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

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

Case No. 5303

STARBAT BY A COTTON

OAH No. 201502912

NATALYA SKYE 14569 Benefit St., #102 Sherman Oaks, CA 91403

STIPULATED SURRENDER OF LICENSE AND ORDER AS AGAINST NATALYA SKYE ONLY

Original Pharmacist License No. RPH 55396

Respondent.

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 October 16, 2015.

It is so ORDERED on September 16, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	Kamala D. Harris Attorney General of California Thomas L. Rinaldi 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 Attorneys for Complainant		
7 8 9	BOARD OF DEPARTMENT OF O	RE THE PHARMACY CONSUMER AFFAIRS CALIFORNIA	
10 11	In the Matter of the First Amended Accusation and Petition to Revoke Probation Against:	Case No. 5303 OAH No. 201502912	
12 13 14	NATALYA SKYE 14569 Benefit St., #102 Sherman Oaks, CA 91403 Original Pharmacist License No. RPH 55396	STIPULATED SURRENDER OF LICENSE AND ORDER [NATALYA SKYE ONLY] 1	
15	Respondent.		
16	IT IS HEREBY STIPULATED AND AGI	REED by and between the parties to the above-	
17	entitled proceedings that the following matters a	re true:	
18	PAR	<u>TIES</u>	
19	1. Virginia Herold (Complainant) is the	e Executive Officer of the Board of Pharmacy.	
20	She brought this action solely in her official capa	acity and is represented in this matter by Kamala	
21	D. Harris, Attorney General of the State of California, by Susan Melton Wilson, Deputy Attorney		
22	General.		
23	2. Natalya Skye (Respondent) is repres	ented in this proceeding by attorney Herbert L.	
24	Weinberg, Esq., whose address is Fenton Law G	roup, LLP, 1990 S. Bundy Drive, Suite 777	
25	Los Angeles, CA 90025.		
26	This matter was initially filed by the Bo	pard of Pharmacy against Respondents Natalya	
27 28	Skye <i>and</i> Michael's Pharmacy Inc. dba Michael as against Michael's Pharmacy Inc. dba Michael effective July 11, 2015.	's Pharmacy. A final order resolving this matter	

3. On or about June 23, 2004, the Board of Pharmacy issued Original Pharmacist License Number RPH 55396 to Respondent Natalya Skye. The Original Pharmacist License expired on March 31, 2014, was renewed on May 1, 2014, and is renewed through March 31, 2016, though currently under an Interim Suspension Order².

JURISDICTION

4. The original 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 21, 2014. Respondent timely filed her Notice of Defense contesting the Accusation and Petition to Revoke Probation. The First Amended Accusation and Petition to Revoke Probation was filed and duly served to Respondent on July 23, 2015. A copy of the First Amended Accusation and Petition to Revoke Probation No. 5303 is attached as **Exhibit A** hereto and incorporated by this reference.

<u>ADVISEMENT AND WAIVERS</u>

- 5. Respondent Skye has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended 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.
- 6. Respondent Skye is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation and Petition to Revoke Probation; 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

² On or about October 29, 2014, pursuant to petition of Complainant under Government Code section 494, an Ex Parte Interim Suspension Order was issued, suspending Respondent's Pharmacist License (RPH 55396), with an assigned effective date of October 31, 2014. On or about November 7, 2014, following noticed hearing of said petition, an Interim Suspension Order was issued, suspending Respondent's license until such time as a final administrative decision and order is made in this matter.

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.

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

CULPABILITY

- 8. Respondent Skye admits the truth of each and every charge and allegation in First Amended Accusation and Petition to Revoke Probation No. 5303, agrees that cause exists for discipline and hereby surrenders her Pharmacist License No. RPH 55396 for the Board's formal acceptance.
- 9. Respondent Skye understands that by signing this stipulation she enables the Board to issue an order accepting the surrender of her Pharmacist License without further process.

CONTINGENCY

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

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

ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 55396, issued to Respondent Natalya Skye, is surrendered and accepted by the Board of Pharmacy.

- 1. The surrender of Respondent's Pharmacist License 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.
- 2. Respondent shall lose all rights and privileges as a Pharmacist in California as of the effective date of the Board's Decision and Order.
- 3. Respondent shall cause to be delivered to the Board her pocket license and, if one was issued, her wall certificate on or before the effective date of the Decision and Order.
- 4. If she 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 understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure. Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the First Amended Accusation and Petition to Revoke Probation shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to taking and passing the California Pharmacist Licensure

1	Examination prior to the issuance of a new license. Respondent is required to report this surrender		
2	as disciplinary action.		
3	5. Respondent shall pay the agency its costs of investigation and enforcement in the		
4	amount of \$55,586.00 prior to issuance of a new or reinstated license.		
5	If Respondent should ever apply or reapply for a new license or certification, or		
6	petition for reinstatement of a license, by any other health care licensing agency in the State of		
7	California, all of the charges and allegations contained in First Amended Accusation and Petition		
8	to Revoke Probation, No. 5303 shall be deemed to be true, correct, and admitted by Respondent		
9	for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict		
10	licensure.		
11			
12	ACCEPTANCE		
13	I have carefully read the above Stipulated Surrender of License and Order and have fully		
14	discussed it with my attorney, Herbert L. Weinberg, Esq I understand the stipulation and the		
15	effect it will have on my Pharmacist License. I enter into this Stipulated Surrender of License		
16	and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and		
17	Order of the Board of Pharmacy.		
18	DATED: July 27, 2015		
19	NATALYA/SKYE Respondent		
20	v v v v v v v v v v v v v v v v v v v		
21	I have read and fully discussed with Respondent Natalya Skye the terms and conditions and		
22	other matters contained in this Stipulated Surrender of License and Order. I approve its form and		
23	content.		
24	DATED: July 27, 2015		
25	HERBERT L. WEINBERG, ESQ. Attorney for Respondent		
26	a ananound and resolvenier		
27			
28			

ENDORSEMENT The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. July 27, 2015 Dated: Respectfully submitted, KAMALA D. HARRIS Attorney General of California THOMAS L. RINALDI Supervising Deputy Attorney General JSAN MELTON WILSON Deputy Attorney General Attorneys for Complainant LA2014512487 51847069.doc

