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

In the Matter of the Accusation and Petition to Revoke Probation Against:

# MICHAEL'S PHARMACY, INC.,

NATALYA SKYE, PHARMACIST-IN-CHARGE 960 East Green Street Pasadena, CA 91106 Pharmacy Permit No. PHY 47549

AND

NATALYA SKYE 14569 Benefit St., #102 Sherman Oaks, CA 91403 Original Pharmacist License No. RPH 55396 Case No. 5303

OAH No. 201502912

# STIPULATED SURRENDER OF LICENSE AND ORDER AS TO RESPONDENT MICHAEL'S PHARMACY ONLY

Respondents.

# **DECISION AND ORDER**

The attached Stipulated Surrender of License and Order is hereby adopted by the

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

This Decision shall become effective on July 13, 2015.

It is so ORDERED on July 2, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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By

AMARYLIS GUTIERREZ Board President

1	Kamala D. Harris		
2	Attorney General of California THOMAS L. RINALDI		
3	Supervising Deputy Attorney General SUSAN MELTON WILSON		
4	Deputy Attorney General State Bar No. 106902		
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
6	Telephone: (213) 897-4942 Facsimile: (213) 897-2804		
7	Attorneys for Complainant		
8		RE THE PHARMACY	
9	DEPARTMENT OF (	CONSUMER AFFAIRS CALIFORNIA	
10		Case No. 5303	
11	In the Matter of the Accusation and Petition to Revoke Probation Against:	OAH No. 201502912	
12	MICHAEL'S PHARMACY, INC.,	STIPULATED SURRENDER OF	
13	NATALYA SKYE, PHARMACIST-IN-CHARGE	LICENSE AND ORDER	
14	960 East Green Street Pasadena, CA 91106		
15	Pharmacy Permit No. PHY 47549	[RESPONDENT MICHAEL'S PHARMACY ONLY]	
16	AND		
17	NATALYA SKYE 14569 Benefit St., #102		
18	Sherman Oaks, CA 91403 Original Pharmacist License No. RPH 55396		
19	Respondents.		
20	incopoliticars.		
21	IT IS HEREBY STIPULATED AND AG	REED by and between the parties to the above-	
22	entitled proceedings that the following matters are true:		
23	PARTIES		
24	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.		
25	She brought this action solely in her official capacity and is represented in this matter by Kamala		
26	D. Harris, Attorney General of the State of California, by Susan Melton Wilson, Deputy Attorney		
27	General.		
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 Natalya Skye is the owner and authorized representative of Respondent Michael's Pharmacy, Inc. dba Michael's Pharmacy (Respondent), which is represented in this proceeding by attorney Herbert L. Weinberg, Esq., whose address is 1800 Century Park East, 8th Fl.Los Angeles, CA 90067.

3. On or about November 7, 2006, the Board of Pharmacy (Board) issued Pharmacy Permit No. PHY 47549 to Michael's Pharmacy Inc. dba Michael's Pharmacy (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2015, unless renewed.

9 4. The Pharmacy Permit held by Respondent is on probation, per the Board's
10 disciplinary decision "In The Matter of the Accusation Against Michael's Pharmacy Inc. d.b.a.
11 Michael's Pharmacy and Natalya Skye etc." case no. 3824, effective February 14, 2014, by which
12 Respondent's permit was revoked. However, the revocation was stayed and Respondent's permit
13 placed on probation for five (5) years with certain terms and conditions.

14 5. On or about October 29, 2014, pursuant to Complainant's Government Code section
15 494 Petition, an Ex Parte Interim Suspension Order was issued, suspending Respondent's
16 Pharmacy Permit No. PHY 47549, effective October 31, 2014.

On or about November 7, 2014, following noticed hearing of said Petition, an Interim
 Suspension Orders was issued, suspending the license of Respondent Pharmacy (Pharmacy
 Permit No. PHY 47549) until such time as the instant pleading could be filed and a final
 administrative decision and order made in the matter,

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# JURISDICTION

7. Accusation and Petition to Revoke Probation No. 5303 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against

Respondent. The Accusation and Petition to Revoke Probation and all other statutorily required
documents were properly served on Respondent on November 24, 2014. Respondent timely filed
its Notice of Defense contesting the Accusation. A copy of Accusation and Petition to Revoke
Probation No. 5303 is attached as Exhibit A and incorporated by reference.

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# ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation and Petition to Revoke Probation No. 5303. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

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

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

# CULPABILITY

11. Respondent understands that by signing this stipulation Entity enables the Board to issue an order accepting the surrender of their Pharmacy Permit without further process.

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### **CONTINGENCY**

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent 19 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may 20 communicate directly with the Board regarding this stipulation and surrender, without notice to or 21 participation by Respondent or its counsel. By signing the stipulation, Respondent understands 22 and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the 23time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its 24 Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or 25 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, 26 and the Board shall not be disqualified from further action by having considered this matter. 27

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

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

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

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### **ORDER**

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 47549, issued to Respondent Michael's Pharmacy, Inc. and/or Natalya Skye, is surrendered and accepted by the Board of Pharmacy.

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

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2. Respondent shall lose all rights and privileges as a licensed pharmacy in California as
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3. Respondent shall cause to be delivered to the Board its pocket license and, if one was
issued, its wall certificate on or before the effective date of the Decision and Order.

4. If Respondent Michael's Pharmacy Inc. or Respondent owner Natalya Skye ever
applies for licensure or petitions for reinstatement in the State of California, the Board shall treat
it as a new application for licensure. Respondent must comply with all the laws, regulations and
procedures for licensure in effect at the time the application or petition is filed, and all of the
charges and allegations contained in Accusation and Petition to Revoke Probation No. 5303 shall

be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant as deay the application or petition.

5. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation and Petition to Revoke No. 5303 shall be decided to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

# ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my altorney. Herberl L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order Voluatarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED 04/28 16

MICHALL'S/PU/RM/CY, INC By: NATALYA/SKTE Respondent

I have read and fully discussed with the owner and authorized representative of Respondent Michael's Plarmacy, Inc., Natalya Skye, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. Tapprove its form and content.

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HERBERT L. WEINBERG, ESO, Attorney for Respondent

Slipulated Surrender of License-Respondent Michael's Pharmacy (Case No. 5303)

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1	be deemed to be true, correct and admitted by Respondent when the Board determines whether to
2	grant or deny the application or petition.
3	5. If Respondent should ever apply or reapply for a new license or certification, or
4	petition for reinstatement of a license, by any other health care licensing agency in the State of
5	California, all of the charges and allegations contained in Accusation and Petition to Revoke No.
6	5303 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any
7	Statement of Issues or any other proceeding seeking to deny or restrict licensure.
8	
9	ACCEPTANCE
10	I have carefully read the above Stipulated Surrender of License and Order and have fully
11	discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it
12	will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order
13	voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
14	Board of Pharmacy.
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16	DATED:
17	MICHAEL'S PHARMACY, INC. By: NATALYA SKYE
18	Respondent
19	I have read and fully discussed with the owner and authorized representative of Respondent
20	Michael's Pharmacy, Inc., Natalya Skye, the terms and conditions and other matters contained in
21	this Stipulated Surrender of License and Order. I approve its form and content
22	Mader Mil
23	DATED: 7777/0 HERBERT L. WEINBERG, ESQ.
24	Attorney for Respondent
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	5 Stipulated Surrender of License- Respondent Michael's Pharmacy (Case No. 5303)

Stipulated Surrender of License- Respondent Michael's Pharmacy (Case No. 5303)<sup>1</sup>

1	ENDORSEMENT		
2	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted		
3	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.		
4	Dated: 5.5.15 Respectfully submitted,		
5	Kamala D. Harris		
6	Attorney General of California THOMAS L. RINALDI		
7	Supervising Deputy Attorney General		
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9 10	SUSAN MELTON WILSON Deputy Attorney General Attorneys for Complainant		
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]	Stipulated Surrender of License- Respondent Michael's Pharmacy (Case No. 5303)		

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# Exhibit A

Accusation and Petition to Revoke Probation No. 5303

Kamala D, Harris	
Attorney General of California	
GREGORY J. SALUTE Supervising Deputy Attorney General	
SUSAN MELTON WILSON	
Deputy Attorney General State Bar No. 106902	
300 So. Spring Street, Suite 1702 Los Angeles, CA 90013	
Los Angeles, CA 90013 Telephone: (213) 897-4942 Facsimile: (213) 897-2804	
Attorneys for Complainant	
BEFO	RETHE
BOARD OF DEPARTMENT OF (	PHARMACY CONSUMER AFFAIRS CALIFORNIA
In the Matter of the Accusation and Petition to Revoke Probation Against:	Case No. 5303
· · · ·	ACCUSATION AND PETITION TO REVOKE PROBATION
MICHAEL'S PHARMACY, INC., NATALYA SKYE,	
PHARMACIST-IN-CHARGE 960 East Green Street	
Pasadena, CA 91106	
Pharmacy Permit No. PHY 47549	
AND	
NATALYA SKYE	
14569 Benefit St., #102 Sherman Oaks, CA 91403 Original Pharmacist License No. RPH 55396	
Respondents.	
Complainant alleges:	
PAR	TIES
1. Virginia Herold (Complainant) bring	gs this Accusation and Petition to Revoke
Probation solely in her official capacity as the E	·
Department of Consumer Affairs.	
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	1 CUSATION AND PETITION TO REVOKE PRO

# MICHAEL'S PHARMACY

2. On or about November 7, 2006, the Board of Pharmacy (Board) issued Pharmacy
Permit No. PHY 47549 to Michael's Pharmacy Inc. dba Michael's Pharmacy (Respondent
Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges
brought herein and will expire on November 1, 2015, unless renewed.

3. The Pharmacy Permit held by Michael's Pharmacy Inc., is currently on probation,
per the Board's disciplinary decision "In The Matter of the Accusation Against Michael's *Pharmacy Inc. d.b.a. Michael's Pharmacy and Natalya Skye etc.*" case no. 3824, effective
February 14, 2014, by which Respondent's permit was revoked. However, the revocation was
stayed and Respondent Pharmacy's permit placed on probation for five (5) years with certain
terms and conditions. A copy of this Decision and Order, of which the Court is asked to take
official notice, is attached to this Petition as Exhibit A.

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NATALYA SKYE

4. On or about June 23, 2004, the Board of Pharmacy issued Original Pharmacist
License Number RPH 55396 to Natalya Skye (Respondent Skye). The Original Pharmacist
License expired on March 31, 2014, was renewed on May 1, 2014, and is due to expire on March
31, 2016, unless renewed.

18 5. Respondent Skye's Pharmacist License RPH 55396 is currently on probation, per the
Board's disciplinary decisions "In The Matter of the Accusation Against Michael's Pharmacy Inc.
20 d.b.a. Michael's Pharmacy and Natalya Skye etc." case no. 3824, effective February 14, 2014, in
21 which Respondent's license was revoked. However, the revocation was stayed and Respondent's
22 license placed on probation for five (5) years with certain terms and conditions. A copy of this
23 Decision and Order, of which the Court is asked to take official notice, is attached to this Petition
24 as Exhibit B.

6. Natalya Skye is and has been 100% owner of Respondent Michael's Pharmacy as
 well as Pharmacist-In-Charge of Respondent Pharmacy at all times since the permit was issued.
 INTERIM SUSPENSION ORDER(S)

7. On or about October 29, 2014, pursuant to petition of Complainant under

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Government Code section 494, an Ex Parte Interim Suspension Order was issued, suspending
 Pharmacy Permit No. PHY 47549 issued to Michael's Pharmacy Inc. dba Michael's Pharmacy
 (Respondent Pharmacy) and suspending Pharmacist License Number RPH 55396 issued to
 Natalya Skye (Respondent Skye), with an assigned effective date of October 31, 2014.

8. On or about November 7, 2014, following noticed hearing of said petition, Interim
 Suspension Orders were issued, suspending both licenses of Respondent Pharmacy (Pharmacy
 Permit No. PHY 47549) and Respondent Skye (Pharmacist License Number RPH 55396) until
 such time as the instant accusation may be filed and final administrative decision and order made
 in this matter,

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# JURISDICTION AND STATUTORY PROVISIONS FOR ACCUSATION

9. This Accusation is brought before the Board of Pharmacy (Board), Department of
Consumer Affairs, under the authority of the following laws.

13 10. Business and Professions Code section 118, subdivision (b) provides that the
14 suspension, expiration, surrender or cancellation of a license shall not deprive the Board of
15 jurisdiction to proceed with a disciplinary action during the period within which the license may
16 be renewed, restored, reissued or reinstated.

11. Business and Professions Code section 4300.1 provides: "The expiration,
cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or
decision of the board or a court of law, the placement of a license on a retired status, or the
voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to
commence or proceed with any investigation of, or action or disciplinary proceeding against, the
licensee or to render a decision suspending or revoking the license."

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12. Business and Profession Code section 4300 states:

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

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

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(1) Suspending judgment.

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(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

6 (c) The board may refuse a license to any applicant guilty of unprofessional conduct.
7 The board may, in its sole discretion, issue a probationary license to any applicant for a license
8 who is guilty of unprofessional conduct and who has met all other requirements for licensure.
9 The board may issue the license subject to any terms or conditions not contrary to public policy,
10 including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

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(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

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(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any

probationary certificate of licensure for any violation of the terms and conditions of probation.
Upon satisfactory completion of probation, the board shall convert the probationary certificate to
a regular certificate, free of conditions.

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

13. Business and Professions Code section 4301 states:

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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: (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.

9 (h) The administering to oneself, of any controlled substance, or the use of any dangerous 10 drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to 11 oneself, to a person holding a license under this chapter, or to any other person or to the public, or 12 to the extent that the use impairs the ability of the person to conduct with safety to the public the 13 practice authorized by the license.

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

(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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14. Business and Professions Code section 4036 defines the term "pharmacist" to mean
a natural person to whom a license has been issued by the board, under Section 4200 except as
specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist
license issued by the board is entitled to practice pharmacy as defined by this chapter, within or
outside of a licensed pharmacy as authorized by this chapter.

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15. Business and Professions Code section 4306.5 provides that unprofessional 1 conduct for a pharmacist may include any of the following: 2 3 4 (b) Acts or omissions that involve, in whole or in part, the failure to exercise or 5 implement his or her best professional judgment or corresponding responsibility with regard to 6 the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or 7 with regard to the provision of services. 8 9 16. Business and Professions Code section 4323 states: 10 Any person who, while on duty, sells, dispenses, or compounds any drug while under the 11 12 influence of any dangerous drug or alcoholic beverages shall be guilty of a misdemeanor. 13 17. Business and Professions Code section 4081 provides : All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 14 (a) 15 or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A 16 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-17 animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 18 19 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 2021 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. 22 (b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-23 24 animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated 25 representative-in-charge, for maintaining the records and inventory described in this section. The pharmacist-in-charge or designated representative-in-charge shall not be 26 (c) 27 criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, 28 6 ACCUSATION AND PETITION TO REVOKE PROBATION or in which he or she did not knowingly participate.

18. Business and Profession Code section **4113** defines the term "pharmacist-incharge" as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

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19. Health and Safety Code section 11153 provides:

7 (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. 8 The responsibility for the proper prescribing and dispensing of controlled substances is upon the . 9 prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the 10 prescription. Except as authorized by this division, the following are not legal prescriptions; (1) 11 an order purporting to be a prescription which is issued not in the usual course of professional 12 treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of 13 controlled substances, which is issued not in the course of professional treatment or as part of an 14 authorized narcotic treatment program, for the purpose of providing the user with controlled 15 substances, sufficient to keep him or her comfortable by maintaining customary use. 16

(b) Any person who knowingly violates this section shall be punished by imprisonment
pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding
one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and
imprisonment.

20. Health and Safety Code section **11170** provides:

No person shall prescribe, administer, or furnish a controlled substance for himself.

# STATE REGULATIONS

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21. Title 16 California Code of Regulations section 1714 provides:

(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.

