legitimate but, upon further investigation, 1-1 Inspector found that none of prescribers' contact information on the prescriptions 12 contained a valid working phone number. Inspector asked Respondent ICE to verify the 13 BIM prescribers on the Medical Board of California's website. The web search revealed that 14 none of the BIM prescribers' listed addresses on the Medical Board's website matched the 15 addresses on the prescriptions. Significantly, Respondent ICE admitted to Inspector that 16 he had never before verified a prescriber using the Medical Board's website. In addition, 17 observed numerous other violations of pharmacy laws. At the conclusion of Inspector 18 the inspection, Inspector prepared an inspection report documenting various pharmacy 19 law violations. Inspector gave a copy of the report to Respondent ICE, and then had 20 obtained Respondent ICE review and sign off on it. During his inspection, Inspector 21 certain documents including prescription documents, dispensing detail reports, and Cardinal 22 Health Narcotic Sales Reports. Inspector also requested FAP to provide additional 23 docurnents and explanations regarding pharmacy law violations indicated in the report. 24 On or about May 30, 2011, Inspector received and reviewed faxed responses 25 28. from FAP. Subsequently, Inspector contacted 15 different prescribers listed as the 26 supposed prescriber on the prescription documents. Inspector sent each prescriber a list 27 of prescriptions from FAP to verify the legitimacy of the prescriptions. Each of the prescribers 28 9

responded with a written statement that they did not authorize the prescriptions from FAP. In 1 fact, one prescriber from Kaiser stated he did not authorize any of the prescriptions and that they 2 were written on prescriptions that were stolen from his locker at the hospital. Additionally, one . 3 prescriber from BIM stated their practice had been closed since June 2009. All the BIM 4 prescription documents that Inspector **Example** sent to the BIM prescribers to review were dated 5 and filled by FAP in 2011. 6

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29. Physician Assistant George Pearson was one of the 15 prescribers that Inspector 7 contacted to verify the legitimacy of the prescription documents he got from FAP. On or 8 about June 7, 2011, Inspector received a response from Mr. Pearson, indicating that he 9 did not authorize the prescriptions and the documents were forgeries. In addition, Mr. Pearson 10 noted that several of the prescription documents were not written on proper controlled substances 11 prescription forms. Significantly, during the May 17, 2011 visit to FAP, Inspector 12 l had made the same observation that FAP had improperly dispensed controlled substances on five 13 invalid prescription documents. These five prescription documents were invalid because they 14 lacked several required security features such as quantity check off boxes, the required statement 15 of "Prescription is void if the number of drugs prescribed is not noted," and the prescriptions were 16 not sequentially numbered. 17

18 Inspector 's investigation revealed that, from October 2009, to about April 19 2011, FAP failed to transmit CURES data to the DOJ. The investigation further showed that, from about July 2010, to May 2011, Respondent INE, and Respondent ICE had filled over 350 20 21 fraudulent prescriptions. Many of these prescription documents contained significant 22 irregularities that should have prompted Respondent INE and Respondent ICE to verify the legitimacy of the prescription before dispensing the controlled substances. In addition, a review 23 of FAP's dispensing printouts obtained during the investigation showed Respondent Ice's initials 24 on most, if not all, of the printouts' "filled by" section. Furthermore, in a written statement, 25 Respondent ICE admitted that he was the pharmacist on duty everyday since the opening of FAP. 26 H27 111 28