Exhibit A

First Amended Accusation and Petition to Revoke Probation No. 5303

1	KAMALA D. HARRIS Attorney General of California			
2	THOMAS L. RINALDI			
3	Supervising Deputy Attorney General SUSAN MELTON WILSON Deputy Attorney General State Bar No. 106902			
4				
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	BEFORE THE BOARD OF PHARMACY			
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
10				
11	In the Matter of the First Amended Accusation and Petition to Revoke Probation Against:			
12.	NATALYA SKYE FIRST AMENDED ACCUSATION AND PETITION TO			
13	14569 Benefit St., #102 Sherman Ooks, CA 91403 REVOKE PROBATION			
14	Original Pharmacist License No. RPH 55396 [Respondent Skye Only] ¹			
15	Respondent.			
16	Complainant alleges:			
17	PARTIES			
18	1. Virginia Herold (Complainant) brings this First Amended Accusation and Petition to			
19	Revoke Probation solely in her official capacity as the Executive Officer of the Board of			
20	Pharmacy, Department of Consumer Affairs.			
21	Natalya Skye			
22	2. On or about June 23, 2004, the Board of Pharmacy issued Original Pharmacist			
23	License Number RPH 55396 to Natalya Skye (Respondent Skye). The Original Pharmacist			
24	License expired on March 31, 2014, was renewed on May 1, 2014, and is renewed through			
25	March 31, 2016, though currently under an Interim Suspension Order, as described below.			
26	This matter was initially filed by the Board of Pharmacy against Respondents Natalya			
27 28	Skye and Michael's Pharmacy Inc. dba Michael's Pharmacy. A final order resolving this matter as against Michael's Pharmacy Inc. dba Michael's Pharmacy only was issued by the Board effective July 11, 2015.			

3. Effective February 14, 2014, Respondent Skye's Pharmacist License was placed on probation, per the Board's disciplinary decision "In The Matter of the Accusation Against Michael's Pharmacy etc. and Natalya Skye" case no. 3824, in which the license was revoked, revocation stayed and placed on probation for five (5) years with certain terms and conditions. A copy of this disciplinary decision is attached hereto as **Exhibit A** and incorporated by this reference.

Interim Suspension Orders

4. On or about October 29, 2014, pursuant to petition of Complainant under Government Code section 494, an Ex Parte Interim Suspension Order was issued, suspending Respondent's Pharmacist License (RPH 55396), with an assigned effective date of October 31, 2014. On or about November 7, 2014, following noticed hearing of said petition, an Interim Suspension Order was issued, suspending Respondent's license until such time as a final administrative decision and order is made in this matter,

Michael's Pharmacy

- 5. On or about November 7, 2006, the Board issued Pharmacy Permit No. PHY 47549 to Michael's Pharmacy Inc. dba Michael's Pharmacy. At all times after issuance of this permit, **Respondent Natalya Skye** was 100% owner of Michael's Pharmacy Inc., as well as designated Pharmacist-In-Charge of Michael's Pharmacy.
- 6. Both Respondent and Michael's Pharmacy Inc., dba Michael's Pharmacy were disciplined, effective February 14, 2014, as a result of disciplinary case no. 3824, referenced in paragraph 3 above. Said permit was revoked, revocation stayed and placed on probation for five (5) years with certain terms and conditions. A copy of this disciplinary decision is attached hereto as **Exhibit B** and incorporated by this reference.
- 7. Both Respondent *and* Michael's Pharmacy Inc., dba Michael's Pharmacy were subject to Interim Suspension Orders described at paragraph 4 above, which were issued pursuant to petition of Complainant under Government Code section 494, on or about October 29, 2014 and November 7, 2014.

Michael's Pharmacy Permit Surrendered

8. On or about April 28, 2015, Respondent Natalya Skye agreed to surrender Pharmacy Permit No. PHY 47549 in order to conclude this disciplinary matter as against Michael's Pharmacy Inc., dba Michael's Pharmacy. Effective July 13, 2015, the Board issued its order accepting the surrender of the permit, in final resolution of this disciplinary matter as against Michael's Pharmacy Inc. dba Michael's Pharmacy only.

JURISDICTION AND STATUTORY PROVISIONS FOR ACCUSATION

- 9. The original Accusation herein, filed concurrently with a Petition to Revoke Probation, was filed on or about November 21, 2014, and duly served to Respondents, each of whom filed a timely Notice of Defense. This First Amended Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws.
- 10. Business and Professions Code 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.
- 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."
 - 12. Business and Profession Code section 4300 states:
 - (a) Every license issued may be suspended or revoked.
- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.

- (2) Placing him or her upon probation.
- (3) Suspending his or her right to practice for a period not exceeding one year.
- (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
- (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 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 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.
 - 13. Business and Professions Code section 4301 states:

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.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony, involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the

qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

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.

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 at sub-section "b" that unprofessional conduct for a pharmacist may include:

22

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

25

16. Business and Professions Code section 4323 states:

27 28

Any person who, while on duty, sells, dispenses, or compounds any drug while under the influence of any dangerous drug or alcoholic beverages shall be guilty of a misdemeanor.

17. Business and Professions Code section 4081 provides:

- (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 foodanimal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- (b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary foodanimal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
- (c) The pharmacist-in-charge or designated 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 designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.
- 18. Business and Profession Code section 4113 defines the term "pharmacist-in-charge" 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.
 - 19. Health and Safety Code section 11153 provides:
- (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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional

treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

- (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

- 21. Title 16 California Code of Regulations section 1714 provides in pertinent part:
- (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
- (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.
 - 22. Title 16 California Code of Regulations section 1735 provides:
- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
 - (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients

(5) The quantity of each component used in compounding the drug product.

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(6) The manufacturer, expiration date and lot number of each component. If the
manufacturer name is demonstrably unavailable, the name of the supplier may be
substituted. Exempt from the requirements in this paragraph are sterile products
compounded on a one-time basis for administration within seventy-two (72) hours and
stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the
United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May
1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed
under section 1250 of the Health and Safety Code.

- (7) A pharmacy assigned reference or lot number for the compounded drug product.
- (8) The expiration date of the final compounded drug product.
- (9) The quantity or amount of drug product compounded.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

- 25. Title 16 California Code of Regulations section 1774 provides:
- (a) Unless otherwise directed by the Board, any pharmacy permit which is on probation to the Board shall be subject to the following conditions:
- (1) Obey all laws and regulations substantially related to the practice of pharmacy;
- (2) The permit, through its officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
- (3) Cooperate with the Board in its inspectional program;
- (4) Post or circulate notice of conditions of probation so that they are available to all employees involved in pharmacy operations;
- (5) Submit the operation of the pharmacy to peer review if deemed necessary by the Board;

- (6) Provide evidence that owners or officers are knowledgeable in the laws pertaining to pharmacy if deemed necessary by the Board.
- (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 case or by stipulation of the parties.
 - 26. Title 16 California Code of Regulations section 1761 provides:
- (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.
- 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

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

DRUG CLASSIFICATIONS

29. Oxycodone / Oxycontin - 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 analysis (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.
- 31. <u>Hydrocodone /APAP</u> is Schedule III controlled substance pursuant to Health and Safety Code Section 11056 (e)(2) and is a dangerous drug within the meaning of Business and Professions Code section 4211 (a) Hydrocodone /APAP is a drug product combining Hydrocodone with Acetaminophen ("APAP").
- 32. <u>Buprenorphine</u> Buprenorphine, also known by the brand name <u>Subutex</u> is a 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 relief and in treatment of opioid dependence. <u>Buprenorphine/Naloxone</u>, also known by the brand name <u>Suboxone</u>, is a drug product combining Buprenorphine with Naloxone, and is also a Schedule V drug pursuant to Health and Safety Code Section 11058 (d), used in treatment for opioid dependence.

