

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

In the Matter of the Accusation
Against:

Case No. 4574

PRITI CHATWANI
3024 Pacific Avenue
Livermore, CA 94550

Pharmacist License No. RPH 53463

Respondent.

REVISED DECISION AND ORDER

Having identified technical errors in the Stipulated Settlement and Disciplinary Order, with the parties' mutual agreement, the Board of Pharmacy hereby revises its prior order, continuing to adopt such stipulation, but with the following technical corrections:

- In the Stipulated Disciplinary Order, the references in terms 9, 10, and 12 to a "designated representative" are revised to refer to a "pharmacist".

This decision shall become effective on August 31, 2015.

It is so ORDERED on July 31, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm. D.
Board President

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

In the Matter of the Accusation Against:

Case No. 4574

PRITI CHATWANI
3024 Pacific Avenue
Livermore, CA 94550

ORDER GRANTING STAY OF
EFFECTIVE DATE OF DECISION

Pharmacist License No. RPH 53463

Respondent.

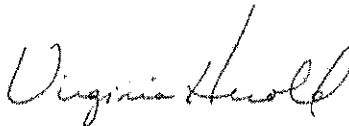
ORDER GRANTING STAY OF EFFECTIVE DATE

Complainant and respondent timely requested reconsideration of the decision in the above-entitled matter pursuant to section 11521 of the Government Code. Good cause appearing, in order to allow the board additional time to consider the petition, in accordance with the provisions of section 11521 of the Government Code,

IT IS HEREBY ORDERED that the effective date of the Decision and Order, in the above-entitled matter is further stayed until 5 p.m. on August 3, 2015.

IT IS SO ORDERED this 21st day of July, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

VIRGINIA HEROLD
Executive Officer

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

In the Matter of the Accusation Against:

Case No. 4574

**PRITI CHATWANI
3024 Pacific Avenue
Livermore, CA 94550**

Pharmacist License No. RPH 53463

Respondent.

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 July 22, 2015.

It is so ORDERED on July 15, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

AMARYLIS GUTIERREZ
Board President

1 KAMALA D. HARRIS
 Attorney General of California
 2 JOSHUA A. ROOM
 Supervising Deputy Attorney General
 3 MARETTA WARD
 Deputy Attorney General
 4 State Bar No. 176470
 455 Golden Gate Avenue, Suite 11000
 5 San Francisco, CA 94102-7004
 Telephone: (415) 703-1384
 6 Facsimile: (415) 703-5480
Attorneys for Complainant

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 8 **BEFORE THE**
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
 9 **STATE OF CALIFORNIA**

10 In the Matter of the Accusation Against:

Case No. 4574

11 **PRITI CHATWANI**
 12 **3024 Pacific Avenue**
 13 **Livermore, CA 94550**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

14 **Pharmacist License No. RPH 53463**

15 Respondent.

16
 17 **IT IS HEREBY STIPULATED AND AGREED** by and between the parties to the above-
 18 entitled proceedings that the following matters are true:

19 **PARTIES**

20 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
 21 She brought this action solely in her official capacity and is represented in this matter by Kamala
 22 D. Harris, Attorney General of the State of California, by Maretta Ward, Deputy Attorney
 23 General.

24 2. Respondent Priti Chatwani ("Respondent") is represented in this proceeding by
 25 attorney Tony Park, whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

26 3. On or about May 7, 2002, the Board of Pharmacy issued Pharmacist License No.
 27 RPH 53463 to Priti Chatwani (Respondent). The Pharmacist License was in full force and effect
 28

1 at all times relevant to the charges brought in Accusation No. 4574 and will expire on April 30,
2 2017, unless renewed.

3 4. Records of the California State Board of Pharmacy show that Priti Chatwani, RPH
4 53463 is and has been President and Pharmacist-in-Charge of Respondent Medicine Shoppe since
5 June 11, 2007.

6 **JURISDICTION**

7 5. Accusation No. 4574 was filed before the Board of Pharmacy (Board), Department
8 of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
9 statutorily required documents were properly served on Respondent on October 14, 2014.
10 Respondent timely filed its Notice of Defense contesting the Accusation.