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1 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice 2 of pharmacy. 3 (d) Each pharmacist while on duty shall be responsible for the security of the prescription 4 department, including provisions for effective control against theft or diversion of dangerous 5 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy 6 7 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist, 8 22, Title 16 California Code of Regulations section 1735 provides: 9 (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, 10 by or under the supervision of a licensed pharmacist, pursuant to a prescription: 11 (1) Altering the dosage form or delivery system of a drug 12 (2) Altering the strength of a drug 13 (3) Combining components or active ingredients 14 15 (4) Preparing a drug product from chemicals or bulk drug substances (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's 16 17 direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability. 18 (c) "Compounding" does not include, except in small quantities under limited 19 circumstances as justified by a specific, documented, medical need, preparation of a compounded 20drug product that is commercially available in the marketplace or that is essentially a copy of a 21 drug product that is commercially available in the marketplace. 22 23 (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply 24 to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.): 25 23. Title 16 California Code of Regulations section 1735.2 provides at subdivision (d). 26 (d) A drug product shall not be compounded until the pharmacy has first prepared a written 27 master formula record that includes at least the following elements: 28

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1	(1) Active ingredients to be used.
2	(2) Equipment to be used.
3	(3) Expiration dating requirements.
4	(4) Inactive ingredients to be used.
5	(5) Process and/or procedure used to prepare the drug.
6	(6) Quality reviews required at each step in preparation of the drug.
7	(7) Post-compounding process or procedures required, if any.
8	24. Title 16 California Code of Regulations section 1735.3 provides:
9	(a) For each compounded drug product, the pharmacy records shall include:
10	(1) The master formula record.
11	(2) The date the drug product was compounded.
12	(3) The identity of the pharmacy personnel who compounded the drug product.
13	(4) The identity of the pharmacist reviewing the final drug product.
14	(5) The quantity of each component used in compounding the drug product.
15	(6) The manufacturer, expiration date and lot number of each component. If the
16	manufacturer name is demonstrably unavailable, the name of the supplier may be
	substituted. Exempt from the requirements in this paragraph are sterile products
18	compounded on a one-time basis for administration within seventy-two (72) hours and
19	stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the
20	United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective Ma
21	1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed
22	under section 1250 of the Health and Safety Code.
23	(7) A pharmacy assigned reference or lot number for the compounded drug product.
. 24	(8) The expiration date of the final compounded drug product.
25	(9) The quantity or amount of drug product compounded.
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(d) Pharmacies shall maintain and retain all records required by this article in the 1 pharmacy in a readily retrievable form for at least three years from the date the record was 2 created. 3 25. Title 16 California Code of Regulations section 1774 provides: 4 (a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to 5 the Board shall be subject to the following conditions: 6 (1) Obey all laws and regulations substantially related to the practice of pharmacy; 7 (2) The permit, through its officer, partners or owners, shall report to the Board or its 8 designees quarterly, either in person or in writing as directed; if the final probation report is 9 not made as directed, the period of probation shall be extended until such time as the final 10 report is made; 11 (3) Cooperate with the Board in its inspectional program; 12 (4) Post or circulate notice of conditions of probation so that they are available to all 13 employees involved in pharmacy operations; 14 (5) Submit the operation of the pharmacy to peer review if deemed necessary by the Board; 15 (6) Provide evidence that owners or officers are knowledgeable in the laws pertaining to 16 pharmacy if deemed necessary by the Board. 17 18 (b) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative 19 case or by stipulation of the parties. 20Title 16 California Code of Regulations section 1761 provides : 26. 21 (a) No pharmacist shall compound or dispense any prescription which contains any 22significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any 23 24 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription. 25 111 2611.1 27 28 10 ACCUSATION AND PETITION TO REVOKE PROBATION (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

27. Title 16, California Code of Regulations section **1709.1**, subdivision (a) provides that the person identified as the pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

#### COST RECOVERY

8 28. Business and Professions Code section **125.3** provides, in pertinent part, that the 9 Board may request the administrative law judge to direct a licentiate found to have committed a 10 violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the 11 investigation and enforcement of the case, with failure of the licentiate to comply subjecting the 12 license to not being renewed or reinstated. If a case settles, recovery of investigation and 13 enforcement costs may be included in a stipulated settlement.

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#### DRUG CLASSIFICATIONS

15 29. <u>Oxycodone / Oxycontin</u> - Oxycodone is a Schedule II controlled substance
pursuant to Health and Safety Code Section 11055 (b)(1)(M) and a dangerous drug within the
meaning of Business and Professions Code section 4022. Oxycodone is a narcotic analgesic used
for the relief of severe pain and is similar in pharmacology to morphine. Oxycodone is marketed
either alone or in controlled release formulations, or in combination with non-narcotic analgesics
(e.g. aspirin or acetaminophen). Oxycontin (OxyContin) is a brand name for a popular extended *release formulation* of oxycodone.

30. <u>Hydrocodone</u> — Hydrocodone is a Schedule II controlled substance pursuant to
Health and Safety Code Section 11055 (b)(1)(J) and is a dangerous drug within the meaning of
Business and Professions Code section 4211(a). Hydrocodone is a narcotic analgesic and used for
the relief of severe pain.

2631.Hydrocodone /APAPis Schedule III controlled substance pursuant to Health and27Safety Code Section 11056 (e)(2) and is a dangerous drug within the meaning of Business and

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Professions Code section 4211 (a) Hydrocodone /APAP is a drug product combining 1 Hydrocodone with Acetaminophen ("APAP"). 2

32. Buprenorphine – Buprenorphine, also known by the brand name Subutex - is a 3 Schedule V controlled substance pursuant to Health and Safety Code Section 11058 (d) and is a dangerous drug within the meaning of Business and Professions Code section 4022, used for pain 5 relief and in treatment of opioid dependence. Buprenorphine/Naloxone, also known by the 6 brand name Suboxone, is a drug product combining Buprenorphine with Naloxone, and is also a 7 Schedule V drug pursuant to Health and Safety Code Section 11058 (d), used in treatment for 8 opioid dependence. 9

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# FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

33. The following allegations are common to all causes for discipline in this matter: At all times relevant herein, Respondent Natalya Skye (Respondent Skye) was 100% 12 a. owner and pharmacist-in-charge of Respondent Michael's Pharmacy (Respondent Pharmacy), a ·13 small retail pharmacy located in Pasadena, CA. 14

The probationary status of both Respondents, effective February 14, 2014, resulted in b. 15 multiple investigatory visits and inspections of the pharmacy between February and August of 16 2014, as detailed below. Additionally, in approximately April of 2014, the Board commenced 17 investigation of two anonymous complaints against Respondent Pharmacy which had been posted 18 on the Board's internet website in January 2014. The first complaint alleged that the pharmacy 19 was selling the drug Oxycontin for street use, stating "all sales are cash and no transactions are 20 shown in (the) database." The second complaint, similarly alleged that two pharmacy technicians 21 at Respondent Pharmacy were entering the store when Respondent Skye was not present, and 22 were conducting large cash-only sales of narcotics "to street drug dealers who routinely stop by 23 the pharmacy (in the evening)." It was further alleged that Respondent Pharmacy was engaged in 24 fraudulent billing and falsifying telephone prescriptions. 25

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### Oxycodone/Oxycontin Audit

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c. On April 24, 2014, a Board Inspector collected Respondent Michael's Pharmacy's biennial inventories, dispensing records and stock on hand records which he then analyzed to conduct an audit of the pharmacy's Oxycodone/Oxycontin traffic.

d. Oxycodone and Oxycontin are technically the same drug. Oxycontin is an extended
release form of Oxycodone - resulting from a chemical mechanism built into the Oxycontin
tablet which makes the distribution of medication prolonged instead of immediate.

8 e. Due to poor record keeping practices of the pharmacy, different audit dates were used
9 (Audit 1: Oxycodone 30mg IR Audit dates : 12/14/2012 to 01/14/2014; Audit 2: Oxycodone
10 <u>30 mg IR</u> Audit dates: 01/14/2014 to 04/24/2014; Audit 3: Oxycontin Audit dates: 01/16/2013
11 to 04/24/2014) – so that calculations covered overlapping time periods between approximately
12 January 2013 and April 2014.

f. Oxycodone Audit Results - Using 2 different audit periods, this targeted audit
 revealed pharmacy drug stock unaccounted for (not in inventory) as follows:

 <u>Oxycodone 30mgIR</u> – For the approximately sixteen month period between 12/14/2012 and 04/24/2014, Michael's Pharmacy could not account for/ was short
 **7, 300 tablets** of Oxycodone (30 mg IR).

<u>Oxycontin 20 mg and 80 mg</u> - For the approximately fifteen month period
 between 01/16/2013 to 04/24/2014, Michael's Pharmacy could not account/was
 short 60 tablets of Oxycontin (20 mg) and 410 tablets of Oxycontin (80 mg).

### Hydrocodone Audit

g. On or about April 25, 2014, a Board Inspector collected Michael's Pharmacy's
purchase, inventory and dispensing records and stock on hand records for a targeted audit of the
pharmacy's Hydrocodone/APAP traffic, following a comment by one of the pharmacy
employees that Respondents "ordered a lot" of Hydrocodone /APAP 10-325..
h. Hydrocodone /APAP is a drug product combining Hydrocodone with

Acetaminophen ("APAP"). Prior to October 2014, Hydrocodone /APAP had been classified as a
Schedule III drug, with a reputation for being easier to divert than higher scheduled drugs.

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i. The audit period chosen was for the recent four (4) month period between April 1. 1 2014 and August 1, 2014, and disclosed as follows: 2 Hydrocodone /APAP [5 mg Hydrocodone - 325mg Acetaminophen] 3 Purchases Dispensed Stock on hand Difference 4 4/1 ---4/1 --4/1 --4/1 --8/19/14 8/19/14 8/19/14 8/19/14 5 2000 769 147 -84 6 7 Hydrocodone /APAP [10 mg Hydrocodone- 325 mg Acetaminophen] Purchases Dispensed Stock on hand Difference 8 4/1 ---4/1-4/1 -4/1 ---8/19/14 8/19/14 8/19/14 8/19/14 9 17,000 5.090 221 -11,739 10 11 Hydrocodone Audit Results - This targeted audit revealed pharmacy drug stock i. 12 unaccounted for as follows: 13 Hydrocodone /APAP [5 mg Hydrocodone - 325 mg Acetaminophen] 1. for the 4 months between April 1 and August 1 of 2014, Michael's Pharmacy could not 14 15 account for/ was short 84 tablets of Hydrocodone /APAP 5-325 16 2. <u>Hvdrocodone /APAP</u> [10 mg Hydrocodone - 325 mg Acetaminophen] 17 for the 4 months between April 1 and August 1 of 2014, Michael's Pharmacy could not 18 account for/ was short 11,739 tablets of Hydrocodone /APAP 10-325." 19 Hydrocodone /APAP is a drug product combining Hydrocodone with 3. 20Acetaminophen. 21 **Corresponding Responsibility Analysis** 22 To investigate controlled substance dispensing practices of Respondents, a Board k. Inspector obtained and analyzed CURES<sup>1</sup> reports for schedule II through IV controlled 23 24 <sup>1</sup> The CURES (Controlled Substance Utilization, Review and Evaluation System) program was initiated in 1998, and requires mandatory monthly pharmacy reporting of dispensed schedule 25 II controlled substances (CII). Enabling statutes were amended in January 2005 to include mandatory weekly reporting of CII-IVs. The CURES program requires pharmacies to send data 26 to a data collection company, which then sends the pharmacy confirmation that the data was received and informs the pharmacy if any data was rejected. The data is collected statewide and 27can be used by healthcare professionals such as pharmacists and prescribers to evaluate and determine whether their patients are utilizing their controlled substances correctly. The data may 28(continued...)

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substances dispensed (and transmitted to CURES) by Michael's Pharmacy from 01/03/2011 to 02/07/2014 for trends and patterns consistent with diversion activity. These patterns included an unusually large proportion of cash sales, and that there was an excessive distance between the locations of the prescriber<sup>2</sup> and Respondent Pharmacy. Reviewing the patient list and dispensed drug list for each prescriber identified – the Inspectors derived a list of prescribing doctors for further investigation including **Dr. Choudhury, Dr. Smith** and **Dr. Swaby**.

7 1. The Inspector sent Dr. Choudhury, Dr. Smith and Dr. Swaby a list of dispensed
8 controlled substances from Respondent Pharmacy obtained from the CURES data, and asked
9 whether they had actually written the prescriptions listed. Each provided attestations to the effect
10 that he had neither had written nor authorized any of the prescriptions listed. Dr. Choudhury
11 and Dr. Swaby further noted that they had changed their DEA registration numbers, but that
12 prescriptions dispensed from Respondent Pharmacy showed their old/previous DEA registration
13 numbers.

On April 24, 2014, the Inspector conducted an inspection of Michael's Pharmacy, m. 14 during which he requested and obtained hard copy prescriptions for each controlled substance 15 16 prescription dispensed under the names of Dr. Choudhury, Dr. Smith and Dr. Swaby, totaling 208 prescriptions, as well as inventory records, and dispensing reports to be used in later analysis. 17 The Inspector further interviewed Respondent Skye about what steps or criteria were used at 18 Respondent Pharmacy to determine whether a prescription was medically legitimate. During that 19 interview. Respondent Skye admitted that she had never spoken to Dr. Choudhury, Dr. Smith or 20 Dr. Swaby, 21

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(...continued)

be used to aid in determining if a patient has been to multiple prescribers and multiple pharmacies to fill controlled substance prescriptions.

<sup>2</sup> A pattern of excessive distance between the locations of physician prescribers and Michael's Pharmacy was clear from the CURES data analysis. Regarding the 3 physicians referenced in this accusation - Dr. Choudhury's office was approximately **31** miles from Respondent Pharmacy; Dr. Smith's office was approximately **11** miles distant, and Dr. Swaby's office was approximately **71** miles distant. With the multitude of pharmacies available in this area, the standard trade distance for a pharmacy is approximately five (5) miles.

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n. Based on evidence thus obtained, the Inspector determined that Respondents did not
 routinely follow any protocol for prescription verification in day-to-day operation of Respondent
 Pharmacy, and had no written policies regarding dispensing of controlled substances. Of 125 hard
 copy prescriptions reviewed for Dr. Choudhury, Dr. Smith and Dr. Swaby, only 8 showed any
 notations or written documentation suggesting verification by the pharmacy was attempted.
 Respondents routinely filled prescriptions without appropriately scrutinizing their own patient
 records to verify medical legitimacy of prescriptions.

8 o. Based on his training and experience, information provided by Respondent Skye, and
9 his analysis of Respondent Pharmacy records related to prescriptions of Dr. Smith, Choudhury
10 and Swaby as described here, the Board inspector concluded that Respondents had failed in their
11 corresponding responsibility to verify the medical legitimacy of prescriptions purportedly written
12 by Smith, Choudhury and Swaby, having ignored key objective factors indicating prescriptions
13 were not legitimate, including but not limited to :

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1. The payment method for controlled substances for Dr. Smith, Choudhury and Swaby exhibited a 99% cash payment method.

2. Irregular pattern of a repeating group of patients exhibiting doctor shopping activity using prescriptions from Dr. Smith, Choudhury and Swaby.

3. Irregular pattern of dispensing prescriptions from Dr. Swaby and Choudhury whose offices were a significant distance away from the pharmacy.

4. Irregular pattern of nearly all diagnoses involved lumbar issues. The diagnoses were not varied.

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5. Varying signatures on prescriptions received, especially for Dr. Choundhury.

6. Lack of specific code signifying a doctor was certified to prescribe buprenorphine for opioid tolerance/dependence.

7. Dr. Smith's prescriptions were written with oddly extended void after dates. In addition, the prescriptions found at Michael's Pharmacy should have not been used after 2006.

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8. Dr. Swaby's prescriptions initiating patients on the highest doses of oxycodone without any pharmacy records showing upward tapering.

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9. Respondent Pharmacy filled prescriptions invalid on their face due to warning notices printed on the forms (e.g. "prescription is void if more than one (1) controlled substance prescription is written per blank").

Looking at the totality of circumstances regarding Dr. Choudhury, Dr. Smith or Dr. 6 p, Swaby - including but not limited to the fact that most were cash sales, the location of the 7 prescriber's practice in relation to the location of Respondent Pharmacy, the volume of the 8 prescriptions presented from these prescribers, Respondent Pharmacy's dispensing history, the 9 manner in which these prescriptions were presented to the pharmacy, and the use of invalid or 10 superseded prescription forms - Respondents should have questioned the legitimacy of the 208 11 prescriptions presented for these prescribers. The result of Respondents' omission to do so was 12 the repeated dispensing of controlled substances to persons diverting controlled substances by use 13 of falsified prescriptions and/or patients engaged in doctor shopping activity. 14

q. Buprenorphine Prescriptions - Respondents' handling of multiple prescriptions for
the drug Buprenorphine provide an example of repeated failure to catch or investigate obvious
prescription errors.

1. Under the Drug Addiction Treatment Act of 2000 (DATA), Buprenorphine products were approved for outpatient treatment for opioid dependence by **specially qualified doctors only**. Buprenorphine alone (Subutex) is recommended for induction therapy (i.e. the first several days of opioid dependency treatment). Buprenorphine in combination with naloxone (Subuxone) is recommended for maintenance therapy due to the presence of naloxone, an opioid antagonist. A pharmacist is reasonably expected to verify that any Buprenorphine prescriptions received were from specially trained physicians in compliance with DATA, as indicated by a specific code on the prescription.