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

- 33. The following allegations are common to all causes for discipline in this matter:
- a. At all times relevant herein, Respondent Natalya Skye (Respondent Skye) was 100% owner and pharmacist-in-charge of Michael's Pharmacy, a small retail pharmacy located in Pasadena, CA.
- b. The probationary status of both Respondent and Michael's Pharmacy effective
 February 14, 2014, resulted in multiple investigatory visits and inspections of the pharmacy
 between February and August of 2014, as detailed below. Additionally, in approximately April of
 2014, the Board commenced investigation of two anonymous complaints against Michael's
 Pharmacy which had been posted on the Board's internet website in January 2014. The <u>first</u>

complaint alleged that the pharmacy was selling the drug Oxycontin for street use, stating "all sales are cash and no transactions are shown in (the) database." The second complaint, similarly alleged that two pharmacy technicians at Michael's Pharmacy were entering the store when Respondent Skye was not present, and were conducting large cash-only sales of narcotics "to street drug dealers who routinely stop by the pharmacy (in the evening)." It was further alleged that Michael's Pharmacy was engaged in fraudulent billing and falsifying telephone prescriptions.

Oxycodone/Oxycontin Audit

- 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.
- e. Due to poor record keeping practices of the pharmacy, different audit dates were used (Audit 1: Oxycodone 30mg IR Audit dates: 12/14/2012 to 01/14/2014; Audit 2: Oxycodone 30 mg IR Audit dates: 01/14/2014 to 04/24/2014; Audit 3: Oxycontin Audit dates: 01/16/2013 to 04/24/2014) so that calculations covered overlapping time periods between approximately 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:
 - 1. Oxycodone 30mgIR 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).
 - 2. Oxycontin 20 mg and 80 mg 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).

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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.
- i. The audit period chosen was for the recent four (4) month period between April 1, 2014 and August 1, 2014, and disclosed as follows:

Hydrocodone / APAP [5 mg Hydrocodone - 325mg Acetaminophen]

Purchases	Dispensed	Stock on hand	Difference
4/1 –	4/1 –	4/1 –	4/1 –
8/19/14	8/19/14	8/19/14	8/19/14
2000	769	147	-84

Hydrocodone / APAP [10 mg Hydrocodone- 325 mg Acetaminophen]

Purchases 4/1 — 8/19/14	Dispensed 4/1 – 8/19/14	Stock on hand 4/1 — 8/19/14	Difference 4/1 – 8/19/14	
17,000	5.090	221	-11,739	_

- j. **Hydrocodone Audit Results** This targeted audit revealed pharmacy drug stock unaccounted for as follows:
 - 1. <u>Hydrocodone /APAP</u> [5 mg Hydrocodone 325 mg Acetaminophen] for the 4 months between April 1 and August 1 of 2014, Michael's Pharmacy could not account for/ was short **84 tablets** of Hydrocodone /APAP 5-325
 - 2. <u>Hydrocodone /APAP</u> [10 mg Hydrocodone 325 mg Acetaminophen] for the 4 months between April 1 and August 1 of 2014, Michael's Pharmacy could not account for/ was short 11,739 tablets of Hydrocodone /APAP 10-325.

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Corresponding Responsibility Analysis

- k. To investigate controlled substance dispensing practices of the pharmacy, a Board Inspector obtained and analyzed CURES² reports for schedule II through IV controlled 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 prescriber³ and Michael's 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**.
- 1. The Inspector sent **Dr. Choudhury**, **Dr. Smith** and **Dr. Swaby** a list of dispensed controlled substances from Michael's pharmacy obtained from the CURES data, and asked whether they had actually written the prescriptions listed. Each provided attestations to the effect that he **had neither had written nor authorized** any of the prescriptions listed. Dr. Choudhury and Dr. Swaby further noted that they had changed their DEA registration numbers, but that prescriptions dispensed from Michael's pharmacy showed their old/previous DEA registration numbers.
- m. On April 24, 2014, the Inspector conducted an inspection of Michael's Pharmacy, during which he requested and obtained hard copy prescriptions for each controlled substance

² The CURES (Controlled Substance Utilization, Review and Evaluation System) program was initiated in 1998, and requires mandatory monthly pharmacy reporting of dispensed schedule 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 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 can 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 be used to aid in determining if a patient has been to multiple prescribers and multiple pharmacies to fill controlled substance prescriptions.

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 Michael's 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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27 28 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. The Inspector further interviewed Respondent Skye about what steps or criteria were used at Michael's pharmacy to determine whether a prescription was medically legitimate. During that interview, Respondent Skye admitted that she had never spoken to Dr. Choudhury, Dr. Smith or Dr. Swaby.

- n. Based on evidence thus obtained, the Inspector determined that the pharmacy did not routinely follow any protocol for prescription verification in day-to-day operation of Michael's 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.
- Based on his training and experience, information provided by Respondent Skye, and o. his analysis of Michael's pharmacy records related to prescriptions of Dr. Smith, Choudhury and Swaby as described here, the Board inspector concluded that Respondents had failed in their corresponding responsibility to verify the medical legitimacy of prescriptions purportedly written by Smith, Choudhury and Swaby, having ignored key objective factors indicating prescriptions were not legitimate, including but not limited to:
 - 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.
 - Irregular pattern of nearly all diagnoses involved lumbar issues. The diagnoses were 4. not varied.
 - 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.
- 8. Dr. Swaby's prescriptions initiating patients on the highest doses of oxycodone without any pharmacy records showing upward tapering.
- 9. Michael's 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").
- p. Looking at the totality of circumstances regarding Dr. Choudhury, Dr. Smith or Dr. Swaby including but not limited to the fact that most were cash sales, the location of the prescriber's practice in relation to the location of Michael's Pharmacy, the volume of the prescriptions presented from these prescribers, Michael's Pharmacy 's dispensing history, the manner in which these prescriptions were presented to the pharmacy, and the use of invalid or superseded prescription forms Respondent should have questioned the legitimacy of the 208 prescriptions presented for these prescribers. The omission to do so resulted in the repeated dispensing of controlled substances to persons diverting controlled substances by use of falsified prescriptions and/or patients engaged in doctor shopping activity.
- q. **Buprenorphine Prescriptions** Respondent's 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. Michael's 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) 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

Compounding Violations (Inspection – April 2014)

v. During an inspection of Michael's Pharmacy on April 24, 2014, a Board inspector observed that Respondents had 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. A recording log was found indicating this same product had been compounded on previous dates. However, the pharmacy did not have a written master formula record for this compounded product. Additionally, the estradiol/testosterone capsules were contained in a bottle with a label indicating the bottle contained 30 capsules – when, in fact, it was found to *actually* contain 89 capsules.