11 6. A copy of Accusation No. 4574 is attached as exhibit A and incorporated herein by
12 reference.

13 **ADVISEMENT AND WAIVERS**

14 7. Respondent has carefully read, fully discussed with counsel, and understands the
15 charges and allegations in Accusation No. 4574. Respondent has also carefully read, fully
16 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
17 Order.

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

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

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28 //

1 CULPABILITY

2 10. Respondent admits the truth of each and every charge and allegation in Accusation
3 No. 4574.

4 11. Respondent agrees that her Pharmacy License is subject to discipline and they agree
5 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

6 CONTINGENCY

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

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

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

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

28 / /

1 **DISCIPLINARY ORDER**

2 **IT IS HEREBY ORDERED** that Pharmacist License No. RPH 53463 to Respondent Priti
3 Chatwani (Respondent) is revoked. However, the revocation is stayed and Respondent is placed
4 on probation for four (4) years on the following terms and conditions.

5 **1. Obey All Laws**

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

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

- 9 an arrest or issuance of a criminal complaint for violation of any provision of the
10 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
11 substances laws
12 an arrest or issuance of a criminal complaint for violation of any state or federal law
13 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
14 criminal complaint, information or indictment
15 a conviction of any crime
16 discipline, citation, or other administrative action filed by any state or federal agency
17 which involves Respondent's Pharmacist License or which is related to the practice of
18 pharmacy or the manufacturing, obtaining, handling or distribution or billing or
19 charging for of any drug, device or controlled substance.

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

21 **2. Report to the Board**

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

1 such time as the final report is made and accepted by the Board.

2 **3. Interview with the Board**

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

8 **4. Cooperate with Board Staff**

9 Respondent shall cooperate with the Board's inspection program and with the Board's
10 monitoring and investigation of Respondent's compliance with the terms and conditions of their
11 probation. Failure to cooperate shall be considered a violation of probation.

12 **5. Notice to Employers**

13 During the period of probation, Respondent shall notify all present and prospective
14 employers of the decision in case number 4574 and the terms, conditions and restrictions imposed
15 on Respondent by the decision, as follows:

16 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
17 Respondent undertaking any new employment, Respondent shall cause their direct supervisor,
18 designated representative-in-charge (including each new designated representative-in-charge
19 employed during Respondent's tenure of employment) and owner to report to the Board in
20 writing acknowledging that the listed individual(s) has/have read the decision in case number
21 4574 and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure
22 that their employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the Board.

23 If Respondent works for or is employed by or through a pharmacy employment service,
24 Respondent must notify their direct supervisor, designated representative-in-charge and owner at
25 each entity licensed by the Board of the terms and conditions of the decision in case number 4574
26 in advance of the Respondent commencing work at each licensed entity. A record of this
27 notification must be provided to the Board upon request.

28 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen

1 (15) days of Respondent undertaking any new employment by or through a pharmacy
2 employment service, Respondent shall cause their direct supervisor with the pharmacy
3 employment service to report to the Board in writing acknowledging that they has read the
4 decision in case number 4574 and the terms and conditions imposed thereby. It shall be the
5 Respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely
6 acknowledgment(s) to the Board.

7 Failure to timely notify present or prospective employer(s) or to cause that/those
8 employer(s) to submit timely acknowledgements to the Board shall be considered a violation of
9 probation.

10 "Employment" within the meaning of this provision shall include any full-time,
11 part-time, temporary or relief service or pharmacy management service as a
12 designated representative or in any position for which a designated representative
13 license is a requirement or criterion for employment, whether the Respondent is
14 considered an employee or independent contractor or volunteer.

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

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

21 **7. Reimbursement of Board Costs**

22 As a condition precedent to successful completion of probation, Respondent shall pay to the
23 Board its costs of investigation and prosecution in the amount of \$17,267.00. Respondent shall
24 make said payments as follows: Payment can be made on a payment plan approved by the Board
25 or its designee. There shall be no deviation from this schedule absent prior written approval by
26 the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a
27 violation of probation.