2. Respondent Pharmacy records show that Buprenorphine was dispensed to patient
Vasily A. 50 (fifty) times from 04/30/2012 to 01/31/2014. Of the 4 prescribers (Abney,
Choudhury, Swaby and "Unknown") – only *one (*"unknown" - identified per DEA number)

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was DATA qualified. Additionally – since Buprenorphine's most typical use, as noted above, is for induction therapy (when a patient initiates weaning off of opioid products) – this patient's purported use of this drug for almost two (2) years is suspicious and reasonably required investigation.

3. Hard copy prescriptions obtained by the Inspector (with hand written indications that these prescriptions were specifically for opioid tolerance/dependence) included: (1) Choudhury RX 388600 written with 3 refills; and (2) Swaby RX 379427 written with 2 refills and RX 381296 written with 2 refills. Michael's Pharmacy dispensed these prescriptions and subsequent refills although the prescriptions were legally invalid, and did not bear a specific code identifying authorized buprenorphine prescribers.

### Practice Without a Valid License (April 2014)

r. Respondent failed to timely submit required paperwork and fees to renew her
pharmacist license, resulting in expiration of her license on March 31, 2014. Respondent then
continued working, often as the sole pharmacist at Michael's Pharmacy - without a current, valid
license - during the month between March 31, 2014 and May 1, 2014, when the license was
renewed.

s. After Respondent's delinquent renewal status came to the attention of the Board's
probation staff, a Board Inspector made an unannounced visit to Michael's Pharmacy, where she
found Respondent working *as the only pharmacist on duty*, inside the pharmacy.

t. Respondent's license had expired on the last day of March, 2014. The Inspector
discerned that Respondent nevertheless had worked as the *only pharmacist on duty* at Michael's
nearly every day of April prior to April 24, 2014.

u. On April 30, 2014, at approximately 1:45 pm the Inspector made a second
unannounced visit, finding (1) Respondent was the only pharmacist on duty ; and (2) Respondent
was observed to be acting in the capacity of a pharmacist

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# Compounding Violations (Inspection – April 2014)

v. During an inspection of Respondent Pharmacy on April 24, 2014, a Board inspector
 observed that Respondents had compounded 89 estradiol/testosterone capsules (1.25/2.5mg)

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1 however no compounding record was found, and the pharmacy technician who compounded the 2 drug admitted that she did not record the capsules she compounded and had poured them into a previously used vial. A recording log was found indicating this same product had been 3 compounded on previous dates. However, the pharmacy did not have a written master formula 4 record for this compounded product. Additionally, the estradiol/testosterone capsules were 5 contained in a bottle with a label indicating the bottle contained 30 capsules – when, in fact, it 6 was found to actually contain 89 capsules. 7

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# Loss of Consciousness While Driving (April 2014)

w. On April 28, 2014, Respondent Skye had an automobile accident, in which she collided with another vehicle on a freeway exit ramp – then was found passed out at the wheel of 10 her car. She was arrested at the scene by California Highway patrol officers pursuant to Vehicle Code section 23152(A) (driving under the influence of alcohol/drug). 12

On or about April 30, 2014, during an in-person interview about the incident with a 13 x. Board Inspector, Respondent admitted that she had lost consciousness while driving, but stated 14 that she did not know why. She additionally reported to the inspector that she'd been in eight (8) 15 car accidents since January, 2014. Subsequent toxicology testing of a fluid sample provided by 16 Respondent on the day of the accident documented that Lorazepam - a drug with a sedative effect 17 (for which Respondent had a prescription) - was in her system at the time of the accident. 18

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## **Overdose at Pharmacy (August 2014)**

On or about August 1, 2014 at a Pasadena hospital following the apparent drug у. 20overdose of Respondent's 66 year-old mother on the premises of Michael's Pharmacy, 2122 Respondent was arrested pursuant to Health and Safety Code section 11550 (Use/Under the influence of Controlled Substance). Respondent's mother was treated by paramedics and 23 transported for emergency treatment following a 911 call from the pharmacy. Respondent was 24 then arrested at approximately 3:50 pm, after a hospital social worker contacted police to report 25 her observations that Respondent appeared altered and was falling in and out of sleep while 26 attending her mother, Respondent voluntarily provided a blood sample at the time of her arrest. 27

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That sample tested positive for both "opiates<sup>3</sup>" and "benzodiazepines<sup>4</sup>."

2 Z, Respondent was working as a pharmacist at Respondent pharmacy on August 1, 2014 prior to the 911 emergency call - though pharmacy employees reported that Respondent was 3 "acting crazy" and "behaving differently" that day:, and that she "appeared unsteady and had 4 slurred speech." Pharmacy employee LO stated that she (LO) had arrived late to work that day, 5 On entering the pharmacy, she observed SR - Respondent's mother - sleeping in a chair. LO 6 stated that SR appeared pale and "didn't look right." Respondent stated that SR was OK - to just 7 let her sleep. However, LO noticed that SR's lips were turning blue - so they tried to wake her. 8 Finding her unresponsive, they called 911. 9

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#### Discovery of Self-Dispensing

aa. Investigating circumstances leading to the 911 call from Respondent pharmacy on
 August 1, 2014 Board Inspectors reviewed Respondent's Prescription Profile from 1/1/2012
 to 8/19/2014, showed multiple controlled substances, including Lorazepam, dispensed to

14 Respondent from Michael's Pharmacy as follows:

1.	Oxycodone/APAP 5-325	#20	7/12/2012
2.	Oxycodone/APAP 5-325	#30	11/26/2013
·3,	Alprazolam 0.25mg	#30	3/21/2014
4.	Lorazepam 2mg	#30	4/7/2014
5.	Amphetamine 10mg	#30	5/22/2014

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bb. The Inspector was told by pharmacy staff that Respondent Skye "always filled all her own prescriptions," information corroborated by pharmacy documents.

### Passcode Violation

cc. During an August 19, 2014 inspection, which occurred while Respondent Skye was enrolled in the Maximus diversion program, and *suspended from practice* per program requirements, the Board inspector inquired of Michael's Pharmacy staff who was ordering Schedule II controlled drugs in Respondent Skye's absence. An unlicensed employee (LO)

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<sup>3</sup> From the class of drugs containing opium or substantially similar in effect.

<sup>4</sup> This term describes a class of drugs that produce central nervous system depression and are typically used to treat insomnia and anxiety. Lorazepam is a benzodiazepine.

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admitted that she (LO) was ordering drugs – and that Respondent had given her the confidential
 CSOS passcode.<sup>5</sup> – and provided documents showing two (2) separate purchases by LO, made
 during Respondent's diversion program suspension
 Termination from Diversion (September 2014)

dd. On or about August 13, 2014, she completed a telephonic intake interview and was
accepted into the Board's Diversion Program ("Maximus"). Twenty-two (22) days later - on or
about September 4, 2014 - Respondent was terminated from the program and deemed a public
risk and "NOT safe to practice" by the Program Manager.

### FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards and Security)

34. Respondents SKYE and MICHAEL'S PHARMACY are subject to disciplinary
action under Business and Professions Code section 4300 for unprofessional conduct as defined
in section 4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of
Regulations section 1714 subdivision (b) and/or (d) in that pursuant to Board audits as noted
below Respondents failed to maintain pharmacy security or provide effective controls against
theft or diversion, resulting in massive inventory losses with no records to account for the
whereabouts or disposition of missing drug stock.

a. Hydrocodone/APAP Inventory Losses - Per Board audit for dates between April 1,
2014 and August 19,2014, Respondents had a shortage of 11,739 tablets of Hydrocodone/APAP
10 -325 tablets and 84 tablets of Hydrocodone /APAP 5-325,

- b. Oxycontin/Oxycodone Inventory Losses Per Board audits encompassing the
  approximately sixteen month period between 12/14/2012 and 04/24/2014 Respondents had a
  shortage of 7, 300 tablets of Oxycodone (30 mg IR), 60 tablets of Oxycontin (20 mg) and 410
  tablets of Oxycontin (80 mg).
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<sup>5</sup> Schedule II narcotics can only be ordered by a pharmacy from a wholesaler by two methods: 1) signing a DEA issued 222 form, or 2) placing the order electronically using a CSOS passcode. A CSOS passcode is pharmacist specific – and used to order Schedule II drugs electronically from a wholesaler.

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# SECOND CAUSE FOR DISCIPLINE

(Failure to Assume Corresponding Responsibility to Assure Legitimacy of Prescriptions) 35. Respondents SKYE and MICHAEL'S PHARMACY are subject to disciplinary action under Business and Professions Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o) in conjunction with Health and Safety Code section 11153, subdivision (a) and Title 16 California Code of Regulations section 1761, in that, between January 3, 2011 and February 7, 2014, Respondents dispensed controlled substance prescriptions pursuant to prescriptions which were invalid and/or falsified and/or contained significant errors, omissions, irregularities, uncertainties and/or ambiguities, which Respondent failed to observe or address, due to their failure to operate Respondent Pharmacy in a manner compliant with corresponding responsibility requirements to verify legitimacy of controlled substance prescriptions, as follows:

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a. Choudhury, Smith and Swaby Prescriptions - Respondents failed in their corresponding responsibility to verify the medical legitimacy of 208 falsified controlled substance prescriptions purportedly written by Dr. Choudhury, Dr. Smith and Dr. Swaby,

b. Buprenorphine Prescriptions - Respondents failed in their corresponding
responsibility to verify the medical legitimacy of prescriptions for the drug Buprenorphine
dispensed on 50 (fifty) instances from 04/30/2012 to 01/31/2014 to patient Vasily A.

c. No Protocol For Verification - Respondents failed in their corresponding responsibility to verify the medical legitimacy of prescriptions due to the failure to use or establish any protocol or implement routine practices for prescription verification in day-today operation of Respondent Pharmacy

### THIRD CAUSE FOR DISCIPLINE

(Failure of Pharmacist to Exercise Corresponding Responsibility)

36. Respondent SKYE is subject to disciplinary action under Business and Professions
Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o)
in conjunction with section 4306.5 subdivision (b) in that between January 3, 2011 and February
7, 2014, Respondent Pharmacy dispensed controlled substance prescriptions pursuant to

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1	prescriptions which were invalid and/or falsified and/or contained significant errors, omissions,		
2	irregularities, uncertainties and/or ambiguities, which Respondents failed to observe or address in		
3	a manner compliant with corresponding responsibility requirements (Health and Safety Code		
4	section 11153(a); Title 16 California Code of Regulations section 1761) as described in		
5	paragraphs 33 and 35 above. As owner and pharmacist-in-charge of Respondent Pharmacy,		
6	Respondent Skye's failure to establish and/or implement routine practices for prescription		
7	verification in day-to-day operation of Michael's Pharmacy, or otherwise ensure compliance		
8	with corresponding responsibility requirements - constitutes acts or omissions that involved the		
9	failure to exercise or implement her best professional judgment or corresponding responsibility.		
0	FOURTH CAUSE FOR DISCIPLINE		
1	(Failure to Maintain Records of Acquisition and Disposition)		
2	37. Respondents SKYE and MICHAEL'S PHARMACY are subject to disciplinary		
3	action under Business and Professions Code section 4300 for unprofessional conduct as defined		
4	in section 4301, subdivisions (j) and (o), in conjunction with section 4081, subdivisions (a) and		
5	(b) requiring that all records of acquisition or disposition of dangerous drugs shall be preserved .		
6	and open to inspection for at least three (3) years for reasons as follows:		
7	a. Hydrocodone/APAP Inventory Losses - Per Board audit for dates between April 1,		
8	2014 and August 19,2014, Respondents had a shortage of 11,739 tablets of Hydrocodone/APAP		
9	10 -325 tablets and 84 tablets of Hydrocodone /APAP 5-325 - with no records to account for the		
0	whereabouts or disposition of the missing drug stock.		
1	b. Oxycontin/Oxycodone Inventory Losses - Per Board audits encompassing the		
2	approximately sixteen month period between 12/14/2012 and 04/24/2014 Respondents had a		
3	shortage of 7, 300 tablets of Oxycodone (30 mg IR), 60 tablets of Oxycontin (20 mg) and 410		
4	tablets of Oxycontin (80 mg) - with no records to account for the whereabouts or disposition of		
5	the missing drug stock.		
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1	FIFTH CAUSE FOR DISCIPLINE			
2	(Operation of Pharmacy With Unlicensed Pharmacist)			
3	38. Respondents SKYE and MICHAEL'S PHARMACY are subject to disciplinary			
4	action under Business and Professions Code section 4300 for unprofessional conduct as defined			
5	in section 4301, subdivisions (j) and (o), in conjunction with section 4036 (which requires that			
6	only the holder of an unexpired and active pharmacist license issued by the Board is entitled to			
7	practice within the licensed pharmacy premises) in that on dates between April 1, 2014 and May			
8	1, 2014:			
9	a. Respondent Pharmacy employed Respondent Skye as pharmacist-in-charge although			
10	her pharmacist license status was delinquent.			
11	b. Respondent Skye maintained her employment as pharmacist-in-charge of Respondent			
12	Pharmacy and in that capacity and otherwise engaged in acts (set forth in Title 16 California Code			
13	of Regulations section 1793.1 <sup>6</sup> ) requiring an unexpired and active pharmacist license			
14	SIXTH CAUSE FOR DISCIPLINE			
15	(Violations Related to Compounded Drug Products)			
16	39. Respondents SKYE and MICHAEL'S PHARMACY are subject to disciplinary			
17	action under Business and Professions Code section 4300 for unprofessional conduct as defined			
18	in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with			
19	Title 16 California Code of Regulations (CCR) sections 1735.2 and 1735.3, subdivision (a), in			
20				
21	<sup>6</sup> Title 16 California Code of Regulations section 1793.1 provides: Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:			
22	<ul> <li>(a) Receive a new prescription order orally from a prescriber or other person authorized by law.</li> <li>(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after</li> </ul>			
23	<ul> <li>dispensing, or regarding any medical information contained in a patient medication record system or patient chart.</li> <li>(c) Identify, evaluate and interpret a prescription.</li> <li>(d) Interpret the clinical data in a patient medication record system or patient chart.</li> <li>(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.</li> </ul>			
24				
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26	(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion,			
27	(g) Perform all functions which require professional judgment.			
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	ACCUSATION AND PETITION TO REVOKE PROBATION			

that during an inspection of Respondent Pharmacy on April 24, 2014, compounded drug products
prepared by the pharmacy were found to be noncompliant with labeling and record-keeping
requirements as follows:

a. 16 CCR § 1735.2 (d) (No Master formula Record) - On or about April
24,2014, Respondents compounded 89 estradiol/testosterone capsules (1.25/2.5mg), and a
recording log was found indicating this same product had been compounded on previous dates.

7 However, the pharmacy did not have a written master formula record for this compounded
8 product as required by 16 C.C.R.section 1735.2(d).

b. 16 CCR §1735.3 (a)(2)(3)(4)(5)(6) (No Compounding Record) On or about
April 24,2014, Respondents compounded 89 estradiol/testosterone capsules (1.25/2.5mg),
however no compounding record was found, and the pharmacy technician who compounded the
drug admitted that she did not record the capsules she compounded and had poured them into a
previously used vial,

c. 16 CCR §1735.3 (a) (5) (Incorrect Quantity on Label) – On or about April 24, 2014, a bottle of estradiol/testosterone capsules prepared for a patient, with a label indicating the bottle contained 30 capsules – was found to *actually* contain 89 capsules.

