

**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

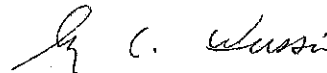
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

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

By



STAN C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 SUSAN MELTON WILSON
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7 *Attorneys for Complainant*

8 **BEFORE THE**
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10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:
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Case No. 3824

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

**[AS AGAINST RESPONDENT
NATALYA SKYE ONLY]**

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.

1 2. Respondent Natalya Skye (Respondent) is represented in this proceeding by attorney
2 Herbert Weinberg, whose address is: Law Offices of McGuire Woods 1800 Century Park West,
3 8th Floor, Los Angeles, CA 90067

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

10 JURISDICTION

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

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

17 ADVISEMENT AND WAIVERS

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

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

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

3 CULPABILITY

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

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

9 CONTINGENCY

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

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

22 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
23 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
24 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
25 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
26 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
27 writing executed by an authorized representative of each of the parties.
28

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

4 **DISCIPLINARY ORDER**

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

8 **1. Suspension**

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

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

19 Respondent shall not engage in any activity that requires the professional judgment of a
20 pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy.
21 Respondent shall not perform the duties of a pharmacy technician or a designated representative
22 for any entity licensed by the board.

23 Subject to the above restrictions, respondent may continue to own or hold an interest in any
24 licensed premises in which she holds an interest at the time this decision becomes effective unless
25 otherwise specified in this order.

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

27 **2. Obey All Laws**

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

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

- 3 • an arrest or issuance of a criminal complaint for violation of any provision of the
4 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
5 substances laws
- 6 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
7 criminal complaint, information or indictment
- 8 • a conviction of any crime
- 9 • discipline, citation, or other administrative action filed by any state or federal agency
10 which involves respondent's pharmacist license or which is related to the practice of
11 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
12 for any drug, device or controlled substance.

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

14 3. Report to the Board

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

23 4. Interview with the Board

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

1 **5. Cooperate with Board Staff**

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

5 **6. Continuing Education**

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

8 **7. Notice to Employers**

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

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

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

24 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
25 (15) days of respondent undertaking any new employment by or through a pharmacy employment
26 service, respondent shall cause her direct supervisor with the pharmacy employment service to
27 report to the board in writing acknowledging that she has read the decision in case number 3824
28

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

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

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

10 **8. Reimbursement of Board Costs**

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

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

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

21 **9. Probation Monitoring Costs**

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

26 **10. Status of License**

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

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

8 **11. License Surrender While on Probation/Suspension**

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

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

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

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

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

3 **13. Tolling of Probation**

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

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

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

18 "Cessation of practice" means any calendar month during which respondent is
19 not practicing as a pharmacist for at least forty (40) hours, as defined by Business
20 and Professions Code section 4000 et seq. "Resumption of practice" means any
21 calendar month during which respondent is practicing as a pharmacist for at least
22 forty (40) hours as a pharmacist as defined by Business and Professions Code section
23 4000 et seq.

24 **14. Violation of Probation**

25 If a respondent has not complied with any term or condition of probation, the board shall
26 have continuing jurisdiction over respondent, and probation shall automatically be extended, until
27 all terms and conditions have been satisfied or the board has taken other action as deemed
28

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

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

10 **15. Completion of Probation**

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

13 **16. Community Services Program**

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

18 Within thirty (30) days of board approval thereof, respondent shall submit documentation
19 to the board demonstrating commencement of the community service program. A record of this
20 notification must be provided to the board upon request. Respondent shall report on progress
21 with the community service program in the quarterly reports. Failure to timely submit,
22 commence, or comply with the program shall be considered a violation of probation.

23 **17. Remedial Education**

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

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

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

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

11 **18. No New Ownership of Licensed Premises**

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

20 **19. Consultant for Owner or Pharmacist-In-Charge**

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

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

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

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

9 **20. Self Assessment Report Must Be Made Quarterly**

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

15 **21. Tolling of Suspension**

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

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

28 **22. Administrative Penalty**

1 Respondent shall be jointly and severally liable with co-respondent to Accusation 3824,
 2 Michael's Pharmacy Inc., to pay an Administrative Penalty in the sum of Twenty Five Thousand
 3 Dollars (\$25,000.00) Payment of the assessed administrative penalty shall be completed during
 4 the first four years of probation, in accord with a payment plan approved by the Board or its
 5 designee. Respondent may pay the full remaining unpaid balance of the assessed administrative
 6 penalty at any time. It shall be Respondent's responsibility to mail or otherwise deliver each
 7 payment directly to the Board at the Board's Sacramento address in a timely manner. Failure to
 8 make any payment when due shall be considered a violation of probation.