28 The filing of bankruptcy by Respondent shall not relieve Respondent of their responsibility

1 to reimburse the Board its costs of investigation and prosecution.

2 Respondent shall be jointly and severally liable for payment of costs of investigation and
3 prosecution with Respondent The Medicine Shoppe.

4 **8. Probation Monitoring Costs**

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

9 **9. Status of License**

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

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

18 **10. License Surrender While on Probation/Suspension**

19 Following the effective date of this decision, should Respondent cease work due to
20 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
21 Respondent may tender their designated representative license to the Board for surrender. The
22 Board or its designee shall have the discretion whether to grant the request for surrender or take
23 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of
24 the license, Respondent will no longer be subject to the terms and conditions of probation. This
25 surrender constitutes a record of discipline and shall become a part of the Respondent's license
26 history with the Board.

27 Upon acceptance of the surrender, Respondent shall relinquish their designated
28 representative license to the Board within ten (10) days of notification by the Board that the

1 surrender is accepted. Respondent may not reapply for any license, permit, or registration from
2 the Board for three (3) years from the effective date of the surrender. Respondent shall meet all
3 requirements applicable to the license sought as of the date the application for that license is
4 submitted to the Board.

5 **11. Notification Change Name, Residence Address, Mailing Address or Employment**

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

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

13 **12. Tolling of Probation**

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

20 Should Respondent, regardless of residency, for any reason (including vacation) cease
21 working as a designated representative for a minimum of 40 hours in California, Respondent must
22 notify the Board in writing within ten (10) days of cessation of work and must further notify the
23 Board in writing within ten (10) days of the resumption of work. Any failure to provide such
24 notification(s) shall be considered a violation of probation.

25 It is a violation of probation for Respondent's probation to remain tolled pursuant to the
26 provisions of this condition for a total period, counting consecutive and non-consecutive months,
27 exceeding thirty-six (36) months.
28

1 "Cessation of work" means any calendar month during which Respondent is not
2 working as a designated representative for at least 40 hours as a designated
3 representative as defined by Business and Professions Code section 4053.

4 "Resumption of work" means any calendar month during which Respondent is
5 working as a designated representative for at least 40 hours as a designated
6 representative as defined by Business and Professions Code section 4053.

7 **13. Violation of Probation**

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

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

20 **14. Completion of Probation**

21 Upon written notice by the Board indicating successful completion of probation,
22 Respondent's designated representative license will be fully restored.

23 **15. No New Ownership of Licensed Premises**

24 Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
25 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
26 business, firm, partnership, or corporation licensed by the Board. If Respondent currently owns
27 or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer,
28 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently

1 or hereinafter licensed by the Board, Respondent may continue to serve in such capacity or hold
2 that interest, but only to the extent of that position or interest as of the effective date of this
3 decision. Violation of this restriction shall be considered a violation of probation.

4 16. Community Services Program

5 Within sixty (60) days of the effective date of this decision, Respondent shall submit to the
6 Board or its designee, for prior approval, a community service program in which Respondent
7 shall provide free health-care related services on a regular basis to a community or charitable
8 facility or agency for at least 56 hours per year for the first four (4) years of probation. Within
9 thirty (30) days of Board approval thereof, Respondent shall submit documentation to the Board
10 demonstrating commencement of the community service program. A record of this notification
11 must be provided to the Board upon request. Respondent shall report on progress with the
12 community service program in the quarterly reports. Failure to timely submit, commence, or
13 comply with the program shall be considered a violation of probation.

14 17. Remedial Education

15 Within sixty (60) days of the effective date of this decision, Respondent shall submit to the
16 Board or its designee, for prior approval, an appropriate program of remedial education related to
17 general compounding and pharmacy law. The program of remedial education shall consist of a
18 total of forty (40) hours. With minimum of ten (10) hours per year, which shall be completed
19 within four (4) years of probation at Respondent's own expense. All remedial education shall be
20 in addition to, and shall not be credited toward, continuing education (CE) courses used for
21 license renewal purposes.

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

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

1 this failure shall be considered a violation of probation. Any such examination failure shall
2 require Respondent to take another course approved by the Board in the same subject area.