### SEVENTH CAUSE FOR DISCIPLINE

(Self-Furnishing of Controlled Substance(s))

40. Respondent SKYE is subject to disciplinary action under Business and Professions
4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in
conjunction with Health and Safety Code section 11170, in that on dates between January 2012
and August 19, 2014, Respondent filled her own prescriptions (furnished to herself) controlled
substances as follows:

1.	Oxycodone/APAP 5-325	#20	7/12/2012
2,	Oxycodone/APAP 5-325	#30	11/26/2013
3,	Alprazolam 0.25mg	#30	3/21/2014
4.	Lorazepam 2mg	#30	4/7/2014
5.	Amphetamine 10mg	#30	5/22/2014
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EIGHTH CAUSE FOR DISCIPLINE 1 (Use of Controlled Substance(s) to the Extent That Use Impairs Safety) 2 41. Respondent SKYE is subject to disciplinary action under Business and 3 4 Professions 4300 for unprofessional conduct as defined in section 4301, subdivision (h) in that, 5 on multiple instances noted below, Respondent used controlled substances to an extent or in a 6 manner dangerous to herself or any other person or the public, or to the extent that such use 7 impaired her ability to conduct with safety the practice authorized by her license, by reason of the 8 following facts: Q. a. April 28, 2014 - On April 28, 2014, shortly after leaving work at Respondent 10 Pharmacy, Respondent Skye had an automobile accident, in which she collided with another 11 12 vehicle on a freeway exit ramp – then was found passed out at the wheel of her car. She was 13 arrested at the scene by California Highway patrol officers pursuant to Vehicle Code section 14 23152(A) (driving under the influence of alcohol/drug). In an subsequent interview about the 15 incident with a Board Inspector, Respondent admitted that she had lost consciousness while 16 driving, but stated that she did not know why. Subsequent toxicology testing of a fluid sample 17 provided by Respondent on the day of the accident documented that Lorazepam – a drug with a 18 sedative effect (for which Respondent had a prescription) - was in her system at the time of the 19 20 accident. 21

b. August 1, 2014 - On August 1, 2014 at a Pasadena hospital following the apparent
drug overdose of Respondent's 66 year-old mother on the premises of Michael's Pharmacy
Respondent was arrested pursuant to Health and Safety Code section 11550 (Use/Under the
influence of Controlled Substance). Respondent's mother was treated by paramedics and
transported for emergency treatment following a 911 call from the pharmacy. Respondent was
then arrested at approximately 3:50 pm, after a hospital social worker contacted police to report
her observations that Respondent appeared altered and was falling in and out of sleep while

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attending her mother. Respondent voluntarily provided a blood sample at the time of her arrest. 1 That sample tested positive for both "opiates<sup>7</sup>" and "benzodiazepines<sup>8</sup>." 2

Respondent was working as a pharmacist at Respondent Pharmacy on August 1, 2014 c. prior to the 911 emergency call - though pharmacy employees reported that Respondent was "acting crazy" and "behaving differently" that day, and that she "appeared unsteady and had slurred speech."

d. Deemed a Risk to Public Safety - On or about August 13, 2014, Respondent Skye was accepted into the Board's Diversion Program for treatment of substance abuse. Twenty-two (22) days later - on or about September 4, 2014 - Respondent was terminated from the program and deemed a public risk and "NOT safe to practice" by the Program Manager. 10

### NINTH CAUSE FOR DISCIPLINE

(Practice as Pharmacist While Under the Influence)

Respondent SKYE is subject to disciplinary action under Business and Professions 42. 13 Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (i) and 14 (o), in conjunction with section 4327, in that Respondent was under the influence of a dangerous 15 drug while on duty and working as a pharmacist at Respondent Pharmacy on or about April 28, 16 2014 and on August 1, 2014 (as detailed in paragraphs 33 and 42 above). 17

### TENTH CAUSE FOR DISCIPLINE

(Violation of Federal Pharmacy Regulations)

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43. Respondent SKYE is subject to disciplinary action under Business and Professions 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code of Federal Regulations section 1311.30, subdivision (c), in that in August, 2014, Respondent gave her confidential CSOS passcode to an unlicensed employee, in order to 23 allow the employee to make two controlled substance purchases (on August 15, 2014 and August 24 18, 2014) during a time when Respondent's license was suspended. 25

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From the class of drugs containing opium or substantially similar in effect. This term describes a class of drugs that produce central nervous system depression and are typically used to treat insomnia and anxiety. Lorazepam is a benzodiazepine.

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# JURISDICTION FOR PETITION TO REVOKE PROBATION

44. This Petition to Revoke Probation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs pursuant to the Decision and Order(s) In the Matter of the accusation Against Michael's Pharmacy, Inc. d.b.a. Michael's Pharmacy and Natalya Skye, Case No. 3824, Condition 12 (Michael's Pharmacy Order – Exhibit A) and Condition 14 (Skye Order- Exhibit B), which term and condition states:

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

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

# FIRST CAUSE TO REVOKE PROBATION

(Respondent Michael's Pharmacy Only - Failure to Obey all Laws)

45. At all times after the effective date of Respondent Michael's Pharmacy's probation, Condition 1 stated in pertinent part:

"Respondent owner shall obey all state and federal laws and regulations."

46. Respondent Michael's Pharmacy's probation is subject to revocation because it/its
owner failed to comply with Probation Condition 1, referenced above. The facts and
circumstances regarding this violation are as follows:

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1	a. All allegations supporting the First, Second, Fourth, Fifth and Sixth Causes for
2	Discipline in the Accusation filed herewith as alleged at paragraphs 33, 34,35,37,38 and 39 above
3	are re-alleged as though fully set forth.
4	SECOND CAUSE TO REVOKE PROBATION
5	(Respondent Skye Only - Failure to Obey all Laws)
6	47. At all times after the effective date of Respondent Natalya Skye's probation,
. 7	Condition 2 stated in pertinent part:
8	"Respondent shall obey all state and federal laws and regulations."
9	48 Respondent Natalya Skye's probation is subject to revocation because she failed to
10	comply with Probation Condition 2, referenced above. The facts and circumstances regarding this
11	violation are as follows:
12	a. All allegations supporting the First, Second, Third, Fourth, Fifth, Sixth, Seventh,
13	Eighth, Ninth and Tenth Causes for Discipline in the Accusation filed herewith as described in
14	paragraphs 33 – through 47 above are re-alleged as though fully set forth.
15	THIRD CAUSE TO REVOKE PROBATION
.16	(Respondent Skye Only - Practiced Pharmacy Without a Current, Valid License)
17	49. At all times after the effective date of Respondent Skye's probation, Condition 10 of
18	the probation order stated in pertinent part:
19	"Status of License - Respondent shall, at all times while on probation, maintain an active,
20	current license with the board, including any period during which suspension or probation s
21	is tolled. Failure to maintain an active, current license shall be considered a violation of
22	probation"
23	50. Respondent Skye's probation is subject to revocation because she failed to comply
24	with Probation Condition 10. The facts and circumstances regarding this violation are as follows:
25	`a. Respondent failed to timely submit required paperwork and fees to renew her
26	pharmacist license, resulting in expiration of her license on March 31, 2014. Respondent then
27	continued working without a current, valid license, as pharmacist-in-charge and was often the
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•	ACCUSATION AND PETITION TO REVOKE PROBATION

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sole pharmacist at Michael's Pharmacy during the month between March 31, 2014 and May 1,
 2014, when the license was renewed.

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# FOURTH CAUSE TO REVOKE PROBATION

(Respondent Skye Only – Violation of Suspension Order)

51. At all times after the effective date of Respondent Skye's probation, Condition 1 of the probation order stated:

" Suspension - As part of probation, respondent is suspended from the practice of pharmacy for forty five (45) days, beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of 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 devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances,

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 unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation." (emphasis added)

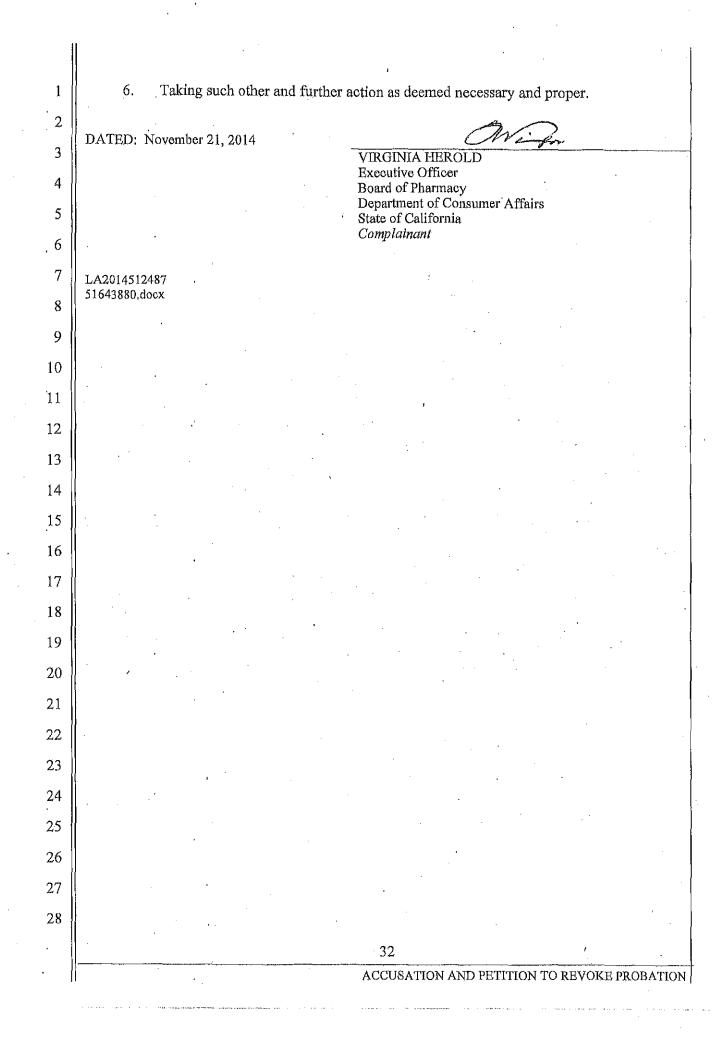
52. Respondent Natalya Skye's probation is subject to revocation because she failed to comply with Probation <u>Condition 10</u>, which Respondent admitted to her probation monitor during

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ACCUSATION AND PETITION TO REVOKE PROBATION

1 an office conference on March 10, 2014. At that time, Respondent stated that she had violated the Board's suspension order, and had worked at Michael's Pharmacy for five (5) days - February 14 2 through 19, 2014. Respondent claimed she was confused about when the suspension began, 3 **OTHER MATTERS** 4 53. In order to determine the degree of discipline, if any, to be imposed on Respondents, 5 Complainant alleges the following: 6 On or about August 22, 2014, Cardinal Health ( a licensed drug wholesaler) notified 7 a. 8 the Board that it had suspended Michael's Pharmacy's account from ordering controlled and 9 monitored substances based in their determination that continued sales to this customer created an unreasonable risk of potential diversion. 10 11 PRAYER WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this 12 Accusation and Petition to Revoke Probation, and that following the hearing, the Board of 13 Pharmacy issue a decision: 14 1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3824 15 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY 16 47549 issued to Michael's Pharmacy, Inc. dba Michael's Pharmacy; 17 2. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3824 18 19 and imposing the disciplinary order that was stayed thereby revoking Pharmacist License Number RPH 55396 to Natalya Skye (Respondent Skye). 20 3. Revoking or suspending Pharmacy Permit No. PHY 47549, issued to Michael's 21 Pharmacy, Inc.dba Michael's Pharmacy; 22 Revoking or suspending Pharmacist License Number RPH 55396 issued to Natalya 4. 23 Skye; 24 5. Ordering Michael's Pharmacy, Inc. and Natalya Skye to pay the Board of Pharmacy 25 the reasonable costs of the investigation and enforcement of this case, pursuant to Business and 26Professions Code section 125.3; and 27 1.11 28 31

ACCUSATION AND PETITION TO REVOKE PROBATION



# EXHIBIT "A"

# EXHIBIT A

Decision and Order as to Respondent Michael's Pharmacy

Board of Pharmacy Case No. 3824

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

In the Matter of the Accusation Against:

# MICHAEL'S PHARMACY, INC., d.b.a, MICHAEL'S PHARMACY NATALYA SKYE, PHARMACIST-IN-CHARGE 960 East Green Stieet Pasadena, CA 91106 Pharmacy Permit No, PHY 47549

AND

NATALYA SKYE 14569 Benefit St., #102 Sherman Oaks, CA 91403 Pharmacist License No. RPH 55396

Respondents.

Case No. 3824

# STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

**(AS RESPONDENT MICHAEL'S** PHARMACY INC. ONLY

# DECISION AND ORDER

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

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

This decision shall become effective on February 14, 2014.

It is so ORDERED on February 7, 2014.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	• - •	
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STAN C. WEISSER Board President

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•	1	KAMALA D, HARRIS Attorney General of California		
	.2	GREGORY J. SALUTE Supervising Deputy Attorney General		
	3	SUSAN MELTON WILSON	· · · · · · · · · · · · · · · · · · ·	
	. 4	State Bar No. 106902 300 So. Spring Street, Suite 1702		
	5	Los Angeles, CA 90013		
	6	Telephone: (213) 897-4942 Facsimile: (213) 897-2804 E-mail: Susan.Wilson@doj.ca.gov		
	7	Attorneys for Complainant	· · ·	
	8		RE THE PHARMACY	
	9	DEPARTMENT OF C	PHARMACY CONSUMER AFFAIRS CALIFORNIA	
	10	STATE OF C		
	11	In the Matter of the Accusation Against:	Case No. 3824	
	12		STIPULATED SETTLEMENT AND	
	13	MICHAEL'S PHARMACY, INC., d.b.a. MICHAEL'S PHARMACY	DISCIPLINARY ORDER	
	14	NATALYA SKYE, PHARMACIST-IN-CHARGE	[RESPONDENT MICHAEL'S PHARMACY INC. ONLY ]	
	. 15	960 East Green Street		
	16	Pasadena, CA 91106 Pharmacy Permit No. PHY 47549		
	17	AND		
	. 18	NATALYA SKYE		
	· 19	14569 Benefit St., #102 Sherman Oaks, CA 91403		
•.	20	Original Pharmacist License No. RPH 55396		
	21	Respondents.		
	22	IT IS HEREBY STIPULATED AND AG	REED by and between the parties to the above-	
	23	entitled proceedings that the following matters a	re true:	
	24	PAR	<u>XTIES</u>	
	25	1. Virginia Herold (Complainant) is the	e Executive Officer of the Board of Pharmacy.	
	26	She brought this action solely in her official capacity and is represented in this matter by Kamala		
	27	D, Harris, Attorney General of the State of Calif	ornia, by Susan Melton Wilson, Deputy Attorney	
	28	General,		
			1 2	
		STIPULATED SE	TTLEMENT- RESPONDENT MICHAEL'S PHARMACY	

2. Respondent Michael's Pharmacy, Inc., d.b.a. Michael's Pharmacy (Respondent), whose legally authorized representative is Natalya Skye, is represented in this proceeding by attorney Herbert Weinberg, whose address is: Law Offices of MoGuire Woods 1800 Century Park East, 8th Floor, Los Angeles, CA 90067

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3. On or about November 7, 2006, the Board of Pharmacy (Board) issued Pharmacy Permit No. PHY 47549 to Michael's Pharmacy Inc. d.b.a. Michael's Pharmacy (Respondent). Natalya Skye is an owner of Respondent and has been Pharmaoist-In-Charge of Respondent since November 7, 2006. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2014, unless renewed.

# JURISDICTION

Accusation No. 3824 was filed before the Board of Pharmacy (Board), Department
 of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
 statutorily required documents were properly served on Respondent on August 14, 2012.
 Respondent timely filed its Notice of Defense contesting the Accusation.

15 5. A copy of Accusation No. 3824 is attached as Exhibit A and incorporated herein by
16 reference.

# ADVISEMENT AND WAIVERS

18 6. Respondent, by its authorized representative, has carefully read, fully discussed with
19 counsel, and understands the charges and allegations in Accusation No. 3824. Respondent has
20 also carefully read, fully discussed with counsel, and understands the effects of this Stipulated
21 Settlement and Disciplinary Order.

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

STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

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

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# CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 3824.

10. Respondent agrees that its Original Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

# CONTINGENCY ·

11. This stipulation shall be subject to approval by the Board of Pharmacy, Respondent 9 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may 10 communicate directly with the Board regarding this stipulation and settlement, without notice to 11 or participation by Respondent or its counsel. By signing the stipulation, Respondent understands 12 and agrees that they may not withdraw its agreement or seek to resolut the stipulation prior to the 13 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its 14 Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or 15 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, 16 and the Board shall not be disqualified from further action by having considered this matter. 17

18 12. The parties understand and agree that facsimile copies of this Stipulated Settlement
and Disciplinary Order, including facsimile signatures thereto, shall have the same force and
effect as the originals.

13. 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.

STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

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

# DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit No. PHY 47549 issued to Respondent Michael's Pharmacy, Inc.; IS REVOKED. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations.

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

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an arrest or issuance of a criminal complaint for violation of any provision of the

Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment

□ a conviction of any crime

□ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or

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

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2, Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of

charging for any drug, device or controlled substance.

STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

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

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# 4. Cooperate with Board Staff

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

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# Reimbursement of Board Costs

Respondent shall be jointly and severally liable with co-respondent to Accusation 3824, Natalya Skye for reimbursement to the Board of its costs of investigation and prosecution in the total sum of Eleven Thousand Dollars (\$11, 000.00). Payment of the total sum shall be a condition precedent to successful completion of probation. Respondent shall make said payment within sixty (60) days of the effective date of this decision.

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.

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

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### 6. Probation Monitoring Costs

Respondent owner 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

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STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

directed shall be considered a violation of probation.

### 7. Status of License

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

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

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### License Surrender While on Probation/Suspension 8.