9 **23. Ethics Course**

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

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

16 ACCEPTANCE

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

22 DATED: 11/15/13
 23 NATALYA SKYE
 Respondent

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

27 DATED: 11/15/13
 28 HERBERT WEINBERG
 Attorney for Respondent

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 Complainant

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51288597.doc

Exhibit A

Accusation No. 3824

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 SUSAN MELTON WILSON
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7 *Attorneys for Complainant*

8 **BEFORE THE**
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10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

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18 **Pharmacy Permit No. PHY 47549**
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20 **AND**
21 **NATALYA SKYE**
22 **14569 Benefit St., #102**
23 **Sherman Oaks, CA 91403**
24 **Original Pharmacist License No. RPH 55396**
25
26 Respondents.

Case No. 3824

ACCUSATION

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
2. On or about November 7, 2006, the Board of Pharmacy (Board) issued Pharmacy Permit No. PHY 47549 to Michael's Pharmacy (Respondent Pharmacy). Natalya Skye is and has been Pharmacist-In-Charge of Respondent Pharmacy since November 7, 2006. The Pharmacy

1 Permit was in full force and effect at all times relevant to the charges brought herein and will
2 expire on November 1, 2012, unless renewed.

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

7 **JURISDICTION**

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

11 **STATUTORY PROVISIONS**

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

16 6. Section 4300 of the Code states:

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

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

21 "(1) Suspending judgment.

22 "(2) Placing him or her upon probation.

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

24 "(4) Revoking his or her license.

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

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

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

4 "(1) Medical or psychiatric evaluation.

5 "(2) Continuing medical or psychiatric treatment.

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

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

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

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

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

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

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

20 7. Section 4301 of the Code states:

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

24 ...

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

28 ...

1 (3) The name of the patient or patients.

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

10 (5) The date of issue.

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

13 (7) The strength of the drug or drugs dispensed.

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

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

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

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

21 (i) Prescriptions dispensed by a veterinarian.

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

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

27 (B) This paragraph applies to outpatient pharmacies only.

28 / / /

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

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

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

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

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

27 10. Section 4081 of the Code states:

28 / / /

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

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

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

17 11. Section 4126.5 of the Code states:

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

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

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

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

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

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

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

3 (7) To another pharmacy under common control.

4 ...

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

8 12. Section 4105 of the Code states:

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

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

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

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

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

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

28 / / /

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

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

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

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

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

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

23 (f) The board shall require an applicant for a licensed premise or for renewal of that
24 license to certify that it meets the requirements of this section at the time of licensure or renewal.

25 (g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain
26 a toilet and wash basin supplied with running water.

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1 14. California Code of Regulations, title 16, section 1718 states:
2 "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code
3 shall be considered to include complete accountability for all dangerous drugs handled by every
4 licensee enumerated in Sections 4081 and 4332. "The controlled substances inventories required
5 by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years
6 after the date of the inventory."

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

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

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

- 13 (1) a patient med pak is reused only for the same patient;
14 (2) no more than a one-month supply is dispensed at one time; and
15 (3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 16. Section 125.3 provides that the Board may request the administrative law judge to
12 direct a licentiate found to have committed a violation or violations of the licensing act to pay a
13 sum not to exceed the reasonable costs of the investigation and enforcement of the case.

14 **FACTS COMMON TO ALL CAUSES FOR DISCIPLINE**

15 17. The following allegations are common to all causes for discipline in this matter:

16 a. At all times relevant herein, Respondent Natalya Skye was an owner and the
17 pharmacist-in-charge of Michael's Pharmacy, Inc., located in Pasadena, CA.

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

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

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

24 d. In later review of prescription records obtained during the July 7 inspection, the
25 Inspector observed that 22 prescriptions purportedly “original telephone prescriptions” were
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1 documented on a telephonic prescription document with a computer print out. The pharmacist did
2 not reduce the telephonic prescription to writing.

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

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

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

14 g. When asked about routine procedures for drug deliveries at Respondent
15 pharmacy, all three pharmacy technicians claimed only the pharmacist on duty signed for drug
16 deliveries. However after later review of records obtained from vendors making deliveries to
17 Respondent pharmacy, the Inspector found non-pharmacists had signed for deliveries on at least
18 twenty nine (29) occasions.
19

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

22 (1) The Inspector noticed a paper shopping bag filled with drugs - which Respondent
23 Skye identified as expired “sample” medications which had been given to Respondent
24 pharmacy by a physician for disposal. The Inspector documented numerous dangerous
25 drugs in the bag which were not expired, including:
26

- 27 1. Tektuna HCT 300/25
- 28 2. Imitrex 100mg

3. Relpax 40mg
4. Maxalt 10mg
5. Micardies 40mg and 80mg
6. Aggrenox 25/200
7. Simcor 500/20
8. Enablex 15 mg
9. Exforge 5/320 and 5/160
10. Seroquel XR 150mg
11. Micardis HCT 80/12.5
12. Aricept 10mg and 5mg
13. 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.