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

Overdose at Pharmacy (August 2014)

y. On or about 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

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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 attending her mother. Respondent voluntarily provided a blood sample at the time of her arrest. That sample tested positive for both "opiates⁴" and "benzodiazepines⁵."

Respondent was working as a pharmacist at Michael's Pharmacy on August 1, 2014 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." Pharmacy employee LO stated that she (LO) had arrived late to work that day. On entering the pharmacy, she observed SR - Respondent's mother - sleeping in a chair. LO stated that SR appeared pale and "didn't look right." Respondent stated that SR was OK - to just let her sleep. However, LO noticed that SR's lips were turning blue - so they tried to wake her. Finding her unresponsive, they called 911.

Discovery of Self-Dispensing

Investigating circumstances leading to the 911 call from Michael's 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 Respondent from Michael's Pharmacy as follows:

1.	Oxycodone/APAP 5-325	#20	7/12/2012
2.	Oxycodone/APAP 5-325	#30	11/26/201
3.	Alprazolam 0.25mg	#30	3/21/2014
4.	Lorazepam 2mg	#30	4/7/2014
5.	Amphetamine 10mg	#30	5/22/2014

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

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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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) admitted that she (LO) was ordering drugs - and that Respondent had given her the confidential CSOS passcode. 6 – and provided documents showing two (2) separate purchases by LO, made during Respondent's diversion program suspension

Termination from Diversion (September 2014)

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)

- Respondent SKYE is subject to disciplinary action under Business and Professions 34. 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 Respondent 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, the pharmacy had a shortage of 11,739 tablets of Hydrocodone/APAP 10 -325 tablets and 84 tablets of Hydrocodone /APAP 5-325.

⁶ 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.

b. Oxycontin/Oxycodone Inventory Losses - Per Board audits encompassing the approximately sixteen month period between 12/14/2012 and 04/24/2014 the pharmacy 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).

SECOND CAUSE FOR DISCIPLINE

(Failure to Assume Corresponding Responsibility to Assure Legitimacy of Prescriptions)

- 35. 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 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, Respondent and Michael's Pharmacy 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 her failure to operate the pharmacy in a manner compliant with corresponding responsibility requirements to verify legitimacy of controlled substance prescriptions, as follows:
 - a. Choudhury, Smith and Swaby Prescriptions Individually and as

 Pharmacist In Charge, Respondent failed in her 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** Individually and as Pharmacist In Charge, Respondent failed in her 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 Individually and as Pharmacist In Charge,
 Respondent failed in her 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-to-day operation of Michael's 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, Michael's Pharmacy 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 Respondents failed to observe or address in a manner compliant with corresponding responsibility requirements (Health and Safety Code section 11153(a); Title 16 California Code of Regulations section 1761) as described in paragraphs 33 and 35 above. As owner and Pharmacist-In-Charge of Michael's Pharmacy, Respondent Skye's failure to establish and/or implement routine practices for prescription verification in day-to-day operation of the pharmacy, or otherwise ensure compliance with corresponding responsibility requirements - constitutes acts or omissions that involved the failure to exercise or implement her best professional judgment or corresponding responsibility.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition and Disposition)

- 37. 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 4081, subdivisions (a) and (b) requiring that all records of acquisition or disposition of dangerous drugs shall be preserved and open to inspection for at least three (3) years for reasons as follows:
 - a. **Hydrocodone/APAP Inventory Losses** Per Board audit for dates between April 1, 2014 and August 19,2014, the pharmacy had a shortage of 11,739 tablets of Hydrocodone/APAP 10 -325 tablets and 84 tablets of Hydrocodone /APAP 5-325 with no records to account for the whereabouts or disposition of the missing drug stock.
 - b. Oxycontin/Oxycodone Inventory Losses Per Board audits encompassing the approximately sixteen month period between 12/14/2012 and 04/24/2014 The pharmacy

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) - with no records to account for the whereabouts or disposition of the missing drug stock.

FIFTH CAUSE FOR DISCIPLINE

(Operation of Pharmacy With Unlicensed Pharmacist)

- 38. 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 4036 (which requires that only the holder of an unexpired and active pharmacist license issued by the Board is entitled to practice within the licensed pharmacy premises) in that on dates between April 1, 2014 and May 1, 2014:
 - a. Respondent Skye maintained her employment as pharmacist-in-charge of Michael's Pharmacy and in that capacity and otherwise engaged in acts (set forth in Title 16 California Code of Regulations section 1793.1⁷) requiring an unexpired and active pharmacist license

SIXTH CAUSE FOR DISCIPLINE

(Violations Related to Compounded Drug Products)

39. Respondent SKYE is subject to disciplinary action under Business and Professions Code section 4300 for unprofessional conduct as defined in Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Title 16 California Code of Regulations (CCR) sections 1735.2 and 1735.3, subdivision (a), in that during an inspection of Michael's Pharmacy on April 24, 2014, compounded drug products prepared by the pharmacy Title 16 California Code of Regulations section 1793.1 provides: Only a pharmacist, or an intern

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(g) Perform all functions which require professional judgment.

⁷ 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:

⁽a) Receive a new prescription order orally from a prescriber or other person authorized by law.

⁽b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

⁽f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

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, the pharmacy 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. However, the pharmacy did not have a written master formula record for this compounded 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, the pharmacy 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

EIGHTH CAUSE FOR DISCIPLINE

(Conviction of a Substantially Related Crime)

41. Respondent SKYE is subject to disciplinary action under Business and Professions 4300 for unprofessional conduct as defined in section 4301, subdivision (I) in that Respondent has

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been convicted of crimes substantially related to the qualifications, functions or duties of a registered nurse which to a substantial degree evidences her present or potential unfitness to practice in a manner consistent with the public health, safety, or welfare, as follows:

UNDER THE INFLUENCE OF CONTROLLED SUBSTANCE (OPIATES) -2015

- On or about February 2, 2015, after pleading nolo contendere, Respondent was a. convicted of one misdemeanor count of violating Health and Safety Code section 11550 (a) [Under The Influence Of A Controlled Substance - Opiates] in the criminal proceeding entitled The People of the State of California v. Natalya Skye (Super. Ct. L.A. County, 2014, No.4PS02484). The Court deferred sentencing and placed Respondent on summary probation – ordering her to complete a 6 month drug counseling program (including drug testing), complete 100 hours of community service, and comply with specified conditions, including a prohibition against use or possession of "any narcotics, dangerous or restricted drugs or associated paraphernalia, except with a valid prescription, and stay away from places where users or sellers congregate." Respondent is also prohibited from "associating with drug users or sellers (unless attending a treatment program)."
- The circumstances underlying the conviction are that on or about August 1, 2014, Respondent's 66 year old mother was treated by paramedics for a drug overdose and transported to a hospital for emergency treatment following a 911 call from "Michael's Pharmacy" – a pharmacy owned and operated by Respondent 8. located in the city of Pasadena. 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 attending her mother. Respondent voluntarily provided a blood sample at the time of her arrest. That sample tested positive for both "opiates⁹" and "benzodiazepines¹⁰."

