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

In the Matter of the Accusation Against:

DANIELS PHARMACY 943 Geneva Avenue San Francisco, CA 94112

Original Permit No. PHY 36740

and

IYAD I. NASRAH 488 Gellert Drive San Francisco, CA 94132

Pharmacist License No. RPH 40241

Case No. 4125

OAH No. 2014100384

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

Respondents.

DECISION AND ORDER

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

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

This Decision shall become effective on June 18, 2015.

It is so ORDERED on June 4, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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AMARYLIS GUTIERREZ Board President

1	Kamala D. Harris	۰ ۱	
2	Attorney General of California FRANK H, PACOE		
3	Supervising Deputy Attorney General JONATHAN D. COOPER		
4	Deputy Attorney General State Bar No. 141461		
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6	Telephone: (415) 703-1404 Facsimile: (415) 703-5480		
7	Attorneys for Complainant	· • •	
8	BEFORE THE		
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10	STATE OF		
10	In the Matter of the Accusation Against:	Case No. 4125	
12	DANIELS PHARMACY	OAH No. 2014100384	
12	943 Geneva Avenue San Francisco, CA 94112	STIPULATED SETTLEMENT AND	
13	Pharmacy License No. PHY 36740	DISCIPLINARY ORDER	
14	and		
16	IYAD I. NASRAH		
17	488 Gellert Drive San Francisco, CA 94132		
18	Pharmacist License No. RPH 40241		
10	Respondents.		
20	and the second		
		lement of this matter, consistent with the public	
21	interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,		
22	the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will		
.23	be submitted to the Board of Pharmacy for approval and adoption as the final disposition of the		
24	Accusation as to both Respondent Daniels Pharmacy and Respondent Iyad I. Nasrah.		
25	PARTIES		
26	1. Virginia Herold ("Complainant"), Executive Officer, Board of Pharmacy, brought this		
27	action solely in her official capacity and is represented in this matter by Kamala D. Harris,		
28	Attorney General of the State of California, by Jonathan D. Cooper, Deputy Attorney General.		
	1 STIPULATED SETTLEMENT (Case No. 4125)		

Respondent Daniels Pharmacy ("Respondent Daniels") and Respondent Iyad I.
 Nasrah ("Respondent Nasrah," collectively "Respondents") are each and both represented in this proceeding by attorney Kurt W. Melchior, whose address is: Nossaman LLP, 50 California
 Street, 34th Floor, San Francisco, CA 94111 (telephone (415) 398-3600).

On or about October 24, 1990, the Board of Pharmacy issued Pharmacy License No.
 PHY 36740 to Respondent Daniels. The Pharmacy License was in full force and effect at all times relevant to the charges herein, and will expire on October 1, 2015, unless renewed.

4. On or about August 20, 1986, the Board of Pharmacy issued Pharmacist License No.
RPH 40241 to Respondent Nasrah. The Pharmacist License was in full force and effect at all
times relevant to the charges herein and will expire on October 31, 2015, unless renewed. Since
on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board
records as the Pharmacist in Charge (PIC) for Respondent Daniels.

JURISDICTION

Accusation No. 4125 was filed before the Board of Pharmacy (Board), Department of
 Consumer Affairs, and is currently pending against Respondents. The Accusation and all other
 statutorily required documents were properly served on Respondents on or about May 27, 2014.
 Respondents timely filed its/his Notice(s) of Defense contesting the Accusation. On or about
 February 12, 2015, a First Amended Accusation and all other statutorily required documents were
 properly served on Respondents. A copy of First Amended Accusation No. 4125 is attached as
 exhibit A and is incorporated herein by reference.

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ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understand the
charges and allegations in First Amended Accusation No. 4125. Respondents have also carefully
read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and
Disciplinary 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 First Amended Accusation; the right to be
represented by counsel at their own expense; the right to confront and cross-examine the

witnesses against them; the right to present evidence and to testify on their own behalf; the right
 to the issuance of subpoenas to compel the attendance of witnesses and the production of
 documents; the right to reconsideration and court review of an adverse decision; and all other
 rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

9. Respondents understand that the charges and allegations in Accusation No. 4125, if proven at a hearing, constitute cause for imposing discipline upon their licenses.

10 10. Respondents admit that at hearing Complainant could establish a factual basis for the
11 charges and allegations in Accusation No. 4125, and that those charges and allegations are cause
12 for discipline. Respondents hereby give up their right to contest those charges and allegations.

Respondent Daniels agrees that its Pharmacy License is subject to discipline and it
 agrees to be bound by the board's probationary terms as set forth in the Disciplinary Order below,
 Respondent Nasrah agrees that his Pharmacist License is subject to discipline and he
 agrees to be bound by the board's probationary terms as set forth in the Disciplinary Order below.

RESERVATION

18 13. Admissions made by Respondents herein 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.

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CONTINGENCY

14. 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 may communicate
directly with the board regarding this stipulation and settlement, without notice to or participation
by Respondents or their counsel. By signing the stipulation, Respondents understand and agree
that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the
board considers and acts upon it. If the board fails to adopt this stipulation as its Decision and
Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for

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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.

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

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

12 17. In consideration of the foregoing, the parties agree that the board may, without
13 further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy License No. PHY 36740, issued to Respondent
Daniels, and Pharmacist License No. RPH 40241, issued to Respondent Nasrah, are each and
both revoked. However, each revocation is stayed and each respondent is placed on probation for
five (5) years on the following terms and conditions.

TERMS APPLICABLE TO BOTH RESPONDENTS¹

1. Obey All Laws

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Each respondent shall obey all state and federal laws and regulations.

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

an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
 substances laws involving either respondent

¹ All actions required of Respondent Daniels shall be undertaken by an owner or officer.

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1	• a plea of guilty or nolo contendere in any state or federal criminal proceeding to any	
2	criminal complaint, information or indictment by either respondent	
3	• a conviction of any crime against either respondent	
4	• discipline, citation, or other administrative action filed by any state or federal agency	
5	which involves either respondent's pharmacy or pharmacist license or which is	
6	related to the practice of pharmacy or the manufacturing, obtaining, handling,	
7	distributing, billing, or charging for any drug, device or controlled substance.	
8	Failure to timely report such occurrence shall be considered a violation of probation.	
9	2. Report to the Board	
10	Each respondent shall report to the board quarterly, on a schedule as directed by the board	
11	or its designee. The reports shall be made either in person or in writing, as directed. Among	
12	other requirements, each respondent shall state in each report under penalty of perjury whether	
13	there has been compliance with all the terms and conditions of probation. Failure to submit	
14	timely reports in a form as directed shall be considered a violation of probation. Any period(s) of	
15	delinquency in submission of reports as directed may be added to the total period of probation.	
16	Moreover, if the final probation report is not made as directed, probation shall be automatically	
17	extended until such time as the final report is made and accepted by the board.	
18	3. Interview with the Board	
19	Upon receipt of reasonable prior notice, each respondent shall appear in person for	
20	interviews with the board or its designee, at such intervals and locations as are determined by the	
.21	board or its designee. Failure to appear for any scheduled interview without prior notification to	
22	board staff, or failure to appear for two (2) or more scheduled interviews with the board or its	
23	designee during the period of probation, shall be considered a violation of probation.	
24	4. Cooperate with Board Staff	
25	Each respondent shall cooperate with the board's inspection program and with the board's	
26	monitoring and investigation of respondents' compliance with the terms and conditions of this	
27	probation. Failure to cooperate shall be considered a violation of probation.	
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ļ	STIPULATED SETTLEMENT (Case No. 4125)	

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondents shall be jointly and severally liable for payment to the board of its costs of investigation and prosecution in case number 4125 of \$25,000.00. Absent prior written approval by the board or its designee, neither respondent may successfully complete probation until this amount is paid in full. Each shall be responsible for the full amount and neither may claim to owe only a portion or a share.

Respondents shall make full payment within ninety (90) days. 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.

10 The filing of bankruptcy by either or both respondents shall not relieve either respondent of 11 its or his responsibility to reimburse the board its costs of investigation and prosecution.

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Probation Monitoring Costs

Each 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.

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Completion of Probation

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

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8. Violation of Probation

If either respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over that respondent, and probation shall automatically be extended as to that respondent, 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/or to impose the penalty that was stayed.

26 If either respondent violates probation in any respect, the board, after giving that respondent 27 notice and an opportunity to be heard, may revoke probation as to that respondent and carry out 28 the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed

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.

ADDITIONAL TERMS APPLICABLE TO RESPONDENT DANIELS

9. Civil Penalty

Respondent shall pay to the Board a civil penalty of \$60,000.00 within ninety (90) days of the effective date of the decision.

Respondent understands and agrees that this civil penalty is an administrative fine as
defined in 11 U.S.C. § 523(a)(7), and is non-dischargeable in bankruptcy. The filing of
bankruptcy by respondent shall not relieve respondent of the obligation to pay the civil penalty.
Failure to timely pay this civil penalty shall be considered a violation of probation. Further,

absent prior written approval by the board or its designee, respondent may not successfully
complete probation until this amount is paid in full.