Following the effective date of this decision, should respondent owner discontinue 14 business, respondent owner may tender the premises license to the board for surrender. The 15 board or its designee shall have the discretion whether to grant the request for surrender or take 16 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of 17 the license, respondent will no longer be subject to the terms and conditions of probation, 18

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and 19 renewal license to the board within ten (10) days of notification by the board that the surrender is 20accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer, 22

Respondent owner shall also, by the effective date of this decision, arrange for the 23continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written 24 notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that 25 identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating 26as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five 27days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy 28

STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years
from the effective date of the surrender. Respondent owner shall meet all requirements applicable
to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of
investigation and prosecution prior to the acceptance of the surrender.

# 9. Notice to Employees

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Respondent owner shall, upon or before the effective date of this decision, ensure that all 11 employees involved in permit operations are made aware of all the terms and conditions of 12 probation, either by posting a notice of the terms and conditions, circulating such notice, or both. .13 If the notice required by this provision is posted, it shall be posted in a prominent place and shall 14 remain posted throughout the probation period. Respondent owner shall ensure that any 15 employees hired or used after the effective date of this decision are made aware of the terms and 16 conditions of probation by posting a notice, circulating a notice, or both. Additionally, 17 respondent owner shall submit written notification to the board, within fifteen (15) days of the 18 effective date of this decision, that this term has been satisfied. Failure to submit such 19 notification to the board shall be considered a violation of probation. 20

> "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.

# 10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, 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, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and

STIPULATED SETTLEMENT- RESPONDENT MICHAEL S FRIARMACT

regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

Posted Notice of Probation 11.

Respondent owner 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.

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

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

Violation of Probation 12.

If a respondent owner has not complied with any term or condition of probation, the board 13 shall have continuing jurisdiction over respondent license, and probation shall be automatically 14 extended until all terms and conditions have been satisfied or the board has taken other action as 15 deemed appropriate to treat the failure to comply as a violation of probation, to terminate 16 probation, and to impose the penalty that was stayed, 17

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If respondent owner violates probation in any respect, the board, after giving respondent 18 owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 19 order that was stayed. Notice and opportunity to be heard are not required for those provisions 20stating that a violation thereof may lead to automatic termination of the stay and/or revocation of 21the license. If a petition to revoke probation or an accusation is filed against respondent during 22 probation, the board shall have continuing jurisdiction and the period of probation shall be 23 automatically extended until the petition to revoke probation or accusation is heard and decided, 24 25

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# **Completion of Probation**

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

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**Community Services Program** 14.

STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHARMACY

Within sixty (60) days of the effective date of this decision, respondent owner shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least seventy five (75) hours during the period of probation.

Within thirty (30) days of board approval thereof, respondent owner shall submit documentation to the board demonstrating commencement of the community service program, Respondent owner 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.

15. Separate File of Records

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

# 16. Administrative Penalty

Respondent shall be jointly and severally liable with co-respondent to Accusation 3824. 16 Natalya Skye, to pay an Administrative Penalty in the sum of Twenty Five Thousand Dollars 17 (\$25,000.00) Payment of the assessed administrative penalty shall be completed during the first 18 19 four years of probation, in accord with a payment plan approved by the Board or its designee. 20Respondent may pay the full remaining unpaid balance of the assessed administrative penalty at any time. It shall be Respondent's responsibility to mail or otherwise deliver each payment 21 directly to the Board at the Board's Sacramento address in a timely manner. Failure to make any 22 payment when due shall be considered a violation of probation, 23

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# ACCEPTANCE

I am an owner and legally authorized representative of Respondent Michael's Pharmacy
Inc., corporate license holder of Pharmacy Permit No. PHY 47549. I have carefully read the
above Stipulated Settlement and Disciplinary Order and have fully discussed it with attorney,
Herbert Weinberg. I understand the stipulation and the effect it will have on Pharmacy Permit

STIPULATED SETTLEMENT- RESPONDENT MICH ' TI 10 MI

2002/003

1	No. PHY 47549. On behalf of Respondent Michael's Pharmacy Inc. I enter into this Stipulat
•	
2	Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree that
. 3	Michael's Pharmacy Inc. will be bound by the Decision and Order of the Board of Pharmacy
4	
5	DATED: 11/10713
c.	NATALYA SKYE
б	Authovized Representative of
7	MICHAEL'S PHARMACY, INC. d.b.a. MICHAEL'S PHARMACY
8	Respondent
9	I have read and fully discussed with the legally anthonized representative(s) of Respon
· 10.	Miobaci's Pharmacy, Inc., all terms and conditions and other matters contained in the above
11	
12	Stipulated Settlement and Disciplinary Order. I approve its formand content.
	DATED: $\frac{11}{12}$
13	HERBERT WEINBERG Autorney for Respondent
14	Charles and a start of the star
15	
16	ENDORSEMENT
	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
. 17	submitted for consideration by the Board of Pharmacy of the Department of Consumer Affai
18	
19	
	KAMALA D. HARRIS Attorney General of California
20	II GURGORY L SALUTE
21	Supervising Deputy Anoracy General
22	N. W.
23	SUSAN MELTON WILSON
	li Demuty Attorney General
24	Allorneys for Complainant
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	STIPULATED SETTLEMENT- RESPONDENT MICHAEL'S PHAR

# Exhibit A

# Accusation No. 3824

II	
· · · ·	
KAMALA D, HARRIS Attorney General of California	
GREGORY J. SALUTE	
Supervising Deputy Attorney General SUSAN MELTON WILSON	
Deputy Attorney General State Bar No. 106902	
300 So., Spring Street, Sulte 1702	
Los Angeles, CA 90013 Telephone: (213) 897-4942	
Telephone: (213) 897-4942 Faosimile: (213) 897-2804 B-mail: Susan, Wilson@doj.ca.gov	
Attorneys for Complainant	
	RETHE
BOARD OF DEPARTMENT OF	' PHARMACY CONSUMER AFFAIRS
STATE OF	CALIFORNIA
In the Matter of the Accusation Against:	Case No. 3824
MICHAEL'S PHARMACY, INC.,	
NATALYA SKYE	ACCUSATION
PHARMACIST-IN-CHARGE 960 East Green Street	
Pasadena, CA 91106	
Pharmacy Perinit No. PHY 47549	
AND	
NATALYA SKYE	
14569 Benefit St., #102 Sherman Oaks, CA 91403	
Original Pharmacist License No. RPH 55396	
Respondents.	
Complainant alleges:	<b>-</b>
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	<u>RTIES</u>
	gs this Accusation solely in her official capacity
as the Executive Officer of the Board of Pharma	acy, Department of Consumer Affairs,
2. On or about November 7, 2006, the	Board of Pharmacy (Board) Issued Pharmacy
Permit No. PHY 47549 to Michael's Pharmacy	(Respondent Pharmacy), Natalya Skye is and has
been Pharmacist-In-Charge of Respondent Phar	macy since November 7, 2006. The Pharmacy
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Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2012, unless renewed. 2

3, On or about June 23, 2004, the Board of Pharmacy issued Orlginal Pharmacist 3 License Number RPH 55396 to Natalya Skye (Respondent Skye). The Original Pharmacist 4 License was in full force and effect at all times relevant to the charges brought herein and will 5 expire on March 31, 2014, unless renewed, 6

### JURISDICTION

This Accusation is brought before the Board, Department of Consumer Affairs, under 4, 8 the authority of the following laws, All section references are to the Business and Professions 9 Code unless otherwise indicated. 10

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### STATUTORY PROVISIONS

5. Section 118, subdivision (b), provides that the suspension, expiration, surrender, or 12 cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary 13 action during the period within which the license may be renewed, restored, reissued or 14 reinstated. 15

> Section 4300 of the Code states; 6.

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

"(b) The board shall discipline the holder of any license issued by the board, whose default 18 has been entered or whose case has been heard by the board and found guilty, by any of the 19 following methods: 20

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its 25 discretion may deem proper. 26

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The 27board may, in its sole discretion, issue a probationary license to any applicant for a license who is 28

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guilty of unprofessional conduct and who has met all other requirements for licensure. The board
 may issue the license subject to any terms or conditions not contrary to public policy, including,

but not limited to, the following:

"(1) Medical or psychiatric evaluation.

"(2) Continuing medical or psychlatric treatment.

"(3) Restriction of type or circumstances of practice.

"(4) Continuing participation in a board-approved rehabilitation program.

"(5) Abstention from the use of alcohol or drugs.

"(6) Random fluid testing for alcohol or drugs.

"(7) Compliance with laws and regulations governing the practice of pharmacy.

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary
certificate of licensure for any violation of the terms and conditions of probation. Upon
satisfactory completion of probation, the board shall convert the probationary certificate to a
regular certificate, free of conditions.

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

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7. Section 4301 of the Code states:

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

"(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.

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

"(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.

8. Section 4059 of the Code states, in pertinent part, that a person may not furnish any 9 dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, 10 veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any 11 dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, 12 veterinarian, or naturopathic doctor pursuant to Section 3640.7. 13

9, Section 4076 of the Code states:

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A pharmacist shall not dispense any prescription except in a container that meets the "(a) 15 requirements of state and federal law and is correctly labeled with all of the following: 16

Except where the prescriber or the certified nurse-midwife who functions pursuant to (1)17 a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who 18 functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the 19 physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who 20 functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the 21 pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either 22subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, 23 subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug 24 or the generic name and the name of the manufacturer. Commonly used abbreviations may be 25 used. Preparations containing two or more active ingredients may be identified by the 26manufacturer's trade name or the commonly used name or the principal active ingredients. 27 (2)28

The directions for the use of the drug.

The name of the patient or patients. • (3) 1 (4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who 2 functions pursuant to a standardized procedure or protocol described in Section 2746.51, the 3 nurse practitioner who functions pursuant to a standardized procedure described in Section 4 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the 5 naturopathic doctor who functions pursuant to a standardized procedure or protocol described in 6 Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol 7 pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of 8 paragraph (5) of, subdivision (a) of Section 4052. 9 The date of issue. (5)10 The name and address of the pharmacy, and prescription number or other means of (6) 11 Identifying the prescription. 12 The strength of the drug or drugs dispensed. (7)13 The quantity of the drug or drugs dispensed. (8) 14 The expiration date of the effectiveness of the drug dispensed. (9) 15 (10) The condition for which the drug was prescribed if requested by the patient and the 16 condition is indicated on the prescription. 17 (11)(A) Commencing January 1, 2006, the physical description of the dispensed 18 medication, including its color, shape, and any identification code that appears on the tablets or 19 capsules, except as follows; 20(i) Prescriptions dispensed by a veterinarian. 21 (ii) An exemption from the requirements of this paragraph shall be granted to a new drug 22 for the first 120 days that the drug is on the market and for the 90 days during which the national 23 reference file has no description on file, 24 (iii) Dispensed medications for which no physical description exists in any commercially 25 available database. 26 (B) This paragraph applies to outpatient pharmacies only. 27 111 28 5 Acquaation

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container,

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

"(b) If a pharmaelst dispenses a prescribed drug by means of a unit dose medication system. 5 as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or 6 other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration. 9

"(o) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to 10 Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose ·11 containers for a specific patient, the name of the certified nurse-midwife who functions pursuant 12 to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who 13 functions pursuant to a standardized procedure described in Section 2836.1, the physician 14 assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions 15 pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist 16 who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of 17 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 18 4052, 19

"(d) If a pharmaelst dispenses a prescription drug for use in a facility licensed pursuant to 20 Section 1250 of the Health and Safety Code, it is not necessary to include the information 21required in paragraph (11) of subdivision (a) when the prescription drug is administered to a 22 patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with 23Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the 24 Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his 25 or her scope of practice," 26

10. Section 4081 of the Code states:

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"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 1 or dangerous devices shall be at all times during business hours open to inspection by authorized 2 officers of the law, and shall be preserved for at least three years from the date of making. A 3 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary 4 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, olinic, hospital, 5 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 6 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 7 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 8 Institutions Code who maintains a stock of dangerous drugs or dangerous devices, 9

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

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

11. Section 4126.5 of the Code states:

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"(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the by the wholesaler from whom thedangerous drug was acquired.

21 22 (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug
that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to
this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized
by law.

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(6) A health care provider that is not pharmacy but that is authorized to purchase dangerous 1 drugs, 2 (7) To another pharmacy under common control. 3 4 (d) For purpose of this section, "common control" means the power to direct or cause the 5 direction of the management and policies of another person whether by ownership, by voting 6 rights, by contract, or by other means. 7 12. Section 4105 of the Code states: 8 "(a) All records or other documentation of the acquisition and disposition of dangerous 9 drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed 10 premises in a readily retrievable form. 11 "(b) The licensee may remove the original records or documentation from the licensed 12 premises on a temporary basis for license-related purposes. However, a duplicate set of those 13 records or other documentation shall be retained on the licensed premises. 14 "(c) The records required by this section shall be retained on the licensed premises for a 15 period of three years from the date of making. 16 "(d) Any records that are maintained electronically shall be maintained so that the 17 pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the 18 ease of a veterinary food-animal drug retailer or wholesaler, the designated representative on 19 duty, shall, at all times during which the licensed premises are open for business, be able to 20produce a hard copy and electronic copy of all records of acquisition or disposition or other drug 21 or dispensing-related records maintained electronically. 22"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, 23 grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), 24 and (c) be kept on the licensed premises. 25 (2) A waiver granted pursuant to this subdivision shall not affect the board's authority 26 under this section or any other provision of this chapter," 27111 28 8 Accusation

13. California Code of Regulations, title 16, section 1714 states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(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.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

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

(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.

(f) The board shall require an applicant for a licensed premise or for renewal of that
 license to certify that it meets the requirements of this section at the time of licensure or renewal,
 (g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain
 a toilet and wash basin supplied with running water.

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14. 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."

California Code of Regulations, title 16, section 1717, states: 15,

"(a) No medication shall be dispensed on prescription except in a new container which 8 conforms with standards established in the official compendia. 9

"Notwithstanding the above, a pharmacist may dispense and refill a prescription for 10 non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided; 12

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

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

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

In addition to the requirements of Section 4040, Business and Professions Code, the "(b) following information shall be maintained for each prescription on file and shall be readily retrievable;

The date dispensed, and the name or initials of the dispensing pharmacist. All (1)19 prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising 20pharmacist before they are dispensed. 21

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the 22 distributor's name which appears on the commercial package label; and 23

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity 24 dispensed, if different, and the initials or name of the dispensing pharmacist. 25

(4) A new prescription must be created if there is a change in the drug, strength, 26 prescriber or directions for use, unless a complete record of all such changes is otherwise 27maintained. 28

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"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

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"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

"Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection,

9 "(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a
10 prescriber licensed in a State other than California in accordance with Business and Professions
11 Code Section 4005,

12 "(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled
13 substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal
14 Regulations, section 1306.26.

"Prescriptions for other dangerous drugs which are not controlled substances may also be 15 transferred by direct communication between pharmacists or by the receiving pharmacist's access 16 to prescriptions or electronic files that have been created or verified by a pharmacist at the 17 transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it 18 as a transferred prescription; and record the date of transfer and the original prescription number. 19 When a prescription transfer is accomplished via direct access by the receiving pharmacist, the 20receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the 21 transferring pharmacy shall then assure that there is a record of the prescription as having been 22 transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and 23 pharmacist accountability and dispense in accordance with the provisions of section 1716 of this 24 Division. Information maintained by each pharmacy shall at least include: 25

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmaoy from which the prescription
 was received or to which the prescription was transferred, as appropriate;

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- (3) Original date and last dispensing date;
- (4) Number of refills and date originally authorized;
- (5) Number of refills remaining but not dispensed;
- (6) Number of refills transferred.

5 "(f) The pharmacy must have written procedures that identify each individual pharmacist 6 responsible for the filling of a prescription and a corresponding entry of information into an 7 automated data processing system, or a manual record system, and the pharmacist shall create in 8 his/her handwriting or through hand-initializing a record of such filling, not later than the begin-9 ing of the pharmacy's next operating day. Such record shall be maintained for at least three years" 10 Section 125.3 provides that the Board may request the administrative law judge to 16, 11 12 direct a licentiate found to have committed a violation or violations of the licensing act to pay a 13 sum not to exceed the reasonable costs of the investigation and enforcement of the case.

# FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

17. The following allegations are common to all causes for discipline in this matter;
a. At all times relevant herein, Respondent Natalya Skye was an owner and the pharmacist-in-charge of Michael's Pharmacy, Inc., located in Pasadena, CA.

# **BOARD INSPECTION - JULY 7, 2009**

b. On or about July 7, 2009, a representative of the Board inspected Respondent Pharmacy.

The Inspector observed that Respondent pharmacy had no self-assessment form,
 and found three prescriptions ready to be dispensed which had no description of the drugs on the
 label. She also collected records from the pharmacy for later analysis.