⁸ As noted above, Respondent holds licenses with the California Board of Pharmacy as a pharmacist (Original Pharmacist License No.55396) and as owner of Michael's Pharmacy (Pharmacy Permit No. PHY 47549).

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.

EXHIBITION OF SPEED - 2014

- c. On or about December 17, 2014, after pleading nolo contendere, pursuant to a plea agreement, Respondent was convicted of one interlineated misdemeanor count of violating Vehicle Code section 23109 C [Exhibit of Speed] in the criminal proceeding entitled *The People of the State of California v. Natalya Skye* (Super. Ct. L.A. County, 2014, No.4VY03383). The Court suspended sentencing and placed Respondent on summary probation for 24 months, ordering payment of restitution and fines, requiring her to comply with specified conditions, including a prohibition against use or possession of "any narcotics, dangerous or restricted drugs or associated paraphernalia, except with a valid prescription, and stay away from places where users or sellers congregate." Respondent is also prohibited from "associating with drug users or sellers (unless attending a treatment program)."
- d. The circumstances underlying the conviction are that on or about April 28, 2014, Respondent 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 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). Subsequent toxicology testing of a fluid sample provided by Respondent on the day of the accident documented that Lorazepam¹¹ a drug with a sedative effect (for which Respondent had a prescription) was in her system at the time of the accident.

NINTH CAUSE FOR DISCIPLINE

(Conviction of a Crime Involving Consumption of Dangerous Drugs)

42. Respondent SKYE is subject to disciplinary action under Business and Professions 4300 for unprofessional conduct as defined in section 4301, subdivision (k) in that on or about December 17, 2014 and on February 2, 2015, Respondent was convicted of misdemeanor crimes

¹¹ See footnote 5

involving use, consumption or self-administration of dangerous drugs. Complainant refers to, and by this reference incorporates, allegations of paragraph 41 above.

TENTH CAUSE FOR DISCIPLINE

(Use of Controlled Substance(s) to the Extent That Use Impairs Safety)

- 43. Respondent SKYE is subject to disciplinary action under Business and Professions 4300 for unprofessional conduct as defined in section 4301, subdivision (h) in that, on multiple instances noted below, Respondent used controlled substances to an extent or in a manner dangerous to herself or any other person or the public, or to the extent that such use impaired her ability to conduct with safety the practice authorized by her license, by reason of the following facts:
 - a. April 28, 2014 On April 28, 2014, shortly after leaving work at Michael's Pharmacy, 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 her car. Respondent's acts and omissions on this date resulted in her criminal conviction of December 17, 2014.
 - 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). A blood sample voluntarily provided by Respondent at the time of her arrest, tested positive for both "opiates¹²" and "benzodiazepines¹³." Respondent's acts and omissions on this date resulted in her criminal conviction of February 2, 2015.
 - Respondent was working as a pharmacist at Michael's Pharmacy on August 1,
 prior to her mother's medical emergency. Pharmacy employees reported to Board

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.

investigators that Respondent was "acting crazy" and "behaving differently" that day, and that she "appeared unsteady and had slurred speech."

d. August 13, 2014 - 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.

ELEVENTH CAUSE FOR DISCIPLINE

(Practice as Pharmacist While Under the Influence)

44. 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 4327, in that Respondent was under the influence of a dangerous drug while on duty and working as a pharmacist at Michael's Pharmacy on or about April 28, 2014 and on August 1, 2014 (as detailed in paragraphs 33 and 42 above).

TWELFTH CAUSE FOR DISCIPLINE

(Violation of Federal Pharmacy Regulations)

45. 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 allow the employee to make two controlled substance purchases (on August 15, 2014 and August 18, 2014) during a time when Respondent's license was suspended.

JURISDICTION FOR PETITION TO REVOKE PROBATION

46. The original Petition to Revoke Probation herein, filed concurrently with an Accusation matter, was filed on or about November 21, 2014, and duly served to Respondents, each of whom filed a timely Notice of Defense. This Petition to Revoke Probation is brought before the Board 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, and

Condition 14 (Skye Order- Exhibit A), and Condition 12 (Michael's Pharmacy 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

(Failure to Obey all Laws)

- 47. At all times after the effective date of Respondent Natalya Skye's probation, Condition 2 stated in pertinent part:
 - "Respondent shall obey all state and federal laws and regulations."
- 48. Respondent Natalya Skye's probation is subject to revocation because she failed to comply with Condition 2, as follows:
 - a. Substantially Related Criminal Convictions Respondent has obtained two criminal convictions, both involving dangerous use of controlled substances, on December 17, 2014 and February 2, 2015, as more fully set forth in the, Eighth, Ninth and Tenth Causes for Discipline (paragraphs 41 through 43) of the Accusation filed herewith.
 - b. **Numerous Violations of Pharmacy Law** Respondent has engaged in numerous violations of pharmacy law, as set forth in more detail in the First through

Twelfth Causes for Discipline (paragraphs 33 through 45), and each of them, in the Accusation filed herewith.

SECOND CAUSE TO REVOKE PROBATION

(Practiced Pharmacy Without a Current, Valid License)

- 49. At all times after the effective date of Respondent Skye's probation, Condition 10 of the probation order stated in pertinent part:
 - "Status of License Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation s is tolled. Failure to maintain an active, current license shall be considered a violation of probation..."
- 50. Respondent Skye's probation is subject to revocation because she failed to comply with Probation Condition 10, in that 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 without a current, valid license, as pharmacist-in-charge and was often the sole pharmacist at Michael's Pharmacy for the month between March 31, 2014 and May 1, 2014- at which time the license was renewed.

THIRD CAUSE TO REVOKE PROBATION

(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 Condition 10, which Respondent admitted to her probation monitor during 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 through 19, 2014. Respondent claimed she was confused about when the suspension began.