3 **18. Consultant for Owner or Pharmacist-in-Charge**

4 During the period of probation, Respondent shall not supervise any intern pharmacist, or
5 serve as a consultant to any entity licensed by the Board. In the event that Respondent is
6 currently the Pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent
7 consultant at its own expense who shall be responsible for reviewing pharmacy operations on a
8 monthly basis for compliance by Respondent with the state and federal laws and regulations
9 governing the practice of pharmacy and for compliance by Respondent with the obligations of
10 pharmacist-in-charge. The basis for review may be reduced to quarterly by the Board or its
11 designee. The consultant shall be a pharmacist licensed by and not on probation with the Board
12 and whose name shall be submitted to the Board or its designee, for prior approval. Within thirty
13 (30) days of the effective date of this decision, Respondent shall not be a pharmacist-in-charge at
14 more than one pharmacy or any pharmacy of which she is not the current PIC. The Board may, in
15 case of an employment change by Respondent or for other reasons deemed appropriate by the
16 Board or its designee, preclude the Respondent from acting as a pharmacist-in-charge. Failure to
17 timely retain, seek approval of, or ensure timely reporting by the consulting shall be considered a
18 violation of probation.

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ACCEPTANCE

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

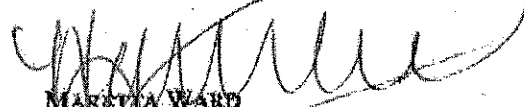
DATED: 5/28/15 
PRITI CHATWANI
Respondent

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

DATED: 05/28/2015 
TONY PARK
Attorney for Respondent

ENDORSEMENT

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

Dated: Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

KAMELA D. HARRIS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4574

1 KAMALA D. HARRIS
Attorney General of California
2 JOSHUA A. ROOM
Supervising Deputy Attorney General
3 MARETTA WARD
Deputy Attorney General
4 State Bar No. 176470
455 Golden Gate Avenue, Suite 11000
5 San Francisco, CA 94102-7004
Telephone: (415) 703-1384
6 Facsimile: (415) 703-5480
Attorneys for Complainant

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8 **BEFORE THE**
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
9 **STATE OF CALIFORNIA**

10 In the Matter of the Citation Against:

Case No. 4574

11 **THE MEDICINE SHOPPE**
12 **3024 Pacific Avenue**
13 **Livermore, CA 94550**

ACCUSATION

14 **Pharmacy License No. PHY 48618**

15 **PRITI CHATWANI**
16 **3024 Pacific Avenue**
17 **Livermore, CA 94550**

18 **Pharmacist License No. RPH 53463**

Respondent.

19
20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about June 11, 2007, the Board of Pharmacy issued Pharmacy License Number
25 PHY 48618 to Puchkar International LLC; Pushkar International Inc., to do business as "The
26 Medicine Shoppe" (Respondent Medicine Shoppe).¹ The Pharmacy License was in full force and

27 _____
28 ¹ The business entity was changed from an LLC to a corporation on September 26, 2009.

1 effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless
2 renewed.

3 3. On or about May 7, 2002, the Board of Pharmacy issued Pharmacist License Number
4 RPH 53463 to Priti Chatwani (Respondent Chatwani). The Pharmacist License was in full force
5 and effect at all times relevant to the charges brought herein and will expire on April 30, 2015,
6 unless renewed.

7 4. Records of the California State Board of Pharmacy show that Priti Chatwani, RPH
8 53463 is and has been President and Pharmacist-in-Charge of Respondent Medicine Shoppe since
9 June 11, 2007.

10 JURISDICTION

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

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

16 7. Section 4300.1 of the Code states:

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

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

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3 **STATUTORY AND REGULATORY PROVISIONS**

4 9. Section 4301 of the Code provides: "The board shall take again any holder of a
5 license who is guilty of unprofessional conduct or whose license has been procured by fraud or
6 misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited
7 to any of the following:

8 . . .
9 (c) Gross Negligence

10 . . .
11 (g) Knowingly making or signing any certificate or other document that falsely
12 represents the existence or nonexistence of a state of facts.