26 d. In later review of prescription records obtained during the July 7 inspection, the
 27 Inspector observed that 22 prescriptions purportedly "original telephone prescriptions" were

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documented on a telephonic prescription document with a computer print out. The pharmacist did not reduce the telephonic prescription to writing,

# **BOARD INSPECTION - NOVEMBER 19, 2009**

e. On or about November 19, 2009, a second inspection was conducted at the pharmacy.

f. Arriving at 9:00 am, the Inspector observed that a pharmacy technician was already inside the Pharmacy – but that the doors were looked and the lights were off. The Inspector asked the Tech to leave and walt with her outside the pharmacy. A second Tech then arrived and let herself into the pharmacy. Again, the Inspector asked the Tech to leave and wait with her outside the pharmacy. A third Tech then arrived. Respondent Skye did not arrive at the pharmacy until approximately 10:00 am. Later, two of the pharmacy technicians admitted that they had a key to the pharmacy

g. When asked about routine procedures for drug deliveries at Respondent pharmacy, all three pharmacy technicians claimed only the pharmacist on duty signed for drug deliveries. However after later review of records obtained from vendors making deliveries to Respondent pharmacy, the Inspector found non-pharmacists had signed for deliveries on at least twenty nine (29) occasions.

h. Once inside the pharmacy, the Inspector observed large quantities of drugs in odd containers throughout the pharmacy:

(1) The Inspector noticed a paper shopping bag filled with drugs - which Respondent Skye identified as expired "sample" medications which had been given to Respondent pharmacy by a physician for disposal. The Inspector documented numerous dangerous drugs in the bag which were not expired, including:

Tektuna HCT 300/25
 Imitrex 100mg

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11	3. Relpax 40mg
ļ	4. Maxalt 10mg
	5. Micardles 40mg and 80mg 6. Aggrenox 25/200
	7. Simoor 500/20
	<ol> <li>8. Enablex 15 mg</li> <li>9. Exforge 5/320 and 5/160</li> </ol>
	10. Seroquel XR 150mg
	<ol> <li>Micardis HCT 80/12,5</li> <li>Aricept 10mg and 5mg</li> </ol>
	13, Aricept ODT 5mg.
	(2) The Inspector also observed large amber yials of medication – some unlabeled and
	containing more than one type of medication - and some which had a sample medication
	label taped to the side of the container. Respondent Skye claimed that the medication in
	the amber vials had been given to the pharmacy by a patient whose husband had died - fo
	disposal. However, she was unable to produce a patient profile accounting for the
	medications she claimed had been returned.
	(3) The Inspector also observed a large quantity of drugs stored in plastic baskets and
	bags full of drugs to be destroyed and/or credited,
	i. The Inspector further observed that the small restroom in the facility had storage
sh	elves immediately adjacent to the toilet, and that pharmacy bottles and caps were stored on the
flo	por next to the toilet.
	j. Further investigation disclosed that on or about December 28, 2009, Respondents
11	egally transferred pharmaceuticals for "disposal" as medical waste by an unlicensed entity
na	med "EnservWest" located in Vernon, CA.
	FIRST CAUSE FOR DISCIPLINE
	(Failure to Comply with Records Requirements)
	18. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
sų	bject to disciplinary action under section 4300 for unprofessional conduct as defined in section
43	101, subdivisions (j) and (o), in conjunction with section 4059, subdivision "b" in that during a

.

Inspection of the Pharmacy on or about November 19, 2009, a representative of the Board discovered a bag of sample medications and drugs allegedly returned from a physician and/or a deceased patient - however, Respondent did not have or could not otherwise show documents required by pharmacy law (e.g. sales and purchase records) to establish where and how the pharmacy acquired the drugs, as described more fully in paragraph 17 above.

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# SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Acquisition/Disposition Records)

Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject 19. 8 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, 9 subdivisions (f) and (o), in conjunction with sections 4081, subdivision (a), and 4105 for failure to 10 maintain all records of acquisition and disposition for three (3) years from date of making and to 11 keep a current inventory of dangerous drugs, in that at the time of a Board inspection on or about 12 November 19, 2009, Respondents were found to have haphazard and disorganized storage of 13 medications, with no organized, accurate and immediately accessible inventory records, as 14 described more fully in paragraph 17 above. 15

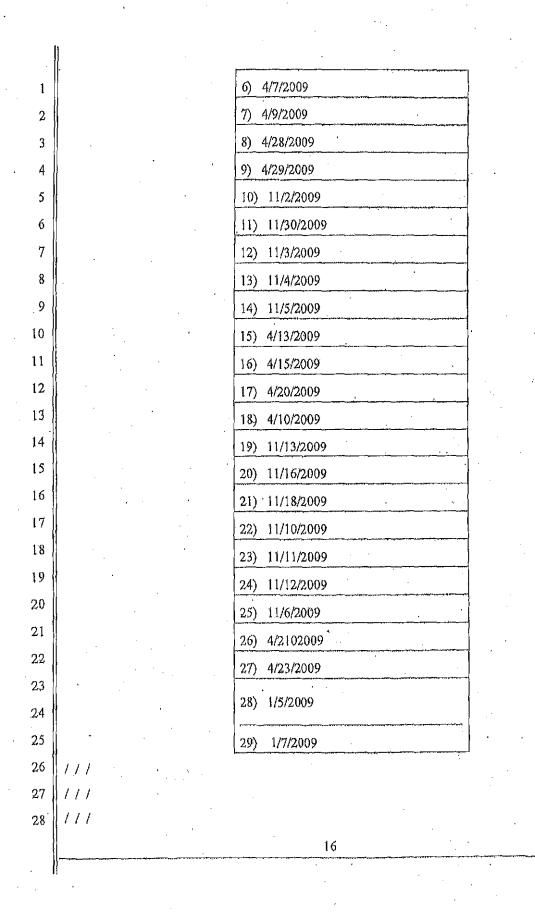
### THIRD CAUSE FOR DISCIPLINE

(Allowing a Non-Pharmacist to Order and Receive Controlled Substances)

20. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
subdivision (o), in conjunction with section 4059.5, subdivision (a), which requires that only a
pharmacist may sign for the delivery of controlled substances and dangerous drugs, in that on
each of the following dates, Respondents allowed a non-pharmacist to sign for delivories at
Respondent Pharmacy:

1)	1/8/2009
2)	1/16/2009
3)	1/21/2009
4)	1/16/2009
5)	4/6/2009
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Accusation



Accusation

# FOURTH CAUSE FOR DISCIPLINE

# (Providing Unapproved Employee With Pharmacy Key)

21. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of Regulations section 1714, subdivisions "d" and "e" which limits individuals who may legally possess a key to 'a pharmacy, in that on or about November 19, 2009, two pharmacy technicians employed at Respondent Pharmacy admitted that they had been given a key to the pharmacy by Respondent Skye, which had been in their possession for an appreciable period of time prior to the inspection, as described more fully in paragraph 17 above.

# FIFTH CAUSE FOR DISCIPLINE

# (No Self Assessment Form During Inspection)

22. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of Regulations section 1715, subdivisions "d which requires that a pharmacy must have a self-assessment form on file for three years, in that during a Board inspection on or about July 7, 2009, Respondent were unable to locate or produce a self assessment form, as described more fully in paragraph 17 above.

# SIXTH CAUSE FOR DISCIPLINE

### (Incorrectly Labeled Prescription Bottles)

23. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), in conjunction with section 4076, subdivision (a)(11)(A) requiring the prescription container must be labeled with a description of the medication dispensed, in that, during a Board inspection on July 7, 2009, the Inspector noticed Respondent Pharmacy had

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and being and	incorrectly labeled medication as follows:
a.	Prescription 343671
	No description of medication
b.	Prescription 341530
	No description of medication
o,	Prescription 342438
	No description of medication
	SEVENTH CAUSE FOR DISCIPLINE
	(Telephone Order Not Reduced to Writing)
24,	Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
disciplinat	y action under section 4300 for unprofessional conduct as defined in section 4301,
subdivisio	n (o), in conjunction with section Title 16, California Code of Regulations section 1
subdivisio	n "c" which requires that an orally transmitted prescription must be promptly reduc
	n "c" which requires that an orally transmitted prescription must be promptly reduc and initialed, in that during a Board inspection on July 7, 2009, the inspector found
to writing	
to writing that prese	and initialed, in that during a Board inspection on July 7, 2009, the inspector found
to writing that prese	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be
to writing that prese reduced to	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be writing in at least 22 instances, as follows:
to writing that prese reduced to 1)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be writing in at least 22 instances, as follows: 340550
to writing that prese reduced to 1) 2)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be writing in at least 22 instances, as follows: 340550 337639
to writing that prese reduced to 1) 2) 3)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be writing in at least 22 instances, as follows: 340550 337639 337633
to writing that prese reduced to 1) 2) 3) 4)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not be writing in at least 22 instances, as follows: 340550 337639 337633 340553
to writing that prese reduced to 1) 2) 3) 4) 5)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not bee writing in at least 22 instances, as follows: 340550 337639 340553 340551
to writing that prese reduced to 1) 2) 3) 4) 5) 6)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled — but had not bee writing in at least 22 instances, as follows: 340550 337639 340553 340551 337638
to writing that prese reduced to 1) 2) 3) 4) 5) 6) 7)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled — but had not bee writing in at least 22 instances, as follows: 340550 337639 340553 340551 337638 337636
to writing that prese reduced to 1) 2) 3) 4) 5) 6) 7) 8)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled – but had not been writing in at least 22 instances, as follows: 340550 337639 337633 340551 337638 337636 337634
to writing that prese reduced to 1) 2) 3) 4) 5) 6) 7) 8) 9)	and initialed, in that during a Board inspection on July 7, 2009, the inspector found riptions which had originated as oral prescriptions, had been filled — but had not been writing in at least 22 instances, as follows: 340550 337639 337633 340553 340551 337638 337636 337634 337640

1	13)	337635
2	14)	337614
3.	15)	340650
4 ·	16)	340555
5	· 17)	340549
6	18)	340547
7	19)	340546
8	20)	340545
9	21)	340544
	22)	340554

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#### EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards)

Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to 25. 13 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, 14 subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1714 15 subdivision "b" (which requires that Respondents maintain the pharmacy facility, and equipment 16 so that drugs are safely and properly prepared, maintained, secured and distributed) and 17 subdivision "c" (which requires that equipment shall be maintained in a clean and orderly 18 condition) in that during a Board inspection on November 19, 2009, the Inspector found 19 prescription bottles and caps stored on the floor of the small restroom next to and below the toilet. 20

## NINTH CAUSE FOR DISCIPLINE

#### (Unauthorized Furnishing)

26. Respondents MICHABL'S PHARMACY and NATALYA SKYE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), in conjunction with section 4163, subdivision (a), and section 4126.5, which limit the persons or organizations that a pharmacy may legally furnish or transfer drugs to, in that on or about December 28, 2009, Respondents illegally 'disposed of' pharmaceuticals through "EnservWest", and unlicensed entity, in violation of pharmacy law, as described more fully in

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paragraph 17 above.	
DISCIPLINARY CONSIDERATIONS	
27. To determine the degree of penalty to be imposed on Respondent(s), if any,	
Complainant makes the following ad	ditional allegations:
Prior Cita	tion – Respondent Michael's Pharmacy
a. On or about November 13, 2008 a representative of the Board inspected	
	rsuant to that Inspection, on April 23, 2009, Administrati
	200839793 was issued to Respondent for violating Codes
	ing in the issuance of a \$ 5,000.00 fine, which Responde
paid in full. The citation is now final Code/Regulations Violated	Description
CARANTER PRANTING IN TAXABA	
a. Bus. & Prof. Code §4342	Stocking dangerous drugs lacking quality or strength Medication containers were found containing
	compounded drugs lacking expiration dates
	(Progesterone 100mg #15 and 50mg #76 Supp.) or drug that had been expired (Estradiaol 250 Vag, Supp #16
	expired 3/21/07, Progesterone 400mg #9 Supp expired
	7/7/05 and 25mg #46 Supp expired 8/4/05, Boric acid
	Vag. Supp #16 expired in 10/21/06) Variation from Prescription
b. CCR, title 16, §1716	On 12/06/2006, Respondent furnished prescription
	301673 for Hydrocodone/APAP 10/500mg #120 to LC
	when the instructions on the face of the prescription
· · ·	stated "Do not dispense before 12/12/06". Specifically on 4/2/08, Michael's Pharmacy furnished Rx 324777
	Oxycontin 80mg #90, Rx 324778 Oxycontin 40mg #50
	to LC when the prescription was dated 4/3/08.
c. CCR, title 16, §1716.2	Failure to comply with Records requirements for compounded medications
	Procedures to take action when licensed individual is
d. Bus, & Prof. Code §4104	impaired or known to have diverted or used drugs,
	written policies; Report; Immunity
e. Health & Safety Code §11165	For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall
	report to the Department of Justice Data required
sub (d)(1-10)	Partial filling of Schedule II prescriptions/Partial filling
f. CCR, title 16, §1745/ Title 21	of prescriptions.
CFR §1306,13 subd. (a)	

Accusation

Prior Citation - Respondent Skye

b. On or about November 13, 2008 a representative of the Board inspected Respondent
Michael's Pharmacy Pursuant to that inspection, on April 23, 2009, Administrative
Cltation/Assessment of Fine No. CI 200839793 was issued to Respondent for violating Codes and
Regulations as set forth below, resulting in the issuance of a \$ 5,000.00 fine, which Respondent
pald in full. The citation is now final.

Code/Regulations Violated	Description
a. Bus. & Prof. Code §4342	Action by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales.
b. CCR, title 16, §1716	Variation from Prescription
c. CCR, title 16, §1716.2	Record requirements—compounding for future furnishing
d. Bus. & Prof. Code §4104	Procedures to take action when licensed individual is impaired or known to have diverted or used drugs, Written policies; Report; Immunity
e. Health & Safety Code §11165	For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the' Department of Justice Data required,
f. CCR, title 16, §1745/Title 21 CFR	Partial filling of Schedule II prescriptions/Partial filling of prescriptions,
§1306013 subd. (a)	

#### 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:

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1. Revoking or suspending Pharmacy Permit No. PHY 47549 issued to Respondent

26 Michael's Pharmacy;

27. 28 2. Revoking or suspending Original Pharmacist License Number RPH 55396, issued to Respondent Natalya Skye ;

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Accusation

3. Ordering Respondent Michael's Pharmacy 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;

4. Ordering Respondent Natalya Skye 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;

5.

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

Accusation

8/31/12 DATED:

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

# EXHIBIT "B"

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# EXHIBIT B

Decision and Order as to Respondent Natalya Skye Board of Pharmacy Case No. 3824

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

In the Matter of the Accusation Against:

#### MICHAEL'S PHARMACY, INC., d.b.a. MICHAEL'S PHARMACY NATALYA SKYE, PHARMACIST-IN-CHARGE 960 East Green Street Pasadena, CA 91106 Pharmacy Permit No. PHY 47549

AND

NATALYA SKYE 14569 Benefit St., #102 Sherman Oaks, CA 91403 Pharmacist License No. RPH 55396

Respondents.

Case No. 3824

#### STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

**JAS AGAINST RESPONDENT** NATALYA SKYE ONLY]

#### DECISION AND ORDER

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

This decision shall become effective on February 14, 2014.

It is so ORDERED on February 7, 2014.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

STAN C. WEISSER

**Board** President

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BOARD AND DO HEREBY CERTIFI

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By

1 KAMALA D. HARRIS Attorney General of California 2 GREGORY J. SALUTE Supervising Deputy Attorney General 3 SUSAN MELTON WILSON Deputy Attorney General 4 State Bar No. 106902 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-4942 Facsimile: (213) 897-2804 5 б E-mail: Susan, Wilson@doj.ca.gov 7 Attorneys for Complainant 8 BEFORE THE **BOARD OF PHARMACY** 9 DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA 10 11 Case No. 3824 In the Matter of the Accusation Against: MICHAEL'S PHARMACY, INC., 12 STIPULATED SETTLEMENT AND d.b.a.MICHAEL'S PHARMACY DISCIPLINARY ORDER NATALYA SKYE, 13 PHARMACIST-IN-CHARGE **[AS AGAINST RESPONDENT** 960 East Green Street 14 NATALYA SKYE ONLY] Pasadena, CA 91106 15 Pharmacy Permit No. PHY 47549. 16 AND 17 NATALYA SKYE 14569 Benefit St., #102 18 Sherman Oaks, CA 91403 Original Pharmacist License No, RPH 55396 19 Respondents, 20 2122IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-23 entitled proceedings that the following matters are true: PARTIES 24 25 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. 26 She brought this action solely in her official capacity and is represented in this matter by Kamala 27 D. Harris, Attorney General of the State of California, by Susan Melton Wilson, Deputy Attorney 28General. STIPULATED SETTLEMENT (3824)

2.. Respondent Natalya Skye (Respondent) is represented in this proceeding by attorney
Herbert Weinberg, whose address is: Law Offices of McGuire Woods 1800 Century Park West,
8th Floor, Los Angeles, CA 90067

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3. On or about June 23, 2004, the Board of Pharmacy issued Original Pharmacist License No. RPH 55396 to Natalya Skye (Respondent). Respondent Skye is and has been Pharmacist-In-Charge of Michael's Pharmacy (Pharmacy Permit No. PHY 47549) since November 7, 2006. Her Original Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 3824 and will expire on March 31, 2014, unless renewed.