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	1	CAUSES OF DISCIPLINE AGAINST RESPONDENT FAP
	2	FIRST CAUSE FOR DISCIPLINE
	3	(Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d))
	4	31. Respondent Fruitvale Avenue Pharmacy's (FAP) Pharmacy License is subject to
	5	disciplinary action under Code section 4301, subdivision (j), because FAP violated Health and
	6	Safety Code section 11165, subdivision (d), in that from on or about October 21, 2009, until
	7	approximately April 2011, FAP failed to transmit dispensing data for Schedule II, Schedule III,
	8	and Schedule IV controlled substances to the Department of Justice for the Controlled Substances
	9	Utilization Review and Evaluation System (CURES) on a weekly basis. The circumstances are
	10	further explained in paragraphs 25-30, above.
	11 12	(Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (0) and 16 CCR § 1761, subd. (a))
	13	32. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
	14	section 4301, subdivision (o), because FAP violated California Code of Regulations, title 16,
8	15	section 1761, subdivision (a), in that pharmacists and staff at FAP filled over 350 irregular
	16	prescriptions. Many of these prescription documents order an unusually large amount of
	17	controlled substances for "as-needed" purposes. The circumstances are further explained in
	18	paragraphs 25-30, above.
	19 20	<u>THIRD CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a))
	21	33. Respondent FAP's Pharmacy License is subject to disciplinary action under Code
	22	section 4301, subdivision (j), because FAP violated Health and Safety Code section 11153,
	23	subdivision (a), in that pharmacists and staff at FAP failed to uphold their corresponding
	24	responsibility of verifying the patient's legitimate medical purposes for controlled substances.
	25	The pharmacists and staff at FAP breached their corresponding responsibility by furnishing
	26	unusually large quantities of controlled substances to patients without confirming with the
	27	supposed prescribers the legitimacy of the prescriptions. In fact, the pharmacists and staff at FA
	28	filled approximately 350 fraudulent prescriptions, many of which were for unusually large
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quantities of controlled substances. The circumstances are further explained in paragraphs 25-30, 1 2 above. 3 FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) 4 (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164) 34. Respondent FAP's Pharmacy License is subject to disciplinary action under Code 5 section 4301, subdivision (j), because FAP violated Health and Safety Code section 11164, in that 6 the pharmacists and staff at FAP furnished controlled substances to patients based on invalid 7 controlled substances prescription forms. Specifically, during May 2011, FAP filled five 8 prescription documents that lacked several required security measures. The circumstances are 9 further explained in paragraphs 25-30, above. 10 CAUSES OF DISCIPLINE AGAINST RESPONDENT INE -11 12 FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) 13 (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11165, subd. (d)) 35. Respondent Ijeoma Nwanyiocha Esomonu (INE), as Pharmacist-in-Charge of FAP, 14 has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision 15 (j), by violating Health and Safety Code sections 11165, subdivision (d), in that from on or about 16 October 21, 2009, until approximately April 2011, INE failed to insure that FAP transmit to the 17 Department of Justice for the Controlled Substances Utilization Review and Evaluation System 18 (CURES) dispensing data for Schedule II, Schedule III, and Schedule IV controlled substances on 19 a weekly basis. The circumstances are further explained in paragraphs 25-30, above. 20 SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (o) and 16 CCR § 1761, subd. (a)) 21 22 23 36. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist License to disciplinary action under Code section 4301, subdivision (o), because she violated 24 California Code of Regulations, title 16, section 1761, subdivision (a), in that pharmacists and 25 26 staff at FAP filled over 350 irregular prescriptions. Many of these prescription documents order 27 an unusually large amount of controlled substances for "as-needed" purposes. The circumstances are further explained in paragraphs 25-30, above. 28 12

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SEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus, & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 37. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 3 License to disciplinary action under Code section 4301, subdivision (i), because she violated 4 Health and Safety Code section 11153, subdivision (a), in that pharmacists and staff at FAP failed 5 to uphold their corresponding responsibility of verifying the patient's legitimate medical purposes 6 for controlled substances. The pharmacists and staff at FAP breached their corresponding 7 responsibility by furnishing unusually large quantities of controlled substances to patients without 8 confirming with the supposed prescribers the legitimady of the prescriptions. In fact, the 9 pharmacists and staff at FAP filled approximately 350 fraudulent prescriptions, many of which 10 were for unusually large quantities of controlled substances. The circumstances are further 11 explained in paragraphs 25-30, above. 12 EIGHTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) 13 (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164) 14 38. Respondent INE, as Pharmacist-in-Charge of FAP, has subjected her Pharmacist 15 License to disciplinary action under Code section 4301, subdivision (j), because she violated 16 Health and Safety Code section 11164, in that the pharmacists and staff at FAP furnished 17 controlled substances to patients based on invalid controlled substances prescription forms. 18 Specifically, during May 2011, FAP filled five prescription documents that lacked several 19 required security measures. The circumstances are further explained in paragraphs 25-30, above. 20CAUSES OF DISCIPLINE AGAINST RESPONDENT ICE 21 NINTH CAUSE FOR DISCIPLINE 22 (Unprofessional Conduct-Filled Prescriptions with Significant Irregularity) (Bus. & Prof. § 4301, subd. (0) and 16 CCR § 1761, subd. (a)) 23 39. Respondent Iroegbu Clifford Esomonu (ICE), as a pharmacist of FAP, has subjected 24 his Pharmacist License to disciplinary action under Code section 4301, subdivision (0), because 25 he violated California Code of Regulations, title 16, section 1761, subdivision (a), in that 26 Respondent ICE filled prescriptions with significant irregularity. Many of the prescriptions order 27 unusually large quantities of controlled substances including oxycodone, hydrocodone with 28 13

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acetaminophen, alprazolam and promethazine with codeine. The circumstances are further explained in paragraphs 25-30, above.