13 . . .
14 (j) The violation of any of the statutes of this state, of any other state, or of the
15 United States regulating controlled substances and dangerous drugs.

16 . . .
17 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
18 abetting the violation of or conspiring to violate any provision or term of this chapter of the
19 applicable federal and state laws and regulations governing pharmacy, including regulations
20 established by the board or by any other state of federal regulatory agency."

21 10. Section 4076, subdivision (a) of the Code states:

22 "A pharmacist shall not dispense any prescriptions except in a container that meets the
23 requirements of the state and federal law and is correctly labeled with all of the following..."

24 . . .
25 "(7) The strength of the drug or the drug dispensed"

26 . . .
27 "(9) The expiration date of the effectiveness of the drug dispensed."

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3 11. Section 4077, subdivision (a) of the Code states:

4 "Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous
5 drug upon prescription except in a container correctly labeled with the information required by
6 section 4076."

7 12. Section 4113, subdivision (c) of the Code states:

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

10 13. California Code of Regulations, title 16, section 1711, provides:

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

14

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

- 20 1. the date, location, and participants in the quality assurance review;
- 21 2. the pertinent data and other information relating to the medication error(s)
22 reviewed and documentation of any patient contact required by subdivision (c).
- 23 3. the findings and determinations generated by the quality assurance review; and,
24 4. recommend changes to pharmacy policy, procedure, systems, or processes, if
25 any.

26 The pharmacy shall inform pharmacy personnel of changes to pharmacy policy,
27 procedure, systems, or processes made as a result of recommendations generated in the quality
28 assurance program."

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3 14. California Code of Regulations, title 16, section 1715 provides:

4 The pharmacist-in-charge of each pharmacy shall complete a self-assessment of the pharmacy's
5 compliance with federal and state pharmacy law before July 1 of every off-numbered year.

6 15. California Code of Regulations, title 16, section 1716, provides:

7 Pharmacists shall not deviate from the requirements of a prescriptions except upon the prior
8 consent of the prescriber.

9 16. California Code of Regulations, title 16, section 1735.2, provides:

10 "(j) prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-
11 charge shall complete a self-assessment for compounding pharmacies developed by the board."

12 . . .

13 "(f) The pharmacist performing or supervising compounding is responsible for the integrity,
14 potency, quality, and labeled strength of a compounded drug product until it is dispensed.

15 17. California Code of Regulations, title 16, section 1735.3, subdivisions (a)(3)(4)(6) and
16 (8) provide: that for each compounded drug product, the pharmacy records shall include the
17 identity of the pharmacy personnel who compounded the product, the identity of the pharmacist
18 reviewing the final drug product, the manufacturer, expiration date and lot number of each
19 component, and the expiration date of the final compounded drug product.

20 18. California Code of Regulations, title 16, section 1735.4, subdivision (a) provides: As
21 related to Business and Professions Code section 4076 subdivision (a)(9), the label of a
22 compounded drug product shall contain the expiration date of the effectiveness of the drug
23 dispensed.

24 19. California Code of Regulations, title 16, section 1735.7, subdivision (a) provides:
25 Any pharmacy engaged in compounding shall maintain written documentation sufficient to
26 demonstrate that pharmacy personnel have the skills and training required to properly and
27 accurately perform their assigned responsibilities relating to compounding.

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20. California Code of Regulations, title 16, section 1735.8, provides:

“(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

“(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounded record and master formula.”

21. California Code of Regulations, title 16, section 1761, provides:

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.

FACTUAL BACKGROUND

22. On or about September 6, 2011, Patient “A” presented with a prescription for liothyronine, thyroid medication, “T-3”, at 3024 Pacific Avenue in Livermore, California, the Respondent pharmacy establishment known as The Medicine Shoppe.^{2 3}

23. Respondent Chatwani compounded and filled the prescription, which was designated as RX 6101993, on or about September 6, 2011. The prescription either read “150 mcg” (150 micrograms), or “150 mg” (150 milligrams). The compounded product was dispensed in a

² Liothyronine or Liothyronine sodium is a synthetic version of one of the two hormones made by the thyroid gland. It is used for treating persons who are hypothyroid (do not produce enough thyroid hormones).