OTHER MATTERS

- 53. In order to determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges the following:
- a. On or about August 22, 2014, Cardinal Health (a licensed drug wholesaler) notified the Board that it had suspended Michael's Pharmacy's account from ordering controlled and monitored substances based in their determination that continued sales to this customer created an unreasonable risk of potential diversion.

PRAYER

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

EXHIBIT A

To First Amended Accusation and Petition to Revoke Probation

<u>Decision and Order as to Respondent Natalya Skye</u>

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

[AS 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

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1	KAMALA D. HARRIS	
2	Attorney General of California GREGORY J. SALUTE	
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	
б	Telephone: (213) 897-4942	
7	Facsimile: (213) 897-2804 E-mail: Susan Wilson@doj.ca.gov Attorneys for Complainant	
8		RE THE
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF CALIFORNIA	
11	In the Matter of the Accusation Against: MICHAEL'S PHARMACY, INC.,	Case No. 3824
12	d.b.a.MICHAEL'S PHARMACY	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER
13	NATALYA SKYE, PHARMACIST-IN-CHARGE	[AS AGAINST RESPONDENT
14	960 East Green Street Pasadena, CA 91106	NATALYA SKYE ONLY]
15	Pharmacy Permit No. PHY 47549	
16	AND	
17	NATALYA SKYE	
18	14569 Benefit St., #102 Sherman Oaks, CA 91403	
19	Original Pharmacist License No. RPH 55396	
20	Respondents.	
21		
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-	
23	entitled proceedings that the following matters are true:	
24	PARTIES	
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	
28	General.	
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STIPULATED SETTLEMENT (3824)

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

ADVISEMENT AND WAIVERS

- 6. 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.

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

CULPABILITY

- 9. Respondent admits the truth of each and every charge and allegation in Accusation No. 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 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board falls to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 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.

23.

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

As part of probation, respondent is suspended from the practice of pharmacy for 30 (thirty) 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 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,

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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

- an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo 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 pharmacist license or which is related to the practice of
 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
 for any drug, device or controlled substance.

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

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

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

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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.

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

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

9. Probation Monitoring Costs

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

10. Status of License

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

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

11. License Surrender While on Probation/Suspension

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

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

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.

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.

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

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

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.

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.

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.

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 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.

18. No New Ownership of Licensed Premises

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

19. Consultant for Owner or Pharmacist-In-Charge

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

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

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.

20. Self Assessment Report Must Be Made Quarterly

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

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.

22. Administrative Penalty

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Respondent shall be jointly and severally liable with co-respondent to Accusation 3824, Michael's Pharmacy Inc., to pay an Administrative Penalty in the sum of Twenty Five Thousand Dollars (\$25,000.00) Payment of the assessed administrative penalty shall be completed during the first four years of probation, in accord with a payment plan approved by the Board or its designee, Respondent 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 directly to the Board at the Board's Sacramento address in a timely manner. Pailuro to make any payment when due shall be considered a violation of probation.

23. Ethics Course

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

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

ACCEPTANCE

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

DATED: 11/5/3

NATALYA SKYB Respondent

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

DATED: 11/15/3

HERBERT WEINEURO Attorney for Respondent

13/

STIPULATED SETTLEMENT (3824)

ENDORSEMENT

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

Dated:

11 - 15-13

Respectfully submitted,

KAMALA D. HARRIS Attorney General of California GREGORY J. SALUTE Supervising Deputy Attorney General

SUSAN MELTON WILSON Deputy Attorney General Attorneys for Complatment

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Exhibit A

Accusation No. 3824

KAMALA D. HARRIS Attorney General of California GREGORY J. SALUTE Supervising Deputy Attorney General SUSAN MELTON WILSON Deputy Attorney General State Bar No. 106902 4 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone; (213) 897-4942 Facsimile: (213) 897-2804 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 In the Matter of the Accusation Against: Case No. 3824 12 MICHAEL'S PHARMACY, INC., 13 ACCUSATION NATALYA SKYE, PHARMACIST-IN-CHARGE 14 960 East Green Street Pasadena, CA 91106 15 Pharmacy Permit No. PHY 47549 16 AND 17 NATALYA SKYE 18 14569 Benefit St., #102 Sherman Oaks, CA 91403 19 Original Pharmacist License No. RPH 55396 20 Respondents. 21 Complainant alleges: 22 PARTIES 23 Virginia Herold (Complainant) brings this Accusation solely in her official capacity 24 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, 25 2. On or about November 7, 2006, the Board of Pharmacy (Board) Issued Pharmacy 26 Permit No. PHY 47549 to Michael's Pharmacy (Respondent Pharmacy), Natalya Skye is and has 27 been Pharmacist-In-Charge of Respondent Pharmacy since November 7, 2006. The Pharmacy 28

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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.

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

STATUTORY PROVISIONS

- 5. 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.
- "(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:
 - "(1) Suspending judgment.
 - "(2) Placing him or her upon probation. .
 - "(3) Suspending his or her right to practice for a period not exceeding one year.
 - "(4) Revoking his or her license,
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
- "(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

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 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."
 - Section 4301 of the Code states;

"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 misdomeanor or not.

"(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.

"(0) 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; ·
- "(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
- (1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
 - (2) The directions for the use of the drug.

 (3) The name of the patient or patients.

- (4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmaoist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
 - (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.
 - (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.
- "(b) If a pharmacist 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 Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052,
- "(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice."
 - 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 or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

"(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 knowlingly 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 the dangerous 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 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.

- (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 voting rights, by contract, or by other means.
 - 12. Section 4105 of the Code states;
- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed 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.
- "(c) The records required by this section shall be retained on the licensed premises for a 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 veterinary 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."

- 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.

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 conforms with standards established in the official compendia.

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

- (1) a patient med pak is reused only for the same patient;
- (2) no more than a one-month supply is dispensed at one time; and
- (3) each patient med pak bears an auxiliary label which reads; store in a cool, dry place.
- "(b) In addition to the requirements of Section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:
- (1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
- (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
- (3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
- (4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

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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.

"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.

- "(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
- "(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

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

- (1) Identification of pharmacist(s) transferring information;
- (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

- (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.
- "(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.