i. 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

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

6 SECOND CAUSE FOR DISCIPLINE

7 **(Failure to Maintain Complete Acquisition/Disposition Records)**

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

16 THIRD CAUSE FOR DISCIPLINE

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

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

23 Respondent Pharmacy:

24	1) 1/8/2009
25	2) 1/16/2009
26	3) 1/21/2009
27	4) 1/16/2009
28	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) 4/21/2009
27) 4/23/2009
28) 1/5/2009
29) 1/7/2009

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FOURTH CAUSE FOR DISCIPLINE

(Providing Unapproved Employee With Pharmacy Key)

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

FIFTH CAUSE FOR DISCIPLINE

(No Self Assessment Form During Inspection)

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

SIXTH CAUSE FOR DISCIPLINE

(Incorrectly Labeled Prescription Bottles)

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

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1 dispensed incorrectly labeled medication as follows:

- 2 a. **Prescription 343671**
- 3 No description of medication
- 4 b. **Prescription 341530**
- 5 No description of medication
- 6 c. **Prescription 342438**
- 7 No description of medication

8 SEVENTH CAUSE FOR DISCIPLINE

9 **(Telephone Order Not Reduced to Writing)**

10 24. Respondents MICHAEL'S PHARMACY and NATALYA SKYE are subject to
11 disciplinary action under section 4300 for unprofessional conduct as defined in section 4301,
12 subdivision (o), in conjunction with section Title 16, California Code of Regulations section 1717
13 subdivision "c" which requires that an orally transmitted prescription must be promptly reduced
14 to writing and initialed, in that during a Board inspection on July 7, 2009, the inspector found
15 that prescriptions which had originated as oral prescriptions, had been filled – but had not been
16 reduced to writing in at least 22 instances, as follows:

- 17 1) 340550
- 18 2) 337639
- 19 3) 337633
- 20 4) 340553
- 21 5) 340551
- 22 6) 337638
- 23 7) 337636
- 24 8) 337634
- 25 9) 337640
- 26 10) 337628
- 27 11) 337637
- 28 12) 337636

- 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 legally furnish or transfer drugs to, in that
27 on or about December 28, 2009, Respondents illegally 'disposed of' pharmaceuticals through
28 "EnservWest", and unlicensed entity, in violation of pharmacy law, as described more fully in

1 paragraph 17 above.

2 **DISCIPLINARY CONSIDERATIONS**

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

5 **Prior Citation – Respondent Michael’s Pharmacy**

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

Code/Regulations Violated	Description
11 a. Bus. & Prof. Code §4342	12 <u>Stocking dangerous drugs lacking quality or strength</u> 13 Medication containers were found containing 14 compounded drugs lacking expiration dates 15 (Progesterone 100mg #15 and 50mg #76 Supp.) or drugs 16 that had been expired (Estradiaol 250 Vag. Supp #16 17 expired 3/21/07, Progesterone 400mg #9 Supp expired 18 7/7/05 and 25mg #46 Supp expired 8/4/05, Boric acid 19 Vag. Supp #16 expired in 10/21/06)
20 b. CCR, title 16, §1716	21 Variation from Prescription 22 On 12/06/2006, Respondent furnished prescription 23 301673 for Hydrocodone/APAP 10/500mg #120 to LC 24 when the instructions on the face of the prescription 25 stated “Do not dispense before 12/12/06”. Specifically, 26 on 4/2/08, Michael’s Pharmacy furnished Rx 324777 27 Oxycontin 80mg #90, Rx 324778 Oxycontin 40mg #50 28 to LC when the prescription was dated 4/3/08.
22 c. CCR, title 16, §1716.2	23 Failure to comply with Records requirements for 24 compounded medications
23 d. Bus. & Prof. Code §4104	24 Procedures to take action when licensed individual is 25 impaired or known to have diverted or used drugs, 26 written policies; Report; Immunity
24 e. Health & Safety Code §11165 25 sub (d)(1-10)	26 For each prescription for a Schedule II or Schedule III 27 controlled substance, the dispensing pharmacy shall 28 report to the Department of Justice . . . Data required . . .
26 f. CCR, title 16, §1745/ Title 21 27 CFR §1306.13 subd. (a)	28 Partial filling of Schedule II prescriptions/Partial filling of prescriptions.

1 **Prior Citation – Respondent Skye**

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

7

Code/Regulations Violated	Description
9 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.
12 b. CCR, title 16, §1716	Variation from Prescription
13 c. CCR, title 16, §1716.2	Record requirements—compounding for future furnishing
14 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
17 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.
19 f. CCR, title 16, §1745/Title 21 CFR 20 §1306013 subd. (a)	Partial filling of Schedule II prescriptions/Partial filling of prescriptions.

21
22 **PRAYER**

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

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

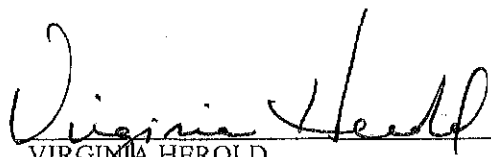
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3. Ordering Respondent Michael's Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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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