#### JURISDICTION

4. Accusation No. 3824 was filed before the Board of Pharmacy (Board), Department
 of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
 statutorily required documents were properly served on Respondent on September 14, 2012.
 Respondent timely filed her Notice of Defense contesting the Accusation.

15 5. A copy of Accusation No. 3824 is attached as Exhibit A and incorporated herein by
16 reference.

#### ADVISEMENT AND WAIVERS

Respondent has carefully read, fully discussed with counsel, and understands the
 charges and allegations in Accusation No. 3824. Respondent has also carefully read, fully
 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
 Order.

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

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STIPULATED SETTLEMENT (3824)

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

## CULPABILITY

 Respondent admits the truth of each and every charge and allegation in Accusation No. 3824.

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

#### CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent 10 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may 11 communicate directly with the Board regarding this stipulation and settlement, without notice to 12 or participation by Respondent or her counsel. By signing the stipulation, Respondent 13 understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation 14 prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation 15 as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or 16 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, 17 and the Board shall not be disqualified from further action by having considered this matter. 18

19 12. The parties understand and agree that facsimile copies of this Stipulated Settlement
20 and Disciplinary Order, including facsimile signatures thereto, shall have the same force and
21 effect as the originals.

13. 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.

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

#### DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacist License No. RPH 55396 issued to
Respondent Natalya Skye (Respondent) IS REVOKED. However, the revocation is stayed and
Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Suspension

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9 As part of probation, respondent is suspended from the practice of pharmacy for 30 (thirty)
10 days beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the 11 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of 12 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices 13 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act 14 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient 15 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the 16 board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs 17 and devices or controlled substances. 18

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 she holds an interest at the time this decision becomes effective unless
otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation,

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2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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STIPULATED SETTI EMENT (3824)

1	Respondent shall report any of the following occurrences to the board, in writing, within
2	seventy-two (72) hours of such occurrence:
3	• an arrest or issuance of a criminal complaint for violation of any provision of the
4.	Pharmacy Law, state and federal food and drug laws, or state and federal controlled
5	substances laws
6	• a plea of guilty or nois contendre in any state or federal criminal proceeding to any
7	criminal complaint, information or indictment
8	a conviction of any crime
9	• discipline, citation, or other administrative action filed by any state or federal agency
10	which involves respondent's pharmacist license or which is related to the practice of
11	pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
12	for any drug, device or controlled substance,
13	Failure to timely report such occurrence shall be considered a violation of probation.
14	3. Report to the Board
15	Respondent shall report to the board quarterly, on a schedule as directed by the board or its
16	designee. The report shall be made either in person or in writing, as directed. Among other
17	requirements, respondent shall state in each report under penalty of perjury whether there has
18	been compliance with all the terms and conditions of probation. Failure to submit timely reports
19	in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
20	in submission of reports as directed may be added to the total period of probation. Moreover, if
21	the final probation report is not made as directed, probation shall be automatically extended until
22	such time as the final report is made and accepted by the board.
23	4. Interview with the Board
24	Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
25	with the board or its designee, at such intervals and locations as are determined by the board or its
26	designee. Failure to appear for any scheduled interview without prior notification to board staff,
27	or failure to appear for two (2) or more scheduled interviews with the board or its designee during
28	the period of probation, shall be considered a violation of probation.
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	STIPULATED SETTLEMENT (3824)

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#### 5. Cooperate with Board Staff

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

6. Continuing Education

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

7. Notice to Employers

During the period of probation, respondent shall notify all present and prospective
employers of the decision in case number 3824 and the terms, conditions and restrictions imposed
on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3824, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

19 If respondent works for or is employed by or through a pharmacy employment service, 20 respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity 21 licensed by the board of the terms and conditions of the decision in case number 3824 in advance 22 of the respondent commencing work at each licensed entity. A record of this notification must be 23 provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that she has read the decision in case number 3824

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STIPULATED SETTLEMENT (3824)

and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

#### 8. Reimbursement of Board Costs

Respondent shall be jointly and severally liable with co-respondent to Accusation 3824,
Michaels' Pharmacy Inc., for reimbursement to the Board of its costs of investigation and
prosecution in the total sum of Eleven Thousand Dollars (\$11, 000,00.) Payment of the total
sum shall be a condition precedent to successful completion of probation. Respondent shall make
said payment within sixty (60) days of the effective date of this decision.

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.

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

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#### 9. Probation Monitoring Costs

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

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#### 10. Status of License

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

4 If respondent's license expires or is cancelled by operation of law or otherwise at any time 5 during the period of probation, including any extensions thereof due to tolling or otherwise, upon 6 renewal or reapplication respondent's license shall be subject to all terms and conditions of this 7 probation not previously satisfied.

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11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to 9 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, 10 respondent may tender her license to the board for surrender. The board or its designee shall have 11 the discretion whether to grant the request for surrender or take any other action it deems 12 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent 13 will no longer be subject to the terms and conditions of probation. This surrender constitutes a 14 record of discipline and shall become a part of the respondent's license history with the board. 15 Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to 16 the board within ten (10) days of notification by the board that the surrender is accepted. 17 Respondent may not reapply for any license from the board for three (3) years from the effective 18 date of the surrender. Respondent shall meet all requirements applicable to the license sought as 19 of the date the application for that license is submitted to the board, including any outstanding 20costs. 21

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

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

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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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13. Tolling of Probation

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

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

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

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

14, Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed

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appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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

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#### 15 Completion of Probation

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

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#### 16. Community Services 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 services on a regular basis to a community of charitable facility or agency for at least seventy five (75) hours during the term probation.

Within thirty (30) days of board approval thereof, respondent shall submit documentation
to the board demonstrating commencement of the community service program. A record of this
notification must be provided to the board upon request. 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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#### 17. Remedial Education .

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to the grounds for discipline. The program of remedial education shall consist of at least ten (10) hours, which shall be completed within the first three (3) years of probation at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward,

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continuing education (CE) courses used for license renewal purposes.

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

Following the completion of each course, the board or its designee may require the 6 respondent, at her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area. 10

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#### 18. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a 12 manager, administrator, member, officer, director, trustee, associate, or partner of any additional 13business, firm, partnership, or corporation licensed by the board. If respondent currently owns or 14 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, 15 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently 16 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold 17 that interest, but only to the extent of that position or interest as of the effective date of this 18 decision. Violation of this restriction shall be considered a violation of probation. 19

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#### 19, **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, respondent shall not supervise any intern pharmacist or 21 serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-22charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, 23 respondent shall retain an independent consultant at her own expense who shall be responsible for 24 reviewing pharmacy operations on a monthly basis for compliance by respondent with state and 25 federal laws and regulations governing the practice of pharmacy and for compliance by 26respondent with the obligations of a pharmacist-in-charge, -27

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After the first year of probation, so long as Respondent is fully compliant with all terms and

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conditions of probation, the Board or its designee may permit the review of pharmacy operations by a consultant on a quarterly basis.

The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

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#### 20. Self Assessment Report Must Be Made Quarterly

10 Respondent shall complete a self assessment report to be submitted quarterly or as directed 11 by the Board. The report shall be co-signed by the consultant, if any, allowed under Condition 19 12 as set forth above. The report shall be delivered or mailed to the board no later than ten (10) days 13 following the end of the reporting period. Failure to timely prepare or submit such reports shall 14 be considered a violation of probation.

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#### 21. Tolling of Suspension

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

Respondent must notify the board in writing within ten (10) days of departure, 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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22. Administrative Penalty

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## 11/15/2019 18:57 FAX 810 815 8210

1	Respondent shall be jointly and severally liable with co-respondent to Accusation 3824,
2	Michael's Pharmacy Inc., to pay an Administrative Penalty in the sum of Twenty Five Thousand
3	Dollars (\$25,000.00) Payment of the assessed administrative penalty shall be completed during
4	the first four years of probation, in accord with a payment plan approved by the Board or its
5	designee, Respondent may pay the full remaining unpaid balance of the assessed administrative
6	penalty at any time. It shall be Respondent's responsibility to mail or otherwise deliver each
7	payment directly to the Board at the Board's Sacramento address in a timely manner. Failure to
. 8	make any payment when due shall be considered a violation of probation.
. 9	23. Ethics Course
10	Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll
11	in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
12	Failure to initiate the course during the first year of probation, and complete it within the second
13	year of probation, is a violation of probation.
14	Respondent shall submit a certificate of completion to the board or its designce within five
15	days after completing the course.
16	ACCEPTANCE
17	I have carefully read the shove Stipulated Soulement and Disciplinary Order and have fully
18	discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it
19	will have on my Original Pharmacist License. I enter into this Stipulated Settlement and
20	Disciplinary Order voluctarily, knowingly, and intelligently, and agree to be bound by the
21	Decision and Order of the Board of Phermacy.
. 22	DATED: 11/15/13
- 23	NATALYA SKYE Respondent
24	I have read and fully discussed with Respondent Natalya Skye the terms and conditions and
25	other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its
26	form and content.
27	DATED: 11/15/3
28	HEREERT WEINBURG Attorney for Respondent
	12 SIDULATED SETTLEMENT (3824)

PAGE 2/2 \* RCVD AT (1/15/2013 8:44:34 PM [Eastern Standard Time] \* SVR:RICRIGHTFAX/0 \* DNIS:3154 \* CBID: \* DURATION (mm·ss):00-41

1	ENDORSEMENT	
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully	
3	submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs,	
4		,
5	Dated: // - / 5 - / 3 Respectfully submitted,	
6	KAMALA D. HARRIS Attorney General of California GREGORY J. SALUTE	
. 7	GREGORY J. SALUTE Supervising Deputy Attorney General	
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	one !!	
9	SUSAN MELTON WILSON Deputy Attorney General Attorneys for Complainant	
10	Attorneys for Complainant	
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## Exhibit A

# Accusation No. 3824

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KAMALA D. HARRIS	
Attorney General of California GREGORY J. SALUTE	•
Supervising Deputy Attorney General	
Susan Melton Wilson Deputy Attorney General	
State Bar No. 106902 300 So. Spring Street, Suite 1702	
Los Angeles, CA 90013	
Telephone: (213) 897-4942 Facsimile: (213) 897-2804	
E-mail: Susan, Wilson@doj.oa.gov Attorneys for Complainant	
	RE THE PHARMACY
DEPARTMENT OF	CONSUMER AFFAIRS
STATE OF	CALIFORNIA
In the Matter of the Accusation Against:	Case No. 3824
In the matter of the Aboutsanon Against	
MICHAEL'S PHARMACY, INC.,	
NATALYA SKYE,	ACCUSATION
PHARMACIST-IN-CHARGE 960 East Green Street	
Pasadena, CA 91106	
Pharmacy Permit No. PHY 47549	
AND	
NATALYA SKYE	
14569 Benefit St., #102 Sherman Oaks, CA 91403	
Original Pharmacist License No. RPH 55396	· · ·
Respondents.	
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Complainant alleges:	
PAJ	RTIES
1. Virginia Herold (Complainant) brin	egs this Accusation solely in her official capacity
<b>-</b>	· · · · ·
as the Executive Officer of the Board of Pharma	
	Board of Pharmacy (Board) issued Pharmacy
Permit No. PHY 47549 to Michael's Pharmacy	(Respondent Pharmacy). Natalya Skye is and has
been Pharmaelst-In-Charge of Respondent Phar	rmacy since November 7, 2006. The Pharmacy
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Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2012, unless renewed.

3. On or about June 23, 2004, the Board of Pharmacy issued Original Pharmacist License Number RPH 55396 to Natalya Skye (Respondent Skye). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2014, unless renewed.

#### JURISDICTION

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

#### STATUTORY PROVISIONS

Section 118, subdivision (b), provides that the suspension, expiration, surrender, or
cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary
action during the period within which the license may be renewed, restored, reissued or
reinstated.

6. Section 4300 of the Code states:

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

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

|| "(1) Suspending Judgment.

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"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license,

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

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The
board may, in its sole discretion, issue a probationary license to any applicant for a license who is

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guilty of unprofessional conduct and who has met all other requirements for licensure. The board
 may issue the license subject to any terms or conditions not contrary to public policy, including,
 but not limited to, the following;

"(1) Medical or psychiatric evaluation.

"(2) Continuing medical or psychiatric freatment,

"(3) Restriction of type or circumstances of practice,

"(4) Continuing participation in a board-approved rehabilitation program,

(5) Abstention from the use of alcohol or drugs.

"(6) Random fluid testing for alcohol or drugs.

"(7) Compliance with laws and regulations governing the practice of pharmacy,

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary
certificate of licensure for any violation of the terms and conditions of probation. Upon
satisfactory completion of probation, the board shall convert the probationary certificate to a
regular certificate, free of conditions.

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

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7. Section 4301 of the Code states:

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

"(f) The commission of any act involving moral turpltude, 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.

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

"(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.

8. Section 4059 of the Code states, in pertinent part, that a person may not furnish any
dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist,
veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any
dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist,
veterinarian, or naturopathic doctor pursuant to Section 3640.7.

9. Section 4076 of the Code states:

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15 "(a) A pharmacist shall not dispense any prescription except in a container that meets the
16 requirements of state and federal law and is correctly labeled with all of the following:

17 Except where the prescriber or the certified nurse-midwlfe who functions pursuant to (1)a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who 18 functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the 19 physician assistant who functions pursuant to Section 3502,1, the naturopathic doctor who 20functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the 21 pharmaelst who functions pursuant to a policy, procedure, or protocol pursuant to either 22 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, 23 subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug 24 or the generic name and the name of the manufacturer. Commonly used abbreviations may be 25 used. Preparations containing two or more active ingredients may be identified by the 26 manufacturer's trade name or the commonly used name or the principal active ingredients, 27 The directions for the use of the drug, 28 (2)

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(3) The name of the patient or patients.

The name of the prescriber or, if applicable, the name of certified nurse-midwife who (4)  $\mathbf{2}$ functions pursuant to a standardized procedure or protocol described in Section 2746.51, the 3 nurse practitioner who functions pursuant to a standardized procedure described in Section 4 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the 5 naturopathic doctor who functions pursuant to a standardized procedure or protocol described in 6 Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol 7 pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of 8 paragraph (5) of; subdivision (a) of Section 4052. 9

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed,

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed
medication, including its color, shape, and any identification code that appears on the tablets or
capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug
for the first 120 days that the drug is on the market and for the 90 days during which the national
reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially
available database.

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(B) This paragraph applies to outpatient pharmacies only.

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(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph. 4

• "(b) If a pharmaoist dispenses a prescribed drug by means of a unit dose medication system. as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

"(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to 10 Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose 11 containers for a specific patient, the name of the certified nurse-midwife who functions pursuant 12 to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who 13 functions pursuant to a standardized procedure described in Section 2836.1, the physician 14 assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions 15 pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist 16 who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of 17 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 18 4052, 19

"(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to 20Section 1250 of the Health and Safety Code, it is not necessary to include the information 21 required in paragraph (11) of subdivision (a) when the prescription drug is administered to a 22 patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with 23 Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the 24 Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his 25 or her scope of practice." 26

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Section 4081 of the Code states:

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

10 "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal
11 drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in12 charge, for maintaining the records and inventory described in this section.

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

11. Section 4126.5 of the Code states:

"(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the by the wholesaler from whom thedangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug
that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuani to
this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage,

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized
by law.

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(6) A health care provider that is not pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control,

(d) For purpose of this section, "common control" means the power to direct or cause the
direction of the management and policies of another person whether by ownership, by yoting
rights, by contract, or by other means.

 $\parallel$  12. Section 4105 of the Code states;

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

"(b) The licensee may remove the original records or documentation from the licensed
premises on a temporary basis for license-related purposes. However, a duplicate set of those
records or other documentation shall be retained on the licensed premises:

15 "(c) The records required by this section shall be retained on the licensed premises for a
16 period of three years from the date of making.