<u>TENTH CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions for Controlled Substances) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11153, subd. (a)) 4 40. Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to 5 disciplinary action under Code section 4301, subdivision (j), because he violated Health and 6 Safety Code section 11153, subdivision (a), in that, on numerous occasions, Respondent ICE 7 failed to verify the legitimate medical purpose for prescribing an unusually large quantity of 8 controlled substances. In fact, FAP's drug dispensing printouts show that Respondent ICE filled 9 approximately 350 fraudulent prescriptions, many which were for unusually large quantities of 10 controlled substances. The circumstances are further explained in paragraphs 25-30, above.... -1-1

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# ELEVENTH CAUSE FOR DISCIPLINE

# (Unprofessional Conduct-Dispensed Controlled Substances on Invalid Prescriptions) (Bus. & Prof. § 4301, subd. (j) and Health and Safety Code § 11164)

41. Respondent ICE, as a pharmacist of FAP, has subjected his Pharmacist License to 14 disciplinary action under Code section 4301, subdivision (j), in that Respondent ICE dispensed 15 controlled substances based on invalid prescription documents. Specifically, Respondent ICE's 16 initials were on the pharmacy dispensing printouts for those five invalid prescription documents. 17 18 The circumstances are further explained in paragraphs 25-30 above.

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# TWELFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Use of Alcohol in a Dangerous Manner) (Bus. & Prof. § 4301, subd. (h))

42, Respondent ICE has subjected his Pharmacist License to disciplinary action under 21 Code section 4301, subdivision (h), in that on or about April 23, 2012, Respondent ICE was 22 arrested by a San Leandro police officer for driving under the influence of alcohol. The 23 circumstances are as follows: 24

43. 25 On or about 12:25 a.m. on April 23, 2012, a San Leandro police officer stopped Respondent's vehicle for a violation of Vehicle Code section 21650 (a vehicle on the highway 26 27 must be driven on the right side of the road). The officer approached Respondent's vehicle and 28 observed symptoms of intoxication including red watery eyes, alcoholic odor emitting from

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Respondent's breath and slurred speech. Respondent failed a series of field sobriety tests. Two breath tests from Respondent at approximately 1:19 a.m. and 1:22 a.m. revealed a blood alcohol concentration (BAC) of .13.

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# THIRTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Conviction) (Bus. & Prof. §§ 490 & 4301, subd. (1))

44. Respondent ICE has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (l), and section 490, in that Respondent ICE was convicted of a crime substantially related to the qualifications, functions and duties of a pharmacist. The circumstances are as follows:

45. On or about December 13, 2012, in a criminal matter entitled *People of the State of California v. Iroegbu Clifford Esomonu*, in the Alameda County Superior Court, Respondent ICE
was convicted upon plea of no contest to the violation of Vehicle Code section 23152,
subdivision (b) (driving with a blood alcohol level of .08 or more), a misdemeanor. Respondent
ICE was ordered to serve 15 days in county jail. Respondent was placed on probation for 3 years
with various conditions including completing a Drinking Driver Program and paying various fees
and fines.

# DISCIPLINE CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondent ICE,
Complainant alleges that on or about December 28, 2010, in a prior action, the Board of
Pharmacy issued Citation Number CI 2010 45230 and ordered Respondent ICE to pay a \$2,500
fine for violating sections 4301, subdivisions (h) and (l) [arrest for driving under the influence
and conviction on the lesser charge of wet/reckless]. That Citation is now final and is
incorporated by reference as if fully set forth.

# PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
Accusation, and that following the hearing, the Board of Pharmacy issue a decision:
Revoking or suspending Pharmacy License Number PHY 50064, issued to

1. Revoking or suspending Pharmacy License Number PHY 50064, issued to Fruitvale Avenue Pharmacy Inc.;

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1	2. Revoking or suspending Pharmacist License Number RPH 53516, issued to
2	ljeoma Nwanyiocha Esomonu, Fruitvale Avenue Pharmacy Inc.;
3	3. Revoking or suspending Pharmacist License Number RPH 53445, issued to
4	Iroegbu Clifford Esomonu, Fruitvale Avenue Pharmacy Inc.;
5	4. Ordering Fruitvale Avenue Pharmacy Inc., Ijeoma Nwanyiocha Esomonu and
6	Iroegbu Clifford Esomonu to pay the Board of Pharmacy the reasonable costs of the investigation
7	and enforcement of this case, pursuant to Business and Professions Code section 125.3;
8	5. Taking such other and further action as deemed necessary and proper.
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11	DATED: 9/6/13
2	VIRGINIA HEROLD
13	Executive Officer Board of Pharmacy
14	Department of Consumer Affairs State of California
5	Complainant
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