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 locked and the lights were off. The Inspector asked the Tech to leave and wait 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

- Reipax 40mg
 Maxalt 10mg
 Micardies 40mg and 80mg
 Aggrenox 25/200
 Simcor 500/20
 Enablex 15 mg
 Exforge 5/320 and 5/160
 Seroquel XR 150mg
- 11. Micardis HCT 80/12.512. Aricept 10mg and 5mg13. Aricept ODT 5mg.
- (2) The Inspector also observed large amber vials 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 for 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.
- 1. The Inspector further observed that the small restroom in the facility had storage shelves immediately adjacent to the toilet, and that pharmacy bottles and caps were stored on the floor next to the toilet.
- J. Further investigation disclosed that on or about December 28, 2009, Respondents illegally transferred pharmaceuticals for "disposal" as medical waste by an unlicensed entity named "Ensery West" located in Vernon, CA.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Records Requirements)

18. Respondents MICHAEL'S PHARMACY and NATALYA SKYB are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (i) and (o), in conjunction with section 4059, subdivision "b" in that during an

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

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 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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6) 4/7/2009
7) 4/9/2009
8) 4/28/2009
9) 4/29/2009
10) 11/2/2009
11) 11/30/2009
12) 11/3/2009
13) 11/4/2009
14) 11/5/2009
15) 4/13/2009
16) 4/15/2009
17) 4/20/2009
18) 4/10/2009
19) 11/13/2009
20) 11/16/2009
21) 11/18/2009
22) 11/10/2009
23) 11/11/2009
24) 11/12/2009
25) 11/6/2009
26) 4/2102009
27) 4/23/2009
28) 1/5/2009
29) 1/7/2009

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 (I) 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.

PIFTH 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 aboye.

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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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
10	22) 340554
11	EIGHTH CAUSE FOR DISCIPLINE
12	(Failure to Maintain Operational Standards)
13	25. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
14	disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
15	subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1714
16	subdivision "b" (which requires that Respondents maintain the pharmacy facility, and equipment
17	so that drugs are safely and properly prepared, maintained, secured and distributed) and
18	subdivision "c" (which requires that equipment shall be maintained in a clean and orderly
19	condition) in that during a Board inspection on November 19, 2009, the Inspector found
20	prescription bottles and caps stored on the floor of the small restroom next to and below the tolle
21	NINTH CAUSE FOR DISCIPLINE
22	(Unauthorized Furnishing)
23	26. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
24	disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
25	subdivision (o), in conjunction with section 4163, subdivision (a), and section 4126.5, which
26	limit the persons or organizations that a pharmacy may legally furnish or transfer drugs to, in that
27	on or about December 28, 2009, Respondents illegally 'disposed of' pharmaceuticals through
28	"EnseryWest", and unlicensed entity, in violation of pharmacy law, as described more fully in

DISCIPLINARY CONSIDERATIONS

To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

Prior Citation - Respondent Michael's Pharmacy

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. Cl 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	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)
b. CCR, title 16, §1716	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.
c. CCR, title 16, §1716.2	Failure to comply with Records requirements for compounded medications
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 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	Partial filling of Schedule II prescriptions/Partial filling of prescriptions.
CFR §1306.13 subd. (a)	

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 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:

- Revoking or suspending Pharmacy Permit No. PHY 47549 issued to Respondent Michael's Pharmacy;
- 2. Revoking or suspending Original Pharmacist License Number RPH 55396, issued to Respondent Natalya Skye;

1	3. Ordering Respondent Michael's Pharmacy to pay the Board of Pharmacy the				
2	reasonable costs of the investigation and enforcement of this case, pursuant to Business and				
3	Professions Code section 125.3;				
4	4. Ordering Respondent Natalya Skye to pay the Board of Pharmacy the reasonable				
5	costs of the investigation and enforcement of this case, pursuant to Business and Professions				
6	Code section 125.3;				
7	 Taking such other and further action as deemed necessary and proper. 				
8					
9	DATED: 8/31/12 1) in the 10				
10	VIRGIMIA HEROLD				
11	Executive Officer Board of Pharmacy				
12	Department of Consumer Affairs State of California				
13	Complainant				
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EXHIBIT B

To First Amended Accusation and Petition to Revoke Probation

<u>Decision and Order as to Michael's Pharmacy</u>

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

[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 Astronis giste Bosis of bijanisch Skirousis giste Bosis of bijanisch MECULA RELUBING REUNT THE ENEX OF THE VICENCY AND CORRECT DAMPE DOCUMENTS VAR LATE VATO CORRECT DAMPE VALUE WITH SECOND PROPERTY OF SECOND PROPERY

- 1			
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		
. 5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
6	Telephone: (213) 897-4942 Facsimile: (213) 897-2804		
7	E-mail: Susan, Wilson@doj.ca.gov Attorneys for Complainant		
8		RE THE	
9	BOARD OF	PHARMACY	
		CONSUMER AFFAIRS CALIFORNIA	
10		1	
11	In the Matter of the Accusation Against:	Case No. 3824	
12	DESCRIPTION DATE TO A CONTROL	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 Original Pharmacist License No. RPH 55396		
20	Respondents.		
21			
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	PAI	RTIES	
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 Calli	Pornia, by Susan Melton Wilson, Deputy Attorney	
28	General,		
.		2	

- 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 McGuire Woods 1800 Century Park East, 8th Floor, 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. d.b.a. Michael's Pharmacy (Respondent). Natalya Skye is an owner of Respondent and has been Pharmacist-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

- 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 August 14, 2012. Respondent timely filed its Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 3824 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent, by its authorized representative, 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 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.

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

CULPABILITY

- 9. Respondent admits the truth of each and every charge and allegation in Accusation No. 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 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 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.

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:

- 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 charging for any drug, device or controlled substance.

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

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

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.

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.

5. 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.

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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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.

8. License Surrender While on Probation/Suspension

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

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

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

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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

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

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

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

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

11. Posted Notice of Probation

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.

12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically 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 owner violates probation in any respect, the board, after giving respondent owner 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.

13. Completion of Probation

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

14. Community Services Program

 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. Failure 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,
Natalya Skye, to pay an Administrative Penalty in the sum of Twenty Five Thousand Dollars
(\$25,000.00) Payment of the assessed administrative penalty shall be completed during the first
four years of probation, in accord with a payment plan approved by the Board or its designee.
Respondent 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
directly to the Board at the Board's Sacramento address in a timely manner. Failure to make any
payment when due shall be considered a violation of probation.