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10. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the board in a place
conspicuous and readable to the public. The probation notice shall remain posted during the
entire period of probation ordered by this decision.

17 Respondent and its employees, contractors, and agents shall not, directly or indirectly,
18 engage in any conduct or make any statement which is intended to mislead or is likely to have the
19 effect of misleading any patient, customer, member of the public, or other person(s) as to the
20 nature of and reason for the probation of the licensed entity.

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Failure to post such notice shall be considered a violation of probation.

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11. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees now or in future involved in pharmacy operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees, contractors, or agents hired or used after the effective date of this decision are made

aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to provide such notice or submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

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12. Pharmacy Consultant

Within thirty (30) days of the effective date of this decision, and prior to the completion of 9 the suspension period ordered by this decision, respondent shall submit to the board or its 10 designee, for prior approval, the name and license number of a pharmacist that shall then be 11 retained by the pharmacy at its own expense as an independent consultant responsible for 12 reviewing pharmacy operations on a monthly basis during the period of probation for compliance 13 by respondent with state and federal laws and regulations governing the practice of pharmacy. 14 The consultant shall be a pharmacist licensed by and not on probation with the board. 15 Respondent shall be responsible for ensuring that the consultant submits timely reports. After six 16 monthly reports have been submitted timely, respondent may request that the board or its 17 designee approve transition to quarterly review and reporting by the consultant. Approval or 18 19 denial of such transition shall be within the discretion of the board or its designee.

If an approved consultant is no longer able or willing to serve as a consultant for respondent, respondent shall seek approval of a new consultant within thirty (30) days, and to ensure timely reporting by the newly-approved consultant. Respondent may not operate as a pharmacy without a consultant approved by the board or its designee, and failure to secure approval of a consultant shall result in a further suspension of the pharmacy's operations until such time as a consultant is approved and respondent is informed by the board or its designee that it may resume pharmacy operations.

Failure to timely seek approval of, retain, or ensure timely reporting by the consultant shallbe considered a violation of probation.

13. Owners and Officers: Knowledge of the Law

Within thirty (30) days of the effective date of this decision, and prior to the completion of the suspension period ordered by this decision, respondent shall submit to the board or its designee signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer(s), stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. Failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

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14. Designation of New Pharmacist in Charge

Within thirty (30) days of the effective date of this decision, and prior to the completion of the suspension period ordered by this decision, respondent shall submit to the board or its designee in writing the name and license number of a pharmacist for which approval of the board or its designee is sought for that pharmacist to serve as pharmacist in charge for respondent.

The board or its designee shall have discretion whether to approve or deny the designated pharmacist in charge. It may not be Respondent Nasrah. Respondent may not operate as a pharmacy without a pharmacist in charge approved by the board or its designee, and failure to secure approval of a designated pharmacist in charge shall result in a further suspension of the pharmacy's operations until such time as a pharmacist in charge is approved and respondent is informed by the board or its designee that it may resume pharmacy operations.

Failure to timely seek approval of, designate, or ensure pharmacy supervision by a new
pharmacist in charge shall be considered a violation of probation.

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15. Community Service Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related goods or services on a regular basis to a community or charitable facility or agency having a total value of at least \$100,000.00 (one hundred thousand dollars).

27 The value of goods and services donated to this program will be determined as follows: services
28 at actual payroll amounts, and goods at retail value.

This total value must be met within the first four (4) years of probation. Examples of goods and services that may be provided to constitute this value include sharps disposal containers, mail-back containers, immunizations, and other similar community/charitable goods and services. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

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16. Status of License

9 Respondent shall, at all times while on probation, maintain current pharmacy licensure with
10 the board. If respondent submits an application to the board, and the application is approved, for
11 a change of location, change of permit or change of ownership, the board shall retain continuing
12 jurisdiction over the license, and respondent shall remain on probation as determined by the
13 board. Failure to maintain current licensure shall be considered a violation of probation.

14 If respondent's license expires or is cancelled by operation of law or otherwise at any time 15 during the period of probation, including any extensions thereof or otherwise, upon renewal or 16 reapplication respondent owner's license shall be subject to all terms and conditions of this 17 probation not previously satisfied.

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17. Prerequisites to Dispensing Controlled Substances

Respondent and its employees, contractors, and agents shall not dispense or furnish any
controlled substances until the pharmacy is notified in writing by the board or its designee that
two prerequisites to doing so have been satisfied:

(1) All pharmacists that perform any dispensing or furnishing in, for, or from respondent, including any full-time, part-time, volunteer, temporary or relief employees or independent contractors employed or hired at any time during probation, have taken all steps necessary for registration with the California Prescription Drug Monitoring Program (PDMP), aka CURES; and

(2) The board or its designee have approved written pharmacy policies and proceduresrelating to dispensing or furnishing controlled substances submitted by the pharmacy.

Dispensing or furnishing of controlled substances by respondent or its employee, contractor, or agent without satisfying these prerequisites and receiving notification from the board or its designee that dispensing or furnishing is permitted shall be considered a violation of probation.

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18. Separate File of Controlled Substance Records

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

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19. Report of Controlled Substances

Respondent shall submit quarterly reports to the board detailing the total acquisition and
disposition of such controlled substances as the board may direct. Respondent shall specify the
manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a
manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report
on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the
board no later than ten (10) days following the end of the reporting period. Failure to timely
prepare or submit such reports shall be considered a violation of probation.

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20. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent discontinue business, 17 respondent may tender the premises license to the board for surrender. The board or its designee 18 shall have the discretion whether to grant the request for surrender or take any other action it 19 deems appropriate and reasonable. Respondent shall reimburse the board for its costs of 20investigation and prosecution prior to the surrender. Upon formal acceptance of the surrender of 21the license, respondent will no longer be subject to the terms and conditions of probation. 22Upon acceptance of the surrender, respondent shall relinquish the premises wall and 23 renewal license to the board within ten (10) days of notification by the board that the surrender is 24 accepted. Respondent shall further submit a completed Discontinuance of Business form 25

- according to board guidelines and shall notify the board of the records inventory transfer.
- 27 Respondent shall also, by the time that the Board notifies respondent that the surrender is

accepted, arrange for the continuation of care for ongoing patients of the pharmacy by, at

minimum, providing a written notice to ongoing patients that specifies the anticipated closing 1 date of the pharmacy and that identifies one or more area pharmacies capable of taking up the 2 patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions 3 for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients. 4 respondent shall provide a copy of the written notice to the board. For the purposes of this 5 provision, "ongoing patients" means those patients for whom the pharmacy has on file a 6 prescription with one or more refills outstanding, or for whom the pharmacy has filled a 7 8 prescription within the preceding sixty (60) days.

Respondent may not apply for any new licensure 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.

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ADDITIONAL TERMS APPLICABLE TO RESPONDENT NASRAH

21. Suspension

As part of probation, Pharmacist License No. RPH 40241, issued to Respondent Nasrah, is suspended for a period of thirty (30) days beginning the effective of this decision.

During the period of suspension, respondent shall not enter any pharmacy area or any 16 portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other 17 distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous 18 drugs and devices or controlled substances are maintained. Respondent shall not practice 19 pharmacy nor do any act involving drug selection, selection of stock, manufacturing, 20compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be 21a consultant to any licensee of the board, or have access to or control the ordering, manufacturing 22 or dispensing of dangerous drugs and devices or controlled substances. 23

During the period of suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective. Failure to comply with this suspension shall be considered a violation of probation.

22. Tolling of Suspension

5 During the period of suspension, respondent shall not leave California for any period 6 exceeding thirty (30) days, regardless of purpose (including vacation). Any such absence in 7 excess of thirty (30) days during suspension shall be considered a violation of probation. 8 Moreover, any absence from California during the period of suspension exceeding ten (10) days 9 shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten 10 (10) days respondent is absent from California. During any such period of tolling of suspension, 11 respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of any departure from California during the period of suspension, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

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23. Ethics Course

Within sixty (60) days of the effective date of this decision, respondent shall enroll in a
course in ethics, at respondent's expense, approved in 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(5) days of completing the course.

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24. Status of License

Respondent shall, at all times while on probation, maintain an active, current pharmacist
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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25. 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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26. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a 9 manager, administrator, member, officer, director, trustee, associate, or partner of any additional 10 business, firm, partnership, or corporation licensed by the board. If respondent currently owns or 11 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, 12 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently 13 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold 14 that interest, but only to the extent of that position or interest as of the effective date of this 15 decision. Violation of this restriction shall be considered a violation of probation. 16

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27. Notification of Change in Employment, Name, or Contact Information

18 Respondent shall notify the board in writing within ten (10) days of any change of 19 employment. Said notification shall include the reasons for leaving, the address of the new 20 employer, the name of the supervisor and owner, and the work schedule if known. Respondent 21 shall further notify the board in writing within ten (10) days of a change in name, residence 22 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.