³ Meg refers to “micrograms.” Mg refers to “milligrams.” Micrograms are 1000 times smaller than milligrams.

1 container that read "150 mcg," but Respondent Chatwani later reported that it was her intention to
2 compound ~~the~~ the product in a 150 mg strength.

3 24. Thereafter, Patient "A" began taking the medication as prepared by Respondents and
4 suffered injury as a result by having to be admitted to a hospital for 7 days.

5 25. Subsequent chemical lab analysis of the T-3 prescription prepared by Respondents
6 demonstrated the compounded capsules were neither 150 micrograms nor 150 milligrams.
7 The T-3 capsules contained on average 9406 mcg of liothyronine – a compound strength that was
8 dangerous to Patient "A" and resulted in her hospitalization.

9 26. On or about May 15, 2012, a Board Inspector conducted an inspection and
10 investigation of Respondent Medicine Shoppe. The inspector met with Respondent Chatwani and
11 noted that RX 6101993 was labeled as T-3 150 mcg but not compounded as such.

12 27. The Board Inspector requested the completed Community Pharmacy Self-
13 Assessment form and Compounding Pharmacy Self-Assessment form. The most recent
14 Community Pharmacy Self-Assessment available was completed on or about July 10, 2009.
15 There was no Compounding Pharmacy Self-Assessment completed. The version of the
16 Community Pharmacy Self-Assessment Respondent Chatwani used on or about July 10, 2009
17 contained sterile compounding questions only and did not apply to Respondent Medicine
18 Shoppe's non-sterile compounding.

19 28. Written training documentation for Respondent Pharmacist-in-Charge Chatwani was
20 not available during inspection.

21 29. The Board Inspector reviewed the pharmacy compounding log books. Respondent
22 Chatwani presented the page and the compound record book containing prescriptions
23 compounded for Patient "A". The Board Inspector noted the compounded records for RX
24 6101991, 6101992 and 6101993 were missing the following required items: (1) the identity of the
25 pharmacy personnel who compounded the drug product; (2) the identity of the pharmacist who
26 reviewed the final drug product; (3) the expiration date of the final compounded drug product;
27 and (4) the lot number for each compound component.

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1 30. The Board Inspector asked Respondent Chatwani if she had completed any
2 compound product testing in the past year. She replied she had not. Respondent Chatwani
3 estimated her
4 pharmacy compounds to be approximately 50 medications each month. Respondent Chatwani
5 further indicated she was the only pharmacist checking compounding medications.

6 31. The Board Inspector asked Respondent Chatwani for the pharmacy's Compounding
7 Policy and Procedures. Respondent Chatwani could not locate the Compounding Policy and
8 Procedures.

9 32. The Board Inspector asked Respondent Chatwani about the incident involving Patient
10 "A" on September 6, 2011. Respondent Chatwani indicated the dose for liothyronine was 150
11 milligrams and stated that she compounded the prescription for 150 milligrams. However, the
12 label for Patient A on RX 6101993 showed "T-3 150 mcg."

13 33. The Board Inspector reviewed the Quality Assurance Report for RX 6101993 for the
14 incident related to Patient "A". The document was missing the date of the review, recorded the
15 complaint as "Mislabel (T-3 150 mcg)" and contained only the comment "Patient states-wrong
16 strength." No other details were provided. There were no findings, determinations, or
17 recommended changes to policies, procedures, systems, or processes.

18
19 **FIRST CAUSE FOR DISCIPLINE**

20 **(Unprofessional Conduct – No Self-Assessment By Pharmacist-In-Charge)**

21 34. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or
22 4113(c), and/or California Code of Regulations, title 16, section 1715 in that Respondents failed
23 to complete a self-assessment as pharmacist-in charge to ensure pharmacy compliance with state
24 and federal law.