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

1	No. PHY 47549. On behalf of Respondent Michael's Pharmacy Inc. I enter into this Stipulated				
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: ///07/3				
6	NATALYA SKYE/ Authorized Representative of				
7	MICHART'S PHARMACY, INC. d.b.a. MICHABL'S PHARMACY				
8	Respondent				
9	I have read and fully discussed with the legally suthorized representative(s) of Respondent				
10.	Michael's Pharmacy, Inc., all terms and conditions and other matters contained in the above				
11	Stipulated Settlement and Disciplinary Order, I approve its formand content.				
12	DATED: 11/17/3				
13	HERBERT WEINBERG Attorney for Respondent				
14					
15	ENDORSEMENT				
16	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully				
17	submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.				
18 19	Dated: //./5./3 Respectfully submitted,				
20	Kamala D. Harris Attorney General of Culifornia				
21	Gregory J. Salute Supervising Doputy Anakacy General				
22					
23	Susan Melton Wilson				
24	Deputy Attorney General Attorneys for Complainant				
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Exhibit A

Accusation No. 3824

1 2 3 4 5 6 7 8	Kamala D, Harris Attorney General of Callfornia 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 B-mail: Susan, Wilson@doj.ca.gov Attorneys for Complainant BEFORE THE BOARD OF PHARMACY			
7	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
10	DATE OF CHILD ONLIN			
11	In the Matter of the Accusation Against: Case No. 3824			
12				
13	MICHAEL'S PHARMACY, INC., NATALYA SKYE, A C C U S A T I O N			
14	PHARMACIST-IN-CHARGE			
	960 East Green Street Pasadena, CA 91106			
15	Pharmacy Permit No. PHY 47549			
16				
17	AND			
1	NATALYA SKYE			
18	14569 Benefit St., #102 Sherman Oaks, CA 91403			
19	Original Pharmacist License No. RPH 55396			
20	Pastandanta			
ZV	Respondents.			
21	Complainant alleges:			
22	Complainan anogos;			
ĺ	PARTIES			
2,3	 Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. 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 			
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26				
27	been Pharmacist-In-Charge of Respondent Pharmacy since November 7, 2006. The Pharmacy			
28	Ocon I nathravistrin-Charge of Respondent Finantiacy since Provention 7, 2000. 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

4. 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

- 5. 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,
- "(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:
 - "(1) Suspending judgment. .
 - "(2) Placing him or her upon probation.
 - "(3) Suspending his or her right to practice for a period not exceeding one year.
 - "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
- "(e) 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

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 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,"

7. Section 4301 of the Code states:

"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.

- "(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:
- "(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
- (1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
 - (2) The directions for the use of the drug,

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

(3) The name of the patient or patients.

- (8) The quantity of the drug of 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:
 - (l) 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.
 - (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.
- "(b) If a pharmacist 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 Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052,
- "(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice."
 - 10. Section 4081 of the Code states:

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

- "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.
- "(e) The pharmacist-in-charge or representative-in-charge shall not be oriminally 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 the dangerous 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 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.

- (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 voting rights, by contract, or by other means.
 - 12. Section 4105 of the Code states;
- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed 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.
- "(c) The records required by this section shall be retained on the licensed premises for a 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 veterinary 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."

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 sultable 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."

- 15. California Code of Regulations, title 16, section 1717, states:
- "(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

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

- (1) a patient med pak is reused only for the same patient;
- (2) no more than a one-month supply is dispensed at one time; and
- (3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.
- "(b) In addition to the requirements of Section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:
- (1) The date dispensed, and the name or initials of the dispensing pharmacist, All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
- (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
- (3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
- (4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

"(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.

"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.

- "(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
- "(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

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

- (1) Identification of pharmacist(s) transferring information;
- (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

- (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.
- "(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 fater 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,

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 locked and the lights were off. The Inspector asked the Tech to leave and wait 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
 - 2. Imitrex 100mg

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- 3: Relpax 40mg Maxalt 10mg 4.
- 5, Micardies 40mg and 80mg
- 6. Aggrenox 25/200
- 7. Simcor 500/20
- 8. Enablex 15 mg
- Exforge 5/320 and 5/160 9.
- 10. Seroquel XR 150mg
- 11, Micardis HCT 80/12.5
- 12. Aricept 10mg and 5mg
- 13. Arlcept ODT 5mg.
- The Inspector also observed large amber yials of medication some unlabeled and (2)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 - for 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.
- The Inspector further observed that the small restroom in the facility had storage shelves immediately adjacent to the toilet, and that pharmacy bottles and caps were stored on the floor next to the toilet.
- j. Further investigation disclosed that on or about December 28, 2009, Respondents illegally transferred pharmaceuticals for "disposal" as medical waste by an unlicensed entity named "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 subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with section 4059, subdivision "b" in that during an

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

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 Respondent Pharmacy:

1)	1/8/2009		<u> </u>
2)	1/16/2009		
3)	1/21/2009	 •	
4)	1/16/2009		
5)	4/6/2009		

6) 4/7/2009	
th 1/0/0000 :	
7) 4/9/2009	. <u></u> .
8) 4/28/2009	
9) 4/29/2009	
10) 11/2/2009	
11) 11/30/2009	
12) 11/3/2009	
13) 11/4/2009	
14) 11/5/2009	
15) 4/13/2009	
.16) 4/15/2009	
17) 4/20/2009	
18) 4/10/2009	
19) 11/13/2009	
20) 11/16/2009	,
21) 11/18/2009	
22) 11/10/2009	
23) 11/11/2009	
24) 11/12/2009	
25) 11/6/2009	
26) 4/2102009	.
27) 4/23/2009	
28) 1/5/2009	
29) 1/7/2009	

FOURTH CAUSE FOR DISCIPLINE .

(Providing Unapproved Employee With Pharmacy Key)

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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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
10	22) 340554
11	EIGHTH CAUSE FOR DISCIPLINE
12	(Failure to Maintain Operational Standards)
13	25. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
14	disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
15	subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1714
16	subdivision "b" (which requires that Respondents maintain the pharmacy facility, and equipment
17	so that drugs are safely and properly prepared, maintained, secured and distributed) and
18	subdivision "c" (which requires that equipment shall be maintained in a clean and orderly
19	condition) in that during a Board inspection on November 19, 2009, the inspector found
20	prescription bottles and caps stored on the floor of the small restroom next to and below the toilet
21	NINTH CAUSE FOR DISCIPLINE
22	(Unauthorized Furnishing)
23	26. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
24	disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
25	subdivision (o), in conjunction with section 4163, subdivision (a), and section 4126.5, which
26	limit the persons or organizations that a pharmacy may logally furnish or transfer drugs to, in that
27	on or about December 28, 2009, Respondents illegally 'disposed of' pharmaceuticals through
28	"Ensery West", and unlicensed entity, in violation of pharmacy law, as described more fully in

paragraph 17 above.

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27 28 DISCIPLINARY CONSIDERATIONS

27. To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

Prior Citation - Respondent Michael's Pharmacy.

a. 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 Stocking dangerous drugs lacking quality or strength a. Bus. & Prof. Code §4342 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 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. Failure to comply with Records requirements for c. CCR, title 16, §1716.2 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 For each prescription for a Schedule II or Schedule III e. Health & Safety Code §11165 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)

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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,

27.

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:

- 1. Revoking or suspending Pharmacy Permit No. PHY 47549 Issued to Respondent Michael's Pharmacy;
- 2. Revoking or suspending Original Pharmacist License Number RPH 55396, issued to Respondent Natalya Skye;

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

DATED: 8/31/12

VIRGINIA HEROLD Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California
Complainant

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