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28. Pharmacist Examination

Respondent shall take and pass the California Pharmacist Jurisprudence Examination
(CPJE) within six (6) months of the effective date of this decision. If respondent fails to take and
pass the examination within six (6) months, respondent shall be automatically suspended from

practice. Respondent shall not resume the practice of pharmacy until he or she takes and passes the CPJE and is notified, in writing, that he or she has passed the examination and may resume practice. Respondent shall bear all costs of the examination(s).

4 During any such suspension, respondent shall not enter any pharmacy area or any portion of $\overline{5}$ the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and 6 devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do 7 any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or 8 patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee 9 of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous 10 drugs and devices or controlled substances. 11

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any
licensed premises in which he holds an interest at the time this decision becomes effective.

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

19 If respondent fails to pass the CPJE after four attempts, respondent shall successfully
20 complete, at a minimum, sixteen (16) additional semester units of pharmacy education as
21 approved by the board.

Failure to take the examination within one (1) year of the effective date of this decision shall be considered a violation of probation. Failure to complete coursework as required shall be considered a violation of probation.

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29. Employment as a Pharmacist/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.

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

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

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30. 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. Assumption of any such unauthorized supervision responsibilities shall
be considered a violation of probation.

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31. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4125 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 his 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 4125, and terms and conditions imposed thereby.

4 It shall be respondent's responsibility to ensure that his 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 his direct supervisor, 6 pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions 7 of the decision in case number 4125 in advance of the respondent commencing work at each 8 licensed entity. A record of this notification must be provided to the board upon request, 9

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen 10 11 (15) days of respondent undertaking any new employment by or through a pharmacy employment 12 service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 4125 13 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure 14 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board. 15

Failure to timely notify present or prospective employer(s) or to cause the employer(s) to 16 17 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.

Supervised Practice 32.

23 During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board, Upon and after the effective date of this 24 decision, respondent shall not practice pharmacy and his license shall be automatically suspended 25 until a supervisor is approved by the board or its designee. The supervision shall be, as required 26by the board or its designee, either: 27

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Continuous - At least 75% of a work week

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Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4125 and is familiar with the required level of supervision as determined by the board or its designee. It shall be respondent's responsibility to ensure that his employer(s), pharmacist-in-charge, and supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be respondent's responsibility to ensure that his 11 new employer(s), pharmacist-in-charge, and supervisor(s) submit timely acknowledgement(s) to 12 the board. Respondent shall have his new supervisor, within fifteen (15) days after employment 13 commences, submit notification to the board in writing stating the direct supervisor and 14 pharmacist-in-charge have read the decision in case number 4125 and are familiar with the level 15 of supervision as determined by the board. Respondent shall not practice pharmacy and his 16 license shall be automatically suspended until the board or its designee approves a new 17 supervisor. Failure to cause the direct supervisor and the pharmaeist-in-charge to submit timely 1819 acknowledgements to the board shall be considered a violation of probation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of 20 the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor 21 22of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do 23 any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or 24 patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee 25 of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous 26 drugs and devices or controlled substances. 27

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective.

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

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33. License Surrender While on Probation/Suspension

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

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

18 Respondent may not reapply for any license from the board for three (3) years from the effective
19 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
20 of the date application for that license is submitted to the Board, including any examination
21 requirements and any outstanding costs.

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1	ACCEPTANCE		
2	I am authorized to sign for Respondent Daniels. I have carefully read the above Stipulated		
3	Settlement and Disciplinary Order and have fully discussed it with my attorney, Kurt W.		
4	Melchior. I understand the stipulation and the effect it will have on my Pharmacy License. I		
5	enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and		
6	intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.		
7			
8	DATED: 4/16/15		
9	Tyza I. Nasrah, for DANIELS PHARMACY		
10	Respondent		
11	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully		
12	discussed it with my attorney, Kurt W. Melchior. I understand the stipulation and the effect it		
13	will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary		
14	Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order		
15	of the Board of Pharmacy.		
- 16			
17-	DATED: 4/16/15		
18	IYAD I. NASRAH Respondent		
19			
20	I have read and fully discussed with Respondent Daniels and Respondent Nasrah the terms		
21	and conditions and other matters contained in the above Stipulated Settlement and Disciplinary		
22	Order. I approve its form and content.		
23			
24	DATED:		
25	KURT W. MELCHIOR Nossaman LLP		
26	Attorneys for Respondents		
27			
28			
I	STIPULATED SETTLEMENT (Case No. 4125)		

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ACCEPTANCE

1 am authorized to sign for Respondent Daniels. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Kurt W. Melchior. I understand the stipulation and the effect it will have on my Pharmacy License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

*DATED:

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lyad I. Nasrah, for DANIELS PHARMACY Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 12 discussed it with my attorney, Kurt W. Melchior. J understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

IYAD I, NASRAH Respondent

I have read and fully discussed with Respondent Daniels and Respondent Nasrah the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

- write cali DATED: (puil 16, 2015 W. MELCHIOR JRT

Nossaman LLP Attorneys for Respondents

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1	ENDORSEMENT	
2	• The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully	
3	submitted for consideration by the Board of Pharmacy.	
4	Dated: 4/12/2015 Respectfully submitted,	
5	KAMALA D. HARRIS	
6	Attorney General of California FRANK H. PACOE	
7	Supervising Deputy Attorney General	
8	ACA	
9	For JONATHAN D. COOPER Deputy Attorney General Attorneys for Complainant	
10	Attorneys for Complainant	
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	STIPULATED SETTLEMENT (Case No. 4125)	

Exhibit A

1	KAMALA D. HARRIS		
2	Attorney General of California FRANK H. PACOE		
3	Supervising Deputy Attorney General JONATHAN D. COOPER		
4	Deputy Attorney General State Bar No. 141461		
5	455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004		
6	Telephone: (415) 703-1404 Facsimile: (415) 703-5480		
7	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. 4125		
12	DANIELS PHARMACY 943 Geneva Avenue		
13	San Francisco, CA 94112 FIRST AMENDED ACCUSATION		
14	Pharmacy License No. PHY 36740		
15	and		
16	IYAD I. NASRAH 488 Gellert Drive		
1.7	San Francisco, CA 94132		
18	Pharmacist License No. RPH 40241		
19	Respondents.		
20	Complainant alleges:		
21	PARTIES		
22			
23	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity		
24	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.		
25	2. On or about October 24, 1990, the Board of Pharmacy issued Pharmacy License No.		
25	PHY 36740 to Daniels Pharmacy (Respondent Daniels). The License was in full force and effect		
20	at all times relevant to the charges herein, and will expire on October 1, 2014, unless renewed.		
28	 On or about August 20, 1986, the Board of Pharmacy issued Pharmacist License No. RPH 40241 to Iyad I. Nasrah (Respondent Nasrah). The License was in full force and effect at all 		
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	First Amended Accusation		

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times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since
 on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board
 records as the Pharmacist in Charge (PIC) for Respondent Daniels.

#### JURISDICTION

4. 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 (Code) unless otherwise indicated.

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

6. Section 4300(a) of the Code provides that every license issued by the Board may be
suspended or revoked.

7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or
suspension of a Board-issued license, the placement of a license on a retired status, or the
voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to
commence or proceed with any investigation of, or action or disciplinary proceeding against, the
licensee or to render a decision suspending or revoking the license.

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#### STATUTORY AND REGULATORY PROVISIONS

**Business and Professions Code:** 

8. Section 4043(a) of the Code states:

21 "Wholesaler" means and includes a person who acts as a wholesale merchant, broker,
22 jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for
23 resale, or negotiates for distribution, or takes possession of, any drug or device included in
24 Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or
25 authorize the storage or warehousing of drugs with any person or at any location not licensed by
26 the board.

9. Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous
drug or dangerous device except upon the prescription of an authorized prescriber.

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10. Section 4059.5 of the Code, in pertinent part, permits ordering/delivery of dangerous drugs or devices only by and to entities licensed by the board and authorized prescribers, and requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

4 11. Section 4061 of the Code provides, in pertinent part, that manufacturers' sales
5 representatives may distribute complimentary samples of drugs only to and pursuant to a written
6 request from an authorized prescriber that specifies the name and quantity of drug desired.

12. Section 4063 of the Code states:

8 No prescription for any dangerous drug or dangerous device may be refilled except upon 9 authorization of the prescriber. The authorization may be given orally or at the time of giving the 10 original prescription. No prescription for any dangerous drug that is a controlled substance may 11 be designated refillable as needed.

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13. Section 4064 of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the
prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the
pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's
ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to thissection.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of anyrefills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every
 reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record,
 including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription
pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug
 or dangerous device furnished without prescription pursuant to this section.