25
26 **SECOND CAUSE FOR DISCIPLINE**

27 **(Unprofessional Conduct – No Compounding Self-Assessment)**

1 35. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or
2 4113(c), and/or California Code of Regulations, title 16, section 1735.2(j) in that Respondents
3 failed to complete a self-assessment for compounding pharmacies prior to allowing any drug to
4 be compounded in the pharmacy.

5 **THIRD CAUSE FOR DISCIPLINE**

6 **(Unprofessional Conduct – Variation from Prescription)**

7 36. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
8 and/or 4113(c), and/or California Code of Regulations, title 16, section 1716, in that Respondents
9 deviated from the requirements of a prescription without the consent of the prescriber.

10 **FOURTH CAUSE FOR DISCIPLINE**

11 **(Unprofessional Conduct – Uncertain Prescription)**

12 37. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
13 and/or 4113(c), and/or California Code of Regulations, title 16, section 1761, in that Respondents
14 compounded or dispensed a prescription which contained a significant error, omission,
15 irregularity, uncertainty, ambiguity or alteration. Specifically, Respondents compounded and
16 dispensed RX 6101993 to Patient "A" without accurately confirming the dose with the prescriber
17 when the prescription appeared to be written with an uncertain dose.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 **(Unprofessional Conduct – Quality Assurance Review Lack of Detail)**

20 38. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
21 and/or 4113(c), and/or California Code of Regulations, title 16, section 1711(e), in that
22 Respondents' Quality Assurance review record for RX 6101993 dispensed to Patient "A" on
23 September 6, 2011, lacked a date, participants, pertinent data reviewed relating to the reported
24 medication error, findings, determinations, and recommendations on changes to or maintaining
25 pharmacy policies, procedures, systems or processes.

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SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Dispensing Dangerous Drug Incorrectly)

39. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or 4076(a)(7)/4077 in that Respondents labeled and dispensed RX 6101993 to Patient "A" as T-3 150 mcg when in fact the product was not compounded as such and therefore did not meet state and federal labeling requirements.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Drugs Lacking Quality or Strength)

40. Respondents are subject to disciplinary action under section 4301 and/or 4113(c) in that Respondents labeled RX 6101993 for Patient "A" as T-3 150 mcg when the compounded medication contained an average of T-3 9,406 mcg per capsule.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure to Exercise Professional Judgment)

41. Respondents are subject to disciplinary action under section 4301 and/or 4306.5, and/or 4113(c), in that according to the compound record and a statement from Respondents, Respondents failed to appropriately exercise professional judgment in preparing a compounded medication that matched neither the prescription authorized by the prescriber nor the label placed on the container.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Gross Negligence)

42. Respondents are subject to disciplinary action under sections 4301(c), and/or 4113(c), in that according to the compound record and a statement from Respondents,

1 Respondents failed to appropriately exercise professional judgment in preparing a compounded
2 medication that matched neither the prescription authorized by the prescriber nor the label placed
3 on the container.

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5 **TENTH CAUSE FOR DISCIPLINE**

6 **(Unprofessional Conduct – No Expiration Dates on Compounded Drugs Labels)**

7 43. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
8 4076(a)(9)/4077, and/or 4113(c), and/or California Code of Regulations, title 16, section
9 1735.4(a) in that Respondents labeled and dispensed RX 6101991, RX 6101992, and RX
10 6101993 to Patient "A" with no product expiration date on the label as required.

11
12 **ELEVENTH CAUSE FOR DISCIPLINE**

13 **(Unprofessional Conduct – Compound Record Missing Required Items)**

14 44. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
15 and/or 4113(c) and/or California Code of Regulations, title 16, section 1735.3(a)(3)(4)(6)(8) and
16 (9), in that Respondents labeled and dispensed RX 6101991, RX 6101992, and RX 6101993 to
17 Patient "A" when the compound record for each was missing: the identity of the pharmacy
18 personnel who compounded the product; the identity of the pharmacist reviewing the final drug
19 product; the lot number of each component.

