

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

In the Matter of the Accusation Against:

**BOB'S GREENLEY PHARMACY, INC.,
dba BOB'S GREENLEY PHARMACY
JOHN WILLIAMS,
aka JOHN ROBERT WILLIAMS,
President/Pharmacist-in-Charge
ROBERT G. WILLIAMS, Secretary
800 Delnero Drive
Sonora, CA 95370
Pharmacy Permit No PHY 45274**

and

**JOHN ROBERT WILLIAMS
800 Delnero Drive
Sonora, CA 95370
Pharmacist License No. RPH 37271**

Respondents.

Case No. 5755

**AS TO RESPONDENT BOB'S
GREENLEY PHARMACY, INC.,
dba BOB'S GREENLEY
PHARMACY
ONLY**

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on March 24, 2017.

It is so ORDERED on February 22, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____

Amy Gutierrez, Pharm.D.
Board President

1 KATHLEEN A. KENEALY
Acting Attorney General of California
KENT D. HARRIS
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8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5755

12 **BOB'S GREENLEY PHARMACY, INC.,**
13 **dba BOB'S GREENLEY PHARMACY**
14 **JOHN WILLIAMS,**
15 **aka JOHN ROBERT WILLIAMS,**
16 **President/Pharmacist-in-Charge**
17 **ROBERT G. WILLIAMS, Secretary**
18 **800 Delnero Drive**
19 **Sonora, CA 95370**

STIPULATED SURRENDER OF
LICENSE AND ORDER AS TO
RESPONDENT BOB'S GREENLEY
PHARMACY, INC., dba BOB'S
GREENLEY PHARMACY ONLY

16 **Pharmacy Permit No. PHY 45274**

17 **and**

18 **JOHN ROBERT WILLIAMS**
19 **800 Delnero Drive**
20 **Sonora, CA 95370**

21 **Pharmacist License No. RPH 37271**

22 Respondents.

23
24 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
25 entitled proceedings that the following matters are true:

26 **PARTIES**

27 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
28 (Board). She brought this action solely in her official capacity and is represented in this matter by

1 Kathleen A. Kenealy, Acting Attorney General of the State of California, by Stanton W. Lee,
2 Deputy Attorney General.

3 2. On or about July 20, 2001, the Board issued Pharmacy Permit No. PHY 45274 to
4 Bob's Greenley Pharmacy, Inc. dba Bob's Greenley Pharmacy (Respondent). The Pharmacy
5 Permit was in full force and effect at all times relevant to the charges brought in Accusation No.
6 5755 and will expire on July 1, 2017, unless renewed.

7 3. Respondent is representing itself in this proceeding and has chosen not to exercise its
8 right to be represented by counsel.

9 JURISDICTION

10 4. Accusation No. 5755 was filed before the (Board), and is currently pending against
11 Respondent. The Accusation and all other statutorily required documents were properly served
12 on Respondent on October 7, 2016. Respondent timely filed its Notice of Defense contesting the
13 Accusation.

14 5. A copy of Accusation No. 5755 is attached as Exhibit A and incorporated by
15 reference.

16 ADVISEMENT AND WAIVERS

17 6. Respondent has carefully read, and understands the charges and allegations in
18 Accusation No. 5755. Respondent also has carefully read, and understands the effects of this
19 Stipulated Surrender of License and Order.

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

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

1 CULPABILITY

2 9. Respondent admits the truth of each and every charge and allegation in Accusation
3 No