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14. Section 4076, subdivision (a), of the Code provides, in pertinent part, that a

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pharmacist shall not dispense any prescription except in a container meeting the requirements of 1 state and federal law that is correctly labeled with information including the following:  $\mathbf{2}$ (1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the 3 drug or the generic name and the name of the manufacturer; 4 (2) The directions for use of the drug; 5 (3) The name of the patient or patients; 6 (4) The name(s) of the prescriber(s): 7 (5) The date of dispensing; 8 (6) The name and address of the pharmacy, and prescription number; 9 (7) The strength of the drug(s) dispensed; 10 (8) The quantity of the drug(s) dispensed; 11 (9) The expiration date of the drug(s) dispensed: 12 (10) If on the prescription, the condition or purpose for which the drug was prescribed; 13 (11) A physical description of the dispensed medication. 14 15. Section 4081 of the Code states, in pertinent part: 15 (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or 16dangerous devices shall be at all times during business hours open to inspection by authorized 17 officers of the law, and shall be preserved for at least three years from the date of making. A 18 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-19 animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 20 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 21 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 22 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 23 Institutions Code who maintains a stock of dangerous drugs or dangerous devices. 24 (b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal 25 drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated 26 representative-in-charge, for maintaining the records and inventory described in this section. 27  $\mathbf{28}$ 4

Section 4105 of the Code requires, in pertinent part, that unless a waiver is granted by 1 16. 2 the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a 3 readily retrievable form, for three years from the date of making. 4

17. Section 4113(c) of the Code states:

6 The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. 7

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18. Section 4115(e) of the Code states:

No person shall act as a pharmacy technician without first being licensed by the board as a 9 pharmacy technician. 10

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Section 4125(a) of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, 12 document medication errors attributable, in whole or in part, to the pharmacy or its personnel, 13 The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy 14 in dispensing or furnishing prescription medications so that the pharmacy may take appropriate 15 action to prevent a recurrence. 16

20, Section 4160(a) of the Code states:

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless 18 he or she has obtained a license from the board. 19

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

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

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(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or 25corruption, whether the act is committed in the course of relations as a licensee or otherwise, and 26 27whether the act is a felony or misdemeanor or not.

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(g) Knowingly making or signing any certificate or other document that falsely represents

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the existence or nonexistence of a state of facts.

(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.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7
 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

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(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.

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22. Section 4324 of the Code states:

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes,
alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any
drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment
pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county
jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged
prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the
Penal Code, or by imprisonment in the county jail for not more than one year.

23. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or

refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

24. Section 4342 of the Code states:

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

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006
shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

Health and Safety Code:

13 25. Health and Safety Code section 11165 provides, in pertinent part, for establishment 14 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) 15 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled 16 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV 17 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information 18 on the patient, prescriber, controlled substance, and prescription, to the California Department of 19 Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

26. Health and Safety Code section 111340 states:

21 Any drug or device is misbranded unless it bears a label containing all of the following 22 information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

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¹ Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

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Reasonable variations from the requirements of subdivision (b) shall be permitted. ļ Requirements for placement and prominence of the information and exemptions as to small 2 packages shall be established in accordance with regulations adopted pursuant to Section 110380. 3 27. Health and Safety Code section 111440 states: 4 It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or 5 device that is misbranded. 6 California Code of Regulations: 7 28. California Code of Regulations, title 16, section 1707.2 states, in pertinent part: 8 9 (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings: 10 11 (1) upon request; or (2) whenever the pharmacist deems it warranted in the exercise of his or her professional 12 judgment. 13 (b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall 14 provide oral consultation to his or her patient or the patient's agent in any care setting in which the 15 patient or agent is present: 16 (A) whenever the prescription drug has not previously been dispensed to a patient; or 17 18 (B) whenever a prescription drug not proviously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy. 19(2) When the patient or agent is not present (including but not limited to a prescription drug 20that was shipped by mall) a pharmacy shall ensure that the patient receives written notice: 21(A) of his or her right to request consultation; and 22 (B) a telephone number from which the patient may obtain oral consultation from a 23 pharmacist who has ready access to the patient's record. 24 (3) A pharmacist is not required by this subsection to provide oral consultation to an 25inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, 26or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the 2728 patient's discharge. A pharmacist is not obligated to consult about discharge medications if a 8

health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 2 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074. 3

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29. California Code of Regulations, title 16, section 1707.3 states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's 6 drug therapy and medication record before each prescription drug is delivered. The review shall 7 8 include screening for severe potential drug therapy problems.

California Code of Regulations, title 16, section 1711 states: 30.

(a) Each pharmacy shall establish or participate in an established quality assurance program 10 which documents and assesses medication errors to determine cause and an appropriate response 11 as part of a mission to improve the quality of pharmacy service and prevent errors. 12

(b) For purposes of this section, "medication error" means any variation from a prescription 13 or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as 14 15 defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law. 16

17 (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. 18

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall 19 as soon as possible: 20

(A) Communicate to the patient or the patient's agent the fact that a medication error has 21 occurred and the steps required to avoid injury or mitigate the error. 22

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(B) Communicate to the prescriber the fact that a medication error has occurred.

24 (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, or if the medication error 25 resulted in a clinically significant delay in therapy. 26

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(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in

1 || paragraph (2) of this subdivision.

2 (d) Each pharmacy shall use the findings of its quality assurance program to develop
3 pharmacy systems and workflow processes designed to prevent medication errors. An
4 investigation of each medication error shall commence as soon as is reasonably possible, but no
5 later than 2 business days from the date the medication error is discovered. All medication errors
6 discovered shall be subject to a quality assurance review.

7 (e) The primary purpose of the quality assurance review shall be to advance error
8 prevention by analyzing, individually and collectively, investigative and other pertinent data
9 collected in response to a medication error to assess the cause and any contributing factors such
10 as system or process failures. A record of the quality assurance review shall be immediately
11 retrievable in the pharmacy. The record shall contain at least the following:

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1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and
documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure,

18 systems, or processes made as a result of recommendations generated in the quality assurance19 program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be
immediately retrievable in the pharmacy for at least one year from the date the record was
created.

(g) The pharmacy's compliance with this section will be considered by the board as a
mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or
otherwise arranging for the provision of personnel or other resources, by a third party or
administrative offices, with such skill or expertise as the pharmacy believes to be necessary to
satisfy the requirements of this section.

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California Code of Regulations, title 16, section 1714 states, in pertinent part: 31.

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

(e) The pharmacy owner, the building owner or manager, or a family member of a 8 pharmacist owner (but not more than one of the aforementioned) may possess a key to the 9 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key 10 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, 11 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that 12 the pharmacist may readily determine whether the key has been removed from the container. 13

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California Code of Regulations, title 16, section 1716 states: 32.

Pharmacists shall not deviate from the requirements of a prescription except upon the prior 16 consent of the prescriber or to select the drug product in accordance with Section 4073 of the 18 Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-19 accepted pharmaceutical practice in the compounding or dispensing of a prescription. 20

33. California Code of Regulations, title 16, section 1717 states, in pertinent part:

(a) No medication shall be dispensed on prescription except in a new container which 22 conforms with standards established in the official compendia. 23

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-24 liquid oral products in a clean multiple-drug patient medication package (patient med pak), 25 provided: 26

2728 (1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

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(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All
prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising
pharmacist before they are dispensed.

8 (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the
9 distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity
dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(f) The pharmacy must have written procedures that identify each individual pharmacist
responsible for the filling of a prescription and a corresponding entry of information into an
automated data processing system, or a manual record system, and the pharmacist shall create in
his/her handwriting or through hand-initializing a record of such filling, not later than the
beginning of the pharmacy's next operating day. Such record shall be maintained for at least three
years.

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34. California Code of Regulations, title 16, section 1718, states:

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

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

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35. California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

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(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensurethat all such activities are performed completely, safely and without risk of harm to patients.

Code of Federal Regulations:

36. Title 21, Code of Federal Regulations, section 1304.04(f) requires, in pertinent part,
that inventories and records of Schedule I and II controlled substances shall be kept separate from
all other records, and that inventories and records of Schedule III-V controlled substances shall be
either kept separate from other records, or be immediately retrievable from the business records.

Controlled Substances/Dangerous Drugs:

37. Section 4021 of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

38. Section 4022 of the Code states, in pertinent part:

17 "Dangerous drug: or "dangerous device" means any drug or device unsafe for self use,
18 except veterinary drugs that are labeled as such, and includes the following:

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

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

39. Klonopin is a brand name for clonazepam, a Schedule IV controlled substance as
designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by
Business and Professions Code section 4022. It is used to treat mental health symptoms.

40. Celexa is a brand name for citalopram, a dangerous drug as designated by Business
and Professions Code section 4022. It is used to treat mental health symptoms.

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41. Zyprexa is a brand name for olanzapine, a dangerous drug as designated by Business

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1 2 and Professions Code section 4022. It is used to treat mental health symptoms.

# COST RECOVERY

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

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# 2011 INSPECTIONS AND INVESTIGATION

8 43. Between in or about January and April 2011, Respondents were the subject(s) of
9 investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping,
10 dispensing, and furnishing practices that failed to comply with the law.

44. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of
 the following deviations from pharmacy requirements was/were noted by the Inspector(s):

a. Included in the active drug inventory for the pharmacy were: (1) a prescription
bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed
on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing;
(ii) several boxes of prescription bottles containing professional drug samples; and (11) one or
more bubble packs or strip packs containing drugs returned from board and care homes. There
were no records of acquisition maintained by Respondents with regard to any of these Items.

b. Respondents used a prescription dispensing software and system to create prefilled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The
software and system did not make note of the identity of the dispensing pharmacist, nor was this
information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said
that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of
the thousands of prescriptions dispensed using this system during the previous nine (9) years.

c. The software and system used to generate the bubble/strip packs for board and
care homes also did not include required information on the label(s) generated during this nine (9)
year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.