20
21 **TWELFTH CAUSE FOR DISCIPLINE**

22 **(Unprofessional Conduct – No Documentation of Training for Compounding Staff)**

23 45. Respondents are subject to disciplinary action under section 4301(j) and/or (o),
24 and/or 4113(c), and/or California Code of Regulations, title 16, section 1735.7(a), in that on May
25 15, 2012, Respondent Chatwani stated during an inspection, and the Board inspector determined,
26 that there was no compounding training documentation on record for Respondent Chatwani as the
27 compounding pharmacist.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - No Compounding Quality Assurance)

46. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and California Code of Regulations, title 16, section 1735.8(c), in that Respondents, during an inspection by the Board on May 15, 2012, had no qualitative or quantitative Compounding Quality Assurance records available from the past year, for a reported volume of approximately 50 compounded prescriptions each month.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Responsibility for Integrity, Potency and Quality of Drug)

47. Respondents are subject to disciplinary action under section 4301 and/or California Code of Regulations, title 16, section 1735.2(f), in that on or about September 6, 2011, Respondents dispensed a compounded product pursuant to RX 6101993 for Patient “A” that was lacking in integrity, potency, quality, and/or label strength.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Making a False Statement)

48. Respondents are subject to disciplinary action under section 4301(g) and/or 4113(c) in that there were conflicts in various records made and provided by Respondents.

• On or about June 13, 2012, Respondents provided a statement about the compounding of RX 6101993 containing information which conflicted with the compounded record provided by the Respondents on May 15, 2012.

1 • The compound record for RX 6101993 stated 4.5 grams of liothyronine powder was
2 used to compound RX 6101993. The Compound Rx Report provided by Respondents and the
3 patient receipt stated .0450 grams of liothyronine powder was used to compound RX 6101993.

4 • The compound record for RX 6101992 stated 0.0008 grams of liothyronine powder
5 and 7.17 grams of cellulose were used to compound RX 6101992. The Compound Rx Report
6 provided by Respondents and the patient receipt for RX 6101992 stated 0.008 grams of
7 liothyronine powder and 5.067 grams of acidophilus lactobacillus powder 1BU/gram was used to
8 compound RX 6101992.

9 **OTHER MATTERS**

10 49. To determine the level of discipline, if any, to be imposed on Respondent Medicine
11 Shoppe and/or Respondent Chatwani (collectively Respondents), Complainant further alleges:

12 a. On or about December 15, 2010, Citation No. CI 2010 46106, was issued to
13 Respondent Medicine Shoppe, for (1) dispensing dangerous drugs incorrectly labeled, Bus. &
14 Prof. Code Section 4077(a)/4076(a)(11)(A); (2) Varying from prescription, California Code of
15 Regulation, Title 16, Section 1716; (3) Failure to have written policies and procedures, Bus. &
16 Prof Code Section 4101(b); (4) Failing to comply with self-assessment form, California Code of
17 Regulations, Title 16 Section 1715(a); (4) unprofessional conduct – false representation, Bus. &
18 Prof. Code Section 4301(g). A fine of \$5,000 was issued and paid.

19 b. On or about December 15, 2010, Citation No. CI 2012 53638 was issued to
20 Respondent Chatwani, for (1) dispensing dangerous drugs incorrectly labeled, Bus. & Prof. Code
21 Section 4077(a)/4076(a)(11)(A); (2) Varying from prescription, California Code of Regulation,
22 Title 16, Section 1716; (3) Failure to have written policies and procedures, Bus. & Prof Code
23 Section 4101(b); (4) Failing to comply with self-assessment form, California Code of
24 Regulations, Title 16 Section 1715(a); (4) unprofessional conduct – false representation, Bus. &
25 Prof. Code Section 4301(g). A fine of \$5,000 was issued and paid.

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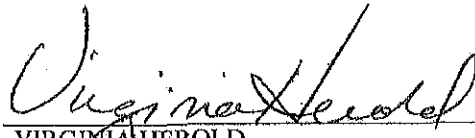
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PRAYER

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 License Number PHY 48618, issued to Respondent Medicine Shoppe;
2. Revoking or suspending Pharmacist License Number RPH 53463, issued to Respondent Chatwani;
3. Ordering Respondents 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. Taking such other and further action as is deemed necessary and proper.

DATED: 9/22/14



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

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