"(d) Any records that are maintained electronically shall be maintained so that the
pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the
case of a voterinary food-animal drug retailer or wholesaler, the designated representative on
duty, shall, at all times during which the licensed premises are open for business, be able to
produce a hard copy and electronic copy of all records of acquisition or disposition or other drug
or dispensing-related records maintained electronically.

"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request,
grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b),
and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority
under this section or any other provision of this chapter."

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13. California Code of Regulations, title 16, section 1714 states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(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.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

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

(c) 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.

(f) The board shall require an applicant for a licensed premise or for renewal of that
 license to certify that it meets the requirements of this section at the time of licensure or renewal.
 (g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain
 a toilet and wash basin supplied with running water.

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14. 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."

15. California Code of Regulations, title 16, section 1717, states:

"(a) No medication shall be dispensed on prescription except in a new container which 8 conforms with standards established in the official compendia.

"Notwithstanding the above, a pharmacist may dispense and refill a prescription for 10 non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), 11 provided: 12

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

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

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

"(b) In addition to the requirements of Section 4040, Business and Professions Code, the 16 following information shall be maintained for each prescription on file and shall be readily 17 retrievable: 18

The date dispensed, and the name or initials of the dispensing pharmacist. All (1)19 prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising 20pharmaclst before they are dispensed, 21

The brand name of the drug or device; or if a generic drug or device is dispensed, the 22 (2)23 distributor's name which appears on the commercial package label; and

If a prescription for a drug or device is refilled, a record of each refill, quantity (3) 24 dispensed, if different, and the initials or name of the dispensing pharmaoist. 25

(4) A new prescription must be created if there is a change in the drug, strength, 26 prescriber or directions for use, unless a complete record of all such changes is otherwise 27 maintained. 28

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"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce 1 it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

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"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior 5 to compounding, filling, disponsing, or furnishing, 6

"Chart orders as defined in Section 4019 of the Business and Professions Code are not 7 subject to the provisions of this subsection. 8

"(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a 9 prescriber licensed in a State other than California in accordance with Business and Professions 10 Code Section 4005. 11

"(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled 12 substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal 13 Regulations, section 1306.26. . 14

"Prescriptions for other dangerous drugs which are not controlled substances may also be 15 transferred by direct communication between pharmacists or by the receiving pharmacist's access 16 to prescriptions or electronic files that have been created or verified by a pharmacist at the 17 transforring pharmacy. The receiving pharmacist shall create a written prescription; identifying it 18 as a transferred prescription; and record the date of transfer and the original prescription number. 19 When a prescription transfer is accomplished via direct access by the receiving pharmacist, the 20receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the 21 transferring pharmacy shall then assure that there is a record of the prescription as having been 22transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and 23 pharmacist accountability and dispense in accordance with the provisions of section 1716 of this 24 Division, Information maintained by each pharmacy shall at least include: 25

Identification of pharmacist(s) transferring information: (1)

(2) Name and identification code or address of the pharmacy from which the prescription 27was received or to which the prescription was transferred, as appropriate; 28

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- (3) Original date and last dispensing date;
- (4) Number of refills and date originally authorized;
- (5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

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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 begining of the pharmacy's next operating day. Such record shall be maintained for at least three years" 16. Section 125.3 provides 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.

#### FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

17. The following allegations are common to all causes for discipline in this matter;
a. At all times relevant herein, Respondent Natalya Skye was an owner and the pharmacist-in-charge of Michael's Pharmacy, Inc., located in Pasadena, CA.

#### BOARD INSPECTION - JULY 7, 2009

b. On or about July 7, 2009, a representative of the Board inspected Respondent Pharmacy.

c. The Inspector observed that Respondent pharmacy had no self-assessment form,
and found three prescriptions ready to be dispensed which had no description of the drugs on the
label. She also collected records from the pharmacy for later analysis.

d. In later review of prescription records obtained during the July 7 inspection, the
Inspector observed that 22 prescriptions purportedly "original telephone prescriptions" were

documented on a telephonic prescription document with a computer print out. The pharmacist did not reduce the telephonic prescription to writing.

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#### BOARD INSPECTION - NOVEMBER 19, 2009

e. On or about November 19, 2009, a second inspection was conducted at the pharmacy.

6 Arriving at 9:00 am, the Inspector observed that a pharmacy technician was f, 7 already inside the Pharmacy - but that the doors were locked and the lights were off. The 8 Inspector asked the Tech to leave and wait with her outside the pharmacy, A second Tech then 9 arrived and let herself into the pharmacy. Again, the Inspector asked the Tech to leave and wait 10 with her outside the pharmacy. A third Tech then arrived. Respondent Skye did not arrive at the 11 pharmacy until approximately 10:00 am. Later, two of the pharmacy technicians admitted that 12 13 they had a key to the pharmacy

g, When asked about routine procedures for drug deliveries at Respondent pharmacy, all three pharmacy technicians claimed only the pharmacist on duty signed for drug deliveries. However after later review of records obtained from vendors making deliveries to Respondent pharmacy, the Inspector found non-pharmacists had signed for deliveries on at least twenty nine (29) occasions.

h. Once inside the pharmacy, the Inspector observed large quantities of drugs in odd containers throughout the pharmacy:

(1) The Inspector noticed a paper shopping bag filled with drugs - which Respondent Skye identified as expired "sample" medications which had been given to Respondent pharmacy by a physician for disposal. The Inspector documented numerous dangerous drugs in the bag which were not expired, including:

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Tektuna HCT 300/25
 Imitrex 100mg

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Relpax 40mg 3: Ţ Maxalt 10mg 4, Micardies 40mg and 80mg 5. 2 Aggrenox 25/200 6. Simcor 500/20 7. 3 Enablex 15 mg 8, Exforge 5/320 and 5/160 4 9. Seroquel XR 150mg 10, 5 Micardis HCT 80/12.5 11. Aricept 10mg and 5mg 12, 6 Aricept ODT 5mg, 13, 7 The Inspector also observed large amber vials of medication - some unlabeled and (2)8 containing more than one type of medication - and some which had a sample medication 9 label taped to the side of the container. Respondent Skye claimed that the medication in 10 the amber yials had been given to the pharmacy by a patient whose husband had died - for 11 disposal. However, she was unable to produce a patient profile accounting for the 12 13 medications she claimed had been returned, 14 The Inspector also observed a large quantity of drugs stored in plastic baskets and (3)15 bags full of drugs to be destroyed and/or credited. 16 The Inspector further observed that the small restroom in the facility had storage i. 17 shelves immediately adjacent to the toilet, and that pharmacy bottles and caps were stored on the 18 floor next to the toilet, 19 20 Further investigation disclosed that on or about December 28, 2009, Respondents j, 21 illegally transferred pharmacouticals for "disposal" as medical waste by an unlicensed entity 22.named "Enserv West" located in Vernon, CA, 23 FIRST CAUSE FOR DISCIPLINE 24 (Failure to Comply with Records Requirements) 25 Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to 18, 26 subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 274301, subdivisions (j) and (o), in conjunction with section 4059, subdivision "b" in that during an 28 14 Accusation

inspection of the Pharmacy on or about November 19, 2009, a representative of the Board discovered a bag of sample medications and drugs allegedly returned from a physician and/or a deceased patient - however, Respondent did not have or could not otherwise show documents required by pharmacy law (e.g. sales and purchase records) to establish where and how the pharmacy acquired the drugs, as described more fully in paragraph 17 above.

#### SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Acquisition/Disposition Records)

19. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject 8 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, 9 subdivisions (j) and (o), in conjunction with sections 4081, subdivision (a), and 4105 for failure to 10 maintain all records of acquisition and disposition for three (3) years from date of making and to 11 keep a current inventory of dangerous drugs, in that at the time of a Board inspection on or about 12 November 19, 2009, Respondents were found to have haphazard and disorganized storage of 13 medications, with no organized, accurate and immediately accessible inventory records, as 14 described more fully in paragraph 17 above. 15

#### THIRD CAUSE FOR DISCIPLINE

(Allowing a Non-Pharmacist to Order and Receive Controlled Substances)

20. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
subdivision (o), in conjunction with section 4059.5, subdivision (a), which requires that only a
pharmacist may sign for the delivery of controlled substances and dangerous drugs, in that on
each of the following dates, Respondents allowed a non-pharmacist to sign for deliveries at

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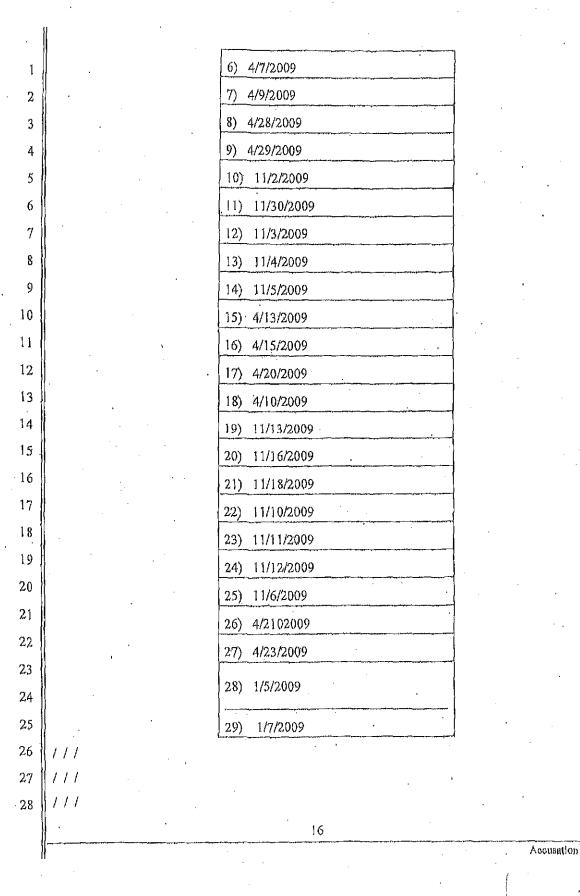
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1)	1/8/2009	
2)	1/16/2009	· · · · · · · · · · · · · · · · · · ·
3)	1/21/2009	· · ·
4)	1/16/2009	
5)	4/6/2009	
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#### FOURTH CAUSE FOR DISCIPLINE

(Providing Unapproved Employee With Pharmacy Key)

21. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of Regulations section 1714, subdivisions "d" and "e" which limits individuals who may legally possess a key to a pharmacy, in that on or about November 19, 2009, two pharmacy technicians employed at Respondent Pharmacy admitted that they had been given a key to the pharmacy by Respondent Skye, which had been in their possession for an appreciable period of time prior to the inspection, as described more fully in paragraph 17 above.

#### FIFTH CAUSE FOR DISCIPLINE

(No Self Assessment Form During Inspection)

22. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
subject to disciplinary action under section 4300 for unprofessional conduct as defined in section
4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of Regulations
section 1715, subdivisions "d which requires that a pharmacy must have a self-assessment form
on file for three years, in that during a Board inspection on or about July 7, 2009, Respondent
were unable to locate or produce a self assessment form, as described more fully in paragraph 17
above.

#### SIXTH CAUSE FOR DISCIPLINE

#### (Incorrectly Labeled Prescription Bottles)

23. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), in conjunction with section 4076, subdivision (a)(11)(A) requiring the prescription container must be labeled with a description of the medication dispensed, in that, during a Board inspection on July 7, 2009, the Inspector noticed Respondent Pharmacy had / / /

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dispensed incorrectly labeled medication as follows: 1 Prescription 343671 2 a, No description of medication 3 Prescription 341530 b, 4 No description of medication 5 Prescription 342438 6 с, No description of medication 7 SEVENTH CAUSE FOR DISCIPLINE 8 (Telephone Order Not Reduced to Writing) 9 Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to 24. 10 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, 11 subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1717 12 subdivision "c" which requires that an orally transmitted prescription must be promptly reduced 13 to writing and initialed, in that during a Board inspection on July 7, 2009, the inspector found 14 that prescriptions which had originated as oral prescriptions, had been filled - but had not been 15 reduced to writing in at least 22 instances, as follows: 16 340550 1) 17 337639 2) 18 337633 3) 19 4) 340553 20 340551 5) 21 337638 22. 6) 337636 23 7) 24 8) 337634 337640 9) 25 337628 10) 26 337637 11)27 337636 28 12) 18

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

#### (Failure to Maintain Operational Standards)

25. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to 13 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, 14 subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1714 15 subdivision "b" (which requires that Respondents maintain the pharmacy facility, and equipment 16 so that drugs are safely and properly prepared, maintained, secured and distributed) and 17 subdivision "c" (which requires that equipment shall be maintained in a clean and orderly 18 condition) in that during a Board inspection on November 19, 2009, the Inspector found 19 prescription bottles and caps stored on the floor of the small restroom next to and below the tollet. 20

#### NINTH CAUSE FOR DISCIPLINE

#### (Unauthorized Furnishing)

26, Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), in conjunction with section 4163, subdivision (a), and section 4126.5, which limit the persons or organizations that a pharmacy may legally furnish or transfer drugs to, in that on or about December 28, 2009, Respondents Illegally 'disposed of' pharmaceuticals through "Ensery West", and unlicensed entity, in violation of pharmacy law, as described more fully in

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	paragraph 17 aboye,	
		TREADY CONSTRUCT A TRONG
	DISCIPLINARY CONSIDERATIONS	
	27. To determine the degree of penalty to be imposed on Respondent(s), if any,	
·    (	Complainant makes the following ad	ditional allegations:
	Prior Cita	tion Respondent Michael's Pharmacy
	a. On or about November 13, 2008 a representative of the Board inspected	
F	Respondent Michael's Pharmacy, Pu	rsuant to that inspection, on April 23, 2009, Administrative
C	Citation/Assessment of Fine No. Cl 2	200839793 was issued to Respondent for violating Codes an
F	Regulations as set forth below, result	ing in the issuance of a \$ 5,000.00 fine, which Respondent
∦ p	aid in full. The citation is now final.	
	Code/Regulations Violated	Description
	<ul> <li>a. Bus. &amp; Prof. Code §4342</li> <li>b. CCR, title 16, §1716</li> </ul>	Stocking dangerous drugs lacking quality or strength Medication containers were found containing compounded drugs lacking expiration dates (Progesterone 100mg #15 and 50mg #76 Supp.) or drugs that had been expired (Estradiaol 250 Vag. Supp #16 expired 3/21/07, Progesterone 400mg #9 Supp expired 7/7/05 and 25mg #46 Supp expired 8/4/05, Boric acid Vag. Supp #16 expired in 10/21/06) Variation from Prescription On 12/06/2006, Respondent furnished prescription 301673 for Hydrocodone/APAP 10/500mg #120 to LC when the instructions on the face of the prescription stated "Do not dispense before 12/12/06". Specifically, on 4/2/08, Michael's Pharmacy furnished Rx 324777 Oxycontin 80mg #90, Rx 324778 Oxycontin 40mg #50 to LC when the prescription was dated 4/3/08. Failure to comply with Records requirements for
	c. CCR, title 16, §1716.2 d. Bus. & Prof. Code §4104	compounded medications Procedures to take action when licensed individual is impaired or known to have diverted or used drugs, written policies; Report; Immunity
	e. Health & Safety Code §11165 sub (d)(1-10)	For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice Data required
	f. CCR, title 16, §1745/ Title 21 CFR §1306,13 subd. (a)	Partial filling of Schedule II prescriptions/Partial filling of prescriptions.

Accusation

Prior Citation - Respondent Skye

b. On or about November 13, 2008 a representative of the Board Inspected Respondent
Michael's Pharmacy Pursuant to that inspection, on April 23, 2009, Administrative
Citation/Assessment of Fine No. CI 200839793 was issued to Respondent for violating Codes and
Regulations as set forth below, resulting in the issuance of a \$ 5,000.00 fine, which Respondent
paid in full. The citation is now final.

Code/Regulations Violated	Description
a. Bus. & Prof. Code §4342	Action by board to prevent sale of proparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales.
b, CCR, title 16, §1716	Variation from Prescription
c. CCR, title 16, §1716.2	Record requirements compounding for future furnishing
d, Bus, & Prof. Code §4104	Procedures to take action when licensed individual is impaired or known to have diverted or used drugs, Written policies; Report; Immunity
e. Health & Safety Code §11165	For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the' Department of Justice Data required,
f. CCR, title 16, §1745/Title 21 CFR	Partial filling of Schedule II prescriptions/Partial filling of prescriptions
§1306013 subd. (a)	

#### PRAYER

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

1. Revoking or suspending Pharmacy Permit No. PHY 47549 issued to Respondent

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2. Revoking or suspending Original Pharmacist License Number RPH 55396, issued to Respondent Natalya Skye;

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Accusation

3. Ordering Respondent Michael's Pharmacy 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;

4. Ordering Respondent Natalya Skye 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;

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

8/31/12 DATED:

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

LA2010600860 60662819,doox(rey)