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d.

In various places in the pharmacy, including in the active inventory, were

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prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete labels affixed. Respondent asserted that these were returned from assisted living facilities.

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e. Since at least October 21, 2009, Respondents had not successfully transmitted
data regarding controlled substances dispensed by the pharmacy to the Controlled Substances
Utilization Review (CURES) database maintained by the California Department of Justice.

f. Controlled substance involces for at least the two months prior to the inspection
were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist
(store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs.
45. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents
dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized
prescriptions and/or refills, including:

a. On at least ten (10) occasions between on or about December 14, 2009 and on
 or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances
 and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for
 controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); six (6) prescriptions for the
 dangerous drug Celexa 40mg; and two (2) prescriptions for the dangerous drug Zyprexa 20mg.

b. On at least twenty-nine (29) occasions between on or about August 2, 2009 and
on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled
substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for
controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); fourteen (14) refills for the
dangerous drug Zyprexa 20mg; and ten (10) refills for the dangerous drug Celexa 40mg.

c. On at least seven (7) occasions between on or about July 10, 2009 and on or
 about January 19, 2010, Respondents created and/or signed prescription documents for DC that
 falsely stated authorization by the prescriber, including: one (1) prescription for controlled
 substance/dangerous drug clonazepam 0.5mg (Klonopin); five (5) prescriptions for the
 dangerous drug Celexa 40mg; and one (1) prescription for the dangerous drug Zyprexa 20mg.
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#### FIRST CAUSE FOR DISCIPLINE

(Incomplete Inventory and/or Records of Acquisition and/or Disposition) 2 46. Respondents are each and severally subject to discipline under section 4301(i) and/or 3 (o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342 4 of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes 5 regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, б attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 7 practice of pharmacy, in that, as described in paragraphs 43-44 above. Respondents failed to 8 maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition 9 and disposition of all dangerous drugs in the pharmacy inventory. 10

#### SECOND CAUSE FOR DISCIPLINE

(Possessing and/or Dispensing/Furnishing Drug Samples)

47. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating
statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents
had in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples.

#### THIRD CAUSE FOR DISCIPLINE

(Failure to Identify Dispensing Pharmacist)

48. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16,
section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or
directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44
above, Respondents dispensed medications without a means of identifying the dispensing
pharmacist.

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#### FOURTH CAUSE FOR DISCIPLINE

(Inadequately Labeled Prescription Containers)

49. Respondents are each and severally subject to discipline under section 4301(i) and/or (o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations б governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents dispensed medications in prescription containers which failed to include required information. 8

# FIFTH CAUSE FOR DISCIPLINE

(Possession of Misbranded Drug Containers)

50. Respondents are each and severally subject to discipline under section 4301(i) and/or 11 (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 12 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or 13 directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws 14 or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 15 above. Respondents possessed drug containers that were misbranded inasmuch as they had 16 affixed to them no or incomplete labels describing the contents, the manufacturer, and other 17 18 required data.

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#### SIXTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Prescriptions to CURES)

51. Respondents are each and severally subject to discipline under section 4301(j) and/or 21(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for 22violating statutes regulating controlled substances or dangerous drugs, and/or directly or 23 indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or 24regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, 25in the period prior to January 12, 2011, the pharmacy had not successfully transmitted any  $\overline{26}$ dispensing data to CURES for controlled substances that were dispensed since at least October 27 $\mathbf{28}$ 21, 2009.

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#### SEVENTH CAUSE FOR DISCIPLINE

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(Failure to Segregate Schedule II Records)

52. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations, section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, on or about January 12, 2011, Schedule II records were not segregated.

# EIGHTH CAUSE FOR DISCIPLINE

(Receipt and Acknowledgment of Delivery by Non-Pharmacist)

11 53. Respondents are each and severally subject to discipline under section 4301(j) and/or 12 (o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code, 13 for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or 14 indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or 15 regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, a 16 non-pharmacist received and/or signed for a delivery of a dangerous drug or device.

#### NINTH CAUSE FOR DISCIPLINE

(Furnishing/Dispensing Prescriptions Without Prescriber Authorization)

19 54. Respondents are each and severally subject to discipline under section 4301(j) and/or
20 (o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating
21 statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
22 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
23 governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents
24 furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber.

## TENTH CAUSE FOR DISCIPLINE

(Furnishing/Dispensing Refills Without Prescriber Authorization)

27 55. Respondents are each and severally subject to discipline under section 4301(j) and/or
28 (o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating

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statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
 governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents
 furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.

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

(Dishonesty/Creation of False Prescription Document(s))

7 56. Respondents are each and severally subject to discipline under section 4301(f) and/or
8 (g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude,
9 dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any
10 certificate or other document that falsely represents the existence or nonexistence of a state of
11 facts in that, as described in paragraph 45 above, Respondents created seven (7) false
12 prescriptions for patient DC.

#### TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition of Drugs)

57. Respondents are each and severally subject to discipline under section 4301(i) and/or 15 (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 16 17 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 18 19 practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294, 20 issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this 21 22item.

#### THIRTEENTH CAUSE FOR DISCIPLINE

#### (Unprofessional Conduct)

58. are each and severally subject to discipline under section 4301 of the Code in that Respondents, as described in paragraphs 43-45 above, engaged in unprofessional conduct.

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#### CASH COMPROMISE OF MEDI-CAL CHARGES

59. On or about June, 2010, the California Department of Health Care Services (hereinafter "Department") audited Respondents' premises and records pertaining to the period of March 1, 2009 through March 31, 2010.

60. Based on this audit, on or about July 16, 2010, the Department took formal action
against Respondents by withholding all Medi-Cal payments to Respondents and by suspending
and deactivating Respondents' Medi-Cal provider number and National Provider Identifier
number. The Department charged Respondents with having violated California Welfare and
Institutions Code section 14107(b) (false and fraudulent claims) and California Code of
Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false
information), based on to the following misconduct:

a) Overbilling for medications;

b) Billing for prescriptions that had not actually been provided to beneficiaries;

c) Falsification of a telephone prescription; and

d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.

61. On or about October 13, 2010, Respondents entered into a cash compromise of the
above-described charges by signing a document entitled "Stipulation And Settlement Agreement
Between The California Department of Health Care Services And Daniel's Pharmacy." The
agreement provided for settlement of the charges in exchange for Respondents' agreement to pay
approximately \$1,000,000.00 to the Department.

## FOURTEENTH CAUSE FOR DISCIPLINE

(Cash Compromise of Medi-Cal Charges)

62. Respondents are each and severally subject to discipline under section 4301(m)
and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of
violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare
and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 59-61.
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#### 2013 INSPECTION

63. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents' 2 pharmacy in order to ascertain whether Respondents continued to be in violation of law. The 3 Inspectors observed numerous violations, as set forth below in the following Causes for 4 5 Discipline.

# FIFTEENTH CAUSE FOR DISCIPLINE

## (Failure to Consult with On-Premises Patient)

64. Respondents are each and severally subject to discipline under section 4301() and/or 8 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 9 section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous 10 drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a 11 violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, 12 Respondents dispensed a prescription to patient DV, which had not previously been dispensed to 13 patient DV, without providing a consultation by a pharmacist. Respondents failed to have a 14 policy or procedure identifying medications for which a consultation should be provided. 15

# SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Consult with Off-Premises Patient)

65. Respondents are each and severally subject to discipline under section 4301(i) and/or 18 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 19 section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs, 20 21 and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, 22 Respondents prepared prescription medication for delivery to a patient, which medication had not 23previously been dispensed to said patient, without providing any notification to the patient 24 regarding the patient's right to request a consultation. 25

#### SEVENTEENTH CAUSE FOR DISCIPLINE

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(Possession of Misbranded Drug Containers)

Respondents are each and severally subject to discipline under section 4301(j) and/or 66.

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(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 1 2 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or З directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, 4 Respondents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs 5 and outdated products in current inventory. Respondents also had in its possession previouslyб dispensed bubble packs of medications which had been returned by board-and-care homes. 7 8 EIGHTEENTH CAUSE FOR DISCIPLINE (Failure to Initiate Quality Assurance Review) 9 Respondents are each and severally subject to discipline under section 4301(j) and/or 67. 10 (o) and/or section 4113(c) of the Code, by reference to Code section 4125(a) and California Code 11 12 of Regulations, Title 16, section 1711, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or 13 abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 14 1, 2013, Respondents admitted to Board Inspectors that they had failed to complete quality 15 assurance reviews, procedures and related forms in the aftermath of dispensing errors. 16 NINETEENTH CAUSE FOR DISCIPLINE 17 (Variation from Prescription) 18 Respondents are each and severally subject to discipline under section 4301(i) and/or 19 68. (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 20section 1716, for violating statutes regulating controlled substances or dangerous drugs, and/or 21 22 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Board 23 Inspectors identified two prescriptions, RX numbers N9878911 and N9879201, which contained 24erroneous directions for use and/or identified the wrong prescriber. 25 TWENTIETH CAUSE FOR DISCIPLINE 26(Improper Supervision of Pharmacy Technician) 27 Respondents are each and severally subject to discipline under section 4301(j) and/or 28 69. 22

(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy technician worked unsupervised in the basement of the facility, and had the ability to override the automated dispensing unit SynMed's scan features when replenishing the dispensing unit.

**TWENTY-FIRST CAUSE FOR DISCIPLINE** 

(Failure to Maintain Operational Standards -- Drugs)

70. Respondents are each and severally subject to discipline under section 4301(j) and/or 10 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 11 section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or 12 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 13 laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' 14 pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without 15 drug name, strength, lot numbers and expiration dates. The premises also contained automated 16 dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on 17 various counters in various locations. 18

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#### TWENTY-SECOND CAUSE FOR DISCIPLINE

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#### (Failure to Maintain Records of Acquisition of Drugs)

71. Respondents are each and severally subject to discipline under section 4301(j) and/or 21(o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 22 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, 23 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 24 practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained 25numerous full bubble packs which had been acquired from board-and-care homes, the 26 receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents 27 were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules 28

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which had evidently previously been issued to patient PL. Respondents had no record of the acquisition of this item.

# **TWENTY-THIRD CAUSE FOR DISCIPLINE**

(Unlicensed Wholesale Activity)

72. Respondents are each and severally subject to discipline under section 4301(f) and/or 5 (i) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating б 7 statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly 8 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations Q, governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were found to be in possession of medications which had been returned to them by board-and-care 10homes, thus constituting wholesaling activity, when Respondents were not licensed as 11 12 wholesalers. Respondents evidently intended to reuse the medications.

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## **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

(False Statements on Certificates or Documents)

73. Respondents are each and severally subject to discipline under section 4301(g) and/or 15 (i) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or 16 17 document and for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 18 19 laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board Inspectors located documents showing that Respondents had filled a prescription for divalproex 2021by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided divalproex by Wockhardt. 22

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# **TWENTY-FIFTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Key)

74. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of

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laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013,
 Respondents admitted that the key to the pharmacy was in the possession of a family member,
 and was not in a tamper-proof container.

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#### 2014 INSPECTION

75. On or about August 5, 2014, Pharmacy Board inspectors inspected Respondents' pharmacy. At that time, the inspectors observed an individual, Lydia Dean, acting as a pharmacy technician, and filling prescriptions, when that individual was not licensed as a pharmacy technician.

#### **TWENTY-SIXTH CAUSE FOR DISCIPLINE**

(Employment of Unlicensed Pharmacy Technician)

76. Respondents are each and severally subject to discipline under Code section 4301,
subsections (j) and/or (o), and under Code sections 4113, subsection (c), and 4115, subsection (e),
in that Respondents employed an unlicensed individual, Lydia Dean, to act as a pharmacy
technician, as set forth above in paragraph 75.

#### DISCIPLINE CONSIDERATIONS

77. To determine the level of discipline, if any, to be imposed on Respondent Daniels and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:

a. On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of \$4,000.00,
was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and
Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions
dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation
System (CURES), in and/or between December 2004 and December 2008. That citation is now
final and is incorporated by reference as if fully set forth herein.

b. On or about October 21, 2009, Citation No. CI 2008 41785, with a fine of \$4,000.00,
was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its
obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV
controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and
Evaluation System (CURES), in and/or between December 2004 and December 2008. That

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1	citation is now final and is incorporated by reference as if fully set forth herein.
2	PRAYER
.3	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
4	and that following the hearing, the Board of Pharmacy issue a decision:
5	1. Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels
6	Pharmacy (Respondent Daniels);
7	2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah
8	(Respondent Nasrah);
9	3. Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be
10	responsible to pay the Board of Pharmacy the reasonable costs of the investigation and
11	enforcement of this case, pursuant to Business and Professions Code section 125.3;
12	4. Taking such other and further action as is deemed necessary and proper.
13	DATED: 1/23/15 ( tierie the old
14	VIRGINIA HEROLD Executive Offilter
15	Board of Pharmacy Department of Consumer Affairs
16	State of California Complainant
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÷ .	First Amended Accusation

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	Attorneys for Complainant	
		RE THE
		'PHARMACY CONSUMER AFFAIRS
		CALIFORNIA
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	In the Matter of the Accusation Against:	Case No. 4125
	DANIELS PHARMACY 943 Geneva Avenue	
ļ	San Francisco, CA 94112	ACCUSATION
	Pharmacy License No. PHY 36740	
1	and	
	IYAD I. NASRAH	
	488 Gellert Drive San Francisco, CA 94132	
]	Pharmacist License No. RPH 40241	
	Respondents.	
	Complainant alleges:	
	PAR	<u>RTIES</u>
	1. Virginia Herold (Complainant) bring	gs this Accusation solely in her official capacity
ę	as the Executive Officer of the Board of Pharma	cy, Department of Consumer Affairs.
	2. On or about October 24, 1990, the B	loard of Pharmacy issued Pharmacy License No
]	PHY 36740 to Daniels Pharmacy (Respondent I	Daniels). The License was in full force and effe
	at all times relevant to the charges herein, and w	• · · · ·
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ł	3. On or about August 20, 1986, the Bo	bard of Pharmacy issued Pharmacist License No
	3. On or about August 20, 1986, the Bo RPH 40241 to Iyad I. Nasrah (Respondent Nasra	·

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times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board records as the Pharmacist in Charge (PIC) for Respondent Daniels.

# JURISDICTION

4. 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 (Code) unless otherwise indicated.

5. 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.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

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#### STATUTORY AND REGULATORY PROVISIONS

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# Business and Professions Code:

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8. Section 4043(a) of the Code states:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker,
jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for
resale, or negotiates for distribution, or takes possession of, any drug or device included in
Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or
authorize the storage or warehousing of drugs with any person or at any location not licensed by
the board.

27 9. Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous
28 drug or dangerous device except upon the prescription of an authorized prescriber.

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10. Section 4059.5 of the Code, in pertinent part, permits ordering/delivery of dangerous drugs or devices only by and to entitles licensed by the board and authorized prescribers, and requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

11. Section **4061** of the Code provides, in pertinent part, that manufacturers' sales representatives may distribute complimentary samples of drugs only to and pursuant to a written request from an authorized prescriber that specifies the name and quantity of drug desired.

12. Section 4063 of the Code states:

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No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

13. Section 4064 of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every
reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record,
including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription
pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug
or dangerous device furnished without prescription pursuant to this section.

14. Section 4076, subdivision (a), of the Code provides, in pertinent part, that a

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1	pharmacist shall not dispense any prescription except in a container meeting the requirements of
2	state and federal law that is correctly labeled with information including the following:
. 3	(1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the
4	drug or the generic name and the name of the manufacturer;
5	(2) The directions for use of the drug;
6	(3) The name of the patient or patients;
7	(4) The name(s) of the prescriber(s);
8	(5) The date of dispensing;
9	(6) The name and address of the pharmacy, and prescription number;
10	(7) The strength of the drug(s) dispensed;
11	(8) The quantity of the drug(s) dispensed;
12	(9) The expiration date of the drug(s) dispensed;
13	(10) If on the prescription, the condition or purpose for which the drug was prescribed;
14	(11) A physical description of the dispensed medication.
15	15. Section 4081 of the Code states, in pertinent part:
16	(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs o
17	dangerous devices shall be at all times during business hours open to inspection by authorized
18.	officers of the law, and shall be preserved for at least three years from the date of making. A
19	current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-
20	animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
21	institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
22	registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
23	Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
24	Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
25	(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal
26	drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated
27	representative-in-charge, for maintaining the records and inventory described in this section.
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16. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.

17. Section **4113(c)** of the Code states:

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

18. Section 4125(a) of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

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19. Section 4160(a) of the Code states:

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless
 he or she has obtained a license from the board.

20. Section **4301** of the Code states, in pertinent part:

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

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

(g) Knowingly making or signing any certificate or other document that falsely represents
the existence or nonexistence of a state of facts.

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(i) The violation of any of the statutes of this state, of any other state, or of the United

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States regulating controlled substances and dangerous drugs.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7
 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(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.

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21. Section 4324 of the Code states:

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes,
alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any
drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment
pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county
jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged
prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the
Penal Code, or by imprisonment in the county jail for not more than one year.

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22. Section 4332 of the Code states:

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

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23. Section 4342 of the Code states:

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

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

Health and Safety Code:

24. Health and Safety Code section 11165 provides, in pertinent part, for establishment and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV controlled substance, the dispensing pharmacy or clinic transmit a report with certain information on the patient, prescriber, controlled substance, and prescription, to the California Department of Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

25. Health and Safety Code section 111340 states;

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted.

25 Requirements for placement and prominence of the information and exemptions as to small

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¹ Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

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	1	packages shall be established in accordance with regulations adopted pursuant to Section 110380.
	2	26. Health and Safety Code section 111440 states:
	3	It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or
	4	device that is misbranded.
	5	California Code of Regulations:
	- 6	27. California Code of Regulations, title 16, section 1707.2 states, in pertinent part:
	7	(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in
	. 8	all care settings:
	9	(1) upon request; or
	10	(2) whenever the pharmacist deems it warranted in the exercise of his or her professional
	11	judgment.
	12	(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall
	13	provide oral consultation to his or her patient or the patient's agent in any care setting in which th
	- 14	patient or agent is present:
	15	(A) whenever the prescription drug has not previously been dispensed to a patient; or
	16	(B) whenever a prescription drug not previously dispensed to a patient in the same dosage
	17	form, strength or with the same written directions, is dispensed by the pharmacy.
	18	(2) When the patient or agent is not present (including but not limited to a prescription drug
	19	that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
· .	20	(A) of his or her right to request consultation; and
	21	(B) a telephone number from which the patient may obtain oral consultation from a
	22	pharmacist who has ready access to the patient's record. (3) A pharmacist is not required by this subsection to provide oral consultation to an
	23	(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code
	24	or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the
	25 26	patient's discharge. A pharmacist is not obligated to consult about discharge medications if a
	20 27	health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250
	27	has implemented a written policy about discharge medications which meets the requirements of
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1	Business and Professions Code Section 4074.
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3	28. California Code of Regulations, title 16, section 1707.3 states:
4	Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's
5	drug therapy and medication record before each prescription drug is delivered. The review shall
6	include screening for severe potential drug therapy problems.
7	29. California Code of Regulations, title 16, section 1711 states:
8	(a) Each pharmacy shall establish or participate in an established quality assurance program
9	which documents and assesses medication errors to determine cause and an appropriate response
10	as part of a mission to improve the quality of pharmacy service and prevent errors.
11	(b) For purposes of this section, "medication error" means any variation from a prescription
12	or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as
13	defined in the section, does not include any variation that is corrected prior to furnishing the drug
14	to the patient or patient's agent or any variation allowed by law.
15	(c)(1) Each quality assurance program shall be managed in accordance with written policies
16	and procedures maintained in the pharmacy in an immediately retrievable form.
17	(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall
18	as soon as possible:
19	(A) Communicate to the patient or the patient's agent the fact that a medication error has
20	occurred and the steps required to avoid injury or mitigate the error.
21	(B) Communicate to the prescriber the fact that a medication error has occurred.
22	(3) The communication requirement in paragraph (2) of this subdivision shall only apply to
23	medication errors if the drug was administered to or by the patient, or if the medication error
24	resulted in a clinically significant delay in therapy.
25	(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a
26	prescriber, the pharmacist is not required to communicate with that individual as required in
27	paragraph (2) of this subdivision.
28	(d) Each pharmacy shall use the findings of its quality assurance program to develop
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pharmacy systems and workflow processes designed to prevent medication 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 error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2, the pertinent data and other information relating to the medication error(s) reviewed and .11 documentation of any patient contact required by subdivision (c); 12

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

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 16 17 program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be 18 immediately retrievable in the pharmacy for at least one year from the date the record was 19 created. 20

(g) The pharmacy's compliance with this section will be considered by the board as a 21mitigating factor in the investigation and evaluation of a medication error. 22

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or 23 otherwise arranging for the provision of personnel or other resources, by a third party or 24 administrative offices, with such skill or expertise as the pharmacy believes to be necessary to 25 satisfy the requirements of this section. 26

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California Code of Regulations, title 16, section 1714 states, in pertinent part: 30.

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

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

31. California Code of Regulations, title 16, section 1716 states:

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

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

32. California Code of Regulations, title 16, section 1717 states, in pertinent part:(a) No medication shall be dispensed on prescription except in a new container which

conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for nonliquid oral products in a clean multiple-drug patient medication package (patient med pak),
provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code section 4040, the

following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber 10 or directions for use, unless a complete record of all such changes is otherwise maintained.

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(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

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California Code of Regulations, title 16, section 1718, states: 33.

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

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

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California Code of Regulations, title 16, section 1793.7 states, in pertinent part: 34.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the

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preparation and dispensing of medications, including the maintenance of appropriate records.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

#### Code of Federal Regulations:

35. Title 21, Code of Federal Regulations, section **1304.04(f)** requires, in pertinent part, that inventories and records of Schedule I and II controlled substances shall be kept separate from all other records, and that inventories and records of Schedule III-V controlled substances shall be either kept separate from other records, or be immediately retrievable from the business records.

# Controlled Substances/Dangerous Drugs:

36. Section 4021 of the Code provides that a "controlled substance" means any substance
listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

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37. Section 4022 of the Code states, in pertinent part:

Dangerous drug: or "dangerous device" means any drug or device unsafe for self use,
except veterinary drugs that are labeled as such, and includes the following:

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

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

38. Klonopin is a brand name for clonazepam, a Schedule IV controlled substance as
designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by
Business and Professions Code section 4022. It is used to treat mental health symptoms.

24 39. Celexa is a brand name for citalopram, a dangerous drug as designated by Business
25 and Professions Code section 4022. It is used to treat mental health symptoms.

26 40; Zyprexa is a brand name for olanzapine, a dangerous drug as designated by Business
 27 and Professions Code section 4022. It is used to treat mental health symptoms.

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# COST RECOVERY

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

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# 2011 INSPECTIONS AND INVESTIGATION

42. Between in or about January and April 2011, Respondents were the subject(s) of investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping, dispensing, and furnishing practices that failed to comply with the law.

10 43. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of
11 the following deviations from pharmacy requirements was/were noted by the Inspector(s):

a. Included in the active drug inventory for the pharmacy were: (i) a prescription
bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed
on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing;
(ii) several boxes of prescription bottles containing professional drug samples; and (iii) one or
more bubble packs or strip packs containing drugs returned from board and care homes. There
were no records of acquisition maintained by Respondents with regard to any of these items.

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b. Respondents used a prescription dispensing software and system to create prefilled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The software and system did not make note of the identity of the dispensing pharmacist, nor was this information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of the thousands of prescriptions dispensed using this system during the previous nine (9) years.

c. The software and system used to generate the bubble/strip packs for board and
care homes also did not include required information on the label(s) generated during this nine (9)
year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.

d. In various places in the pharmacy, including in the active inventory, were
prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete

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labels affixed. Respondent asserted that these were returned from assisted living facilities.

e. Since at least October 21, 2009, Respondents had not successfully transmitted data regarding controlled substances dispensed by the pharmacy to the Controlled Substances Utilization Review (CURES) database maintained by the California Department of Justice,

f. Controlled substance invoices for at least the two months prior to the inspection were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist (store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs,

9 44. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents
10 dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized
11 prescriptions and/or refills, including:

a. On at least ten (10) occasions between on or about December 14, 2009 and on
or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances
and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for
controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); six (6) prescriptions for the
dangerous drug Celexa 40mg; and two (2) prescriptions for the dangerous drug Zyprexa 20mg.

b. On at least twenty-nine (29) occasions between on or about August 2, 2009 and
on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled
substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for
controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); fourteen (14) refills for the
dangerous drug Zyprexa 20mg; and ten (10) refills for the dangerous drug Celexa 40mg.

c. On at least seven (7) occasions between on or about July 10, 2009 and on or
 about January 19, 2010, Respondents created and/or signed prescription documents for DC that
 falsely stated authorization by the prescriber, including: one (1) prescription for controlled
 substance/dangerous drug clonazepam 0.5mg (Klonopin); five (5) prescriptions for the
 dangerous drug Celexa 40mg; and one (1) prescription for the dangerous drug Zyprexa 20mg.
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#### FIRST CAUSE FOR DISCIPLINE 1 (Incomplete Inventory and/or Records of Acquisition and/or Disposition) 2 Respondents are each and severally subject to discipline under section 4301(j) and/or 3 45. (o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342 4 of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes 5 regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, 6 7 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 8 practice of pharmacy, in that, as described in paragraph 43 above, Respondents failed to maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition and 9 disposition of all dangerous drugs in the pharmacy inventory. 10 SECOND CAUSE FOR DISCIPLINE 11 (Possessing and/or Dispensing/Furnishing Drug Samples) 12 46. Respondents are each and severally subject to discipline under section 4301(i) and/or 13 14 (o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly 15 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations 16 governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents had 17 in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples, 18 THIRD CAUSE FOR DISCIPLINE 19 (Failure to Identify Dispensing Pharmacist) 2047. Respondents are each and severally subject to discipline under section 4301(j) and/or 21 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, 22 section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or 23 directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws 24 or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, 25 Respondents dispensed medications without a means of identifying the dispensing pharmacist. 26 $\parallel \mid$ 27 111 28 16

# FOURTH CAUSE FOR DISCIPLINE

(Inadequately Labeled Prescription Containers)
48. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents dispensed medications in prescription containers which failed to include required information. **FIFTH CAUSE FOR DISCIPLINE**(Possession of Misbranded Drug Containers)
49. Respondents are each and severally subject to discipline under section 4301(j) and/or

(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340
and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or
directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above,
Respondents possessed drug containers that were misbranded inasmuch as they had affixed to
them no or incomplete labels describing the contents, the manufacturer, and other required data.

# SIXTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Prescriptions to CURES)

50. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, in the period prior to January 12, 2011, the pharmacy had not successfully transmitted any dispensing data to CURES for controlled substances that were dispensed since at least October 21, 2009. 

# SEVENTH CAUSE FOR DISCIPLINE

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(Failure to Segregate Schedule II Records)

2 51. Respondents are each and severally subject to discipline under section 4301(i) and/or 3 (o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations. 4 section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, 5 and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a б violation of laws or regulations governing the practice of pharmacy, in that, as described in 7 paragraph 43 above, on or about January 12, 2011, Schedule II records were not segregated. 8 EIGHTH CAUSE FOR DISCIPLINE 9 (Receipt and Acknowledgment of Delivery by Non-Pharmacist) 10 52. Respondents are each and severally subject to discipline under section 4301(j) and/or 11 (o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code, 12 for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or 13 indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or 14 regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, a 15 non-pharmacist received and/or signed for a delivery of a dangerous drug or device. 16 NINTH CAUSE FOR DISCIPLINE 17 (Furnishing/Dispensing Prescriptions Without Prescriber Authorization) 18 53. Respondents are each and severally subject to discipline under section 4301(j) and/or 19 (o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating 20statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly 21 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations 22 governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents 23 furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber. 24

#### TENTH CAUSE FOR DISCIPLINE

(Furnishing/Dispensing Refills Without Prescriber Authorization)

54. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating

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statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.

# **ELEVENTH CAUSE FOR DISCIPLINE**

(Dishonesty/Creation of False Prescription Document(s))

55. Respondents are each and severally subject to discipline under section 4301(f) and/or (g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude, dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts in that, as described in paragraph 44 above, Respondents created seven (7) false prescriptions for patient DC.

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## TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition of Drugs)

Respondents are each and severally subject to discipline under section 4301(j) and/or 56. 15 (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 16 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, 17 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 18 practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a 19 prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294, 20issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this 21 item. 22

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# THIRTEENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct)

57. Respondent is subject to discipline under section 4301 of the Code in that Respondents, as described in paragraphs 42-44 above, engaged in unprofessional conduct.

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	CASH COMPROMISE OF MEDI-CAL CHARGES	
	58. On or about June, 2010, the California Department of Health Care Services	
	(hereinafter "Department") audited Respondents' premises and records pertaining to the period of	
	March 1, 2009 through March 31, 2010.	
	59. Based on this audit, on or about July 16, 2010, the Department took formal action	
	against Respondents by withholding all Medi-Cal payments to Respondents and by suspending	
	and deactivating Respondents' Medi-Cal provider number and National Provider Identifier	
	number. The Department charged Respondents with having violated California Welfare and	
	Institutions Code section 14107(b) (false and fraudulent claims) and California Code of	
	Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false	
	information), based on to the following misconduct:	ļ
	a) Overbilling for medications;	:
	b) Billing for prescriptions that had not actually been provided to beneficiaries;	
	c) Falsification of a telephone prescription; and	
	d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.	4
	60. On or about October 13, 2010, Respondents entered into a cash compromise of the	د ۳
	above-described charges by signing a document entitled "Stipulation And Settlement Agreement	
	Between The California Department of Health Care Services And Daniel's Pharmacy." The	-
	agreement provided for settlement of the charges in exchange for Respondents' agreement to pay	;
	approximately \$1,000,000.00 to the Department.	a 11 aug
	FOURTEENTH CAUSE FOR DISCIPLINE	
	(Cash Compromise of Medi-Cal Charges)	and a second second
	61. Respondents are each and severally subject to discipline under section 4301(m)	1. 1. 1
	and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of	- La Lange
	violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare	
	and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 55-57.	
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#### 2013 INSPECTION

62. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents' pharmacy in order to ascertain whether Respondents continued to be in violation of law. The Inspectors observed numerous violations, as set forth below in the following Causes for Discipline.

#### FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Consult with On-Premises Patient)

63. Respondents are each and severally subject to discipline under section 4301(i) and/or 8 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 9 section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous 10 drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a 11 violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, 12 Respondents dispensed a prescription to patient DV, which had not previously been dispensed to 13 patient DV, without providing a consultation by a pharmacist. Respondents failed to have a 14 policy or procedure identifying medications for which a consultation should be provided. 15

# SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Consult with Off-Premises Patient)

64. Respondents are each and severally subject to discipline under section 4301(j) and/or 18 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 19 section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs, 20 and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a 21 violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, 22 Respondents prepared prescription medication for delivery to a patient, which medication had not 23 previously been dispensed to said patient, without providing any notification to the patient 24 regarding the patient's right to request a consultation, 25

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# SEVENTEENTH CAUSE FOR DISCIPLINE

(Possession of Misbranded Drug Containers)

65. Respondents are each and severally subject to discipline under section 4301(j) and/or

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(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Respondents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs and outdated products in current inventory. Respondents also had in its possession previously-

# dispensed bubble packs of medications which had been returned by board-and-care homes.

# **EIGHTEENTH CAUSE FOR DISCIPLINE**

(Failure to Initiate Quality Assurance Review)

66. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to Code section 4125(a) and California Code
of Regulations, Title 16, section 1711, for violating statutes regulating controlled substances or
dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or
abetting a violation of laws or regulations governing the practice of pharmacy, in that on August
1, 2013, Respondents admitted to Board Inspectors that they had failed to complete quality
assurance reviews, procedures and related forms in the aftermath of dispensing errors.

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## NINETEENTH CAUSE FOR DISCIPLINE

(Variation from Prescription)

67. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1716, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, altempting to violate, or assisting in or abetting a violation of
laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Board
Inspectors identified two prescriptions, RX numbers N9878911 and N9879201, which contained
erroneous directions for use and/or identified the wrong prescriber.

# TWENTIETH CAUSE FOR DISCIPLINE

(Improper Supervision of Pharmacy Technician)

68. Respondents are each and severally subject to discipline under section 4301(j) and/or

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(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy technician worked unsupervised in the basement of the facility, and had the ability to override the automated dispensing unit SynMed's scan features when replenishing the dispensing unit.

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# **TWENTY-FIRST CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Drugs)

69. 10 Respondents are each and severally subject to discipline under section 4301(i) and/or (c) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 11 12 section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 13 laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' 14 pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without 15 drug name, strength, lot numbers and expiration dates. The premises also contained automated 16 dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on 17 various counters in various locations, 18

# TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition of Drugs)

70. Respondents are each and severally subject to discipline under section 4301(j) and/or 21 (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 22 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, 23attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 24 practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained 25 numerous full bubble packs which had been acquired from board-and-care homes, the 26 27 receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules 28

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which had evidently previously been issued to patient PL. Respondents had no record of the acquisition of this item.

#### **TWENTY-THIRD CAUSE FOR DISCIPLINE**

(Unlicensed Wholesale Activity)

71. Respondents are each and severally subject to discipline under section 4301(f) and/or (j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were found to be in possession of medications which had been returned to them by board-and-care homes, thus constituting wholesaling activity, when Respondents were not licensed as wholesalers. Respondents evidently intended to reuse the medications.

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#### **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

(False Statements on Certificates or Documents)

72. Respondents are each and severally subject to discipline under section 4301(g) and/or 15 (i) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or 16 document and for violating statutes regulating controlled substances or dangerous drugs, and/or 17 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 18 laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board 19 Inspectors located documents showing that Respondents had filled a prescription for divalproex 2021 by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided divalproex by Wockhardt. 22

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#### TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards --- Key)

73. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of

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laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013, Respondents admitted that the key to the pharmacy was in the possession of a family member, and was not in a tamper-proof container.

#### **DISCIPLINE CONSIDERATIONS**

74. To determine the level of discipline, if any, to be imposed on Respondent Daniels and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:

a. On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of \$4,000,00, was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation System (CURES), in and/or between December 2004 and December 2008. That citation is now final and is incorporated by reference as if fully set forth herein.

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b. On or about October 21, 2009, Citation No. CJ 2008 41785, with a fine of \$4,000.00,
was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its
obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV
controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and
Evaluation System (CURES), in and/or between December 2004 and December 2008. That
citation is now final and is incorporated by reference as if fully set forth herein.

#### PRAYER

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

Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels
 Pharmacy (Respondent Daniels);

24 2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah
25 (Respondent Nasrah);

3. Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be
responsible 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;

Taking such other and further action as is deemed necessary and proper. 4. 5/81 DATED: VIRGINIA/HEROLD Executive Officer Board of Pharmacy Department of Consumer Affairs State of California *Complainant*  $\mathbf{28}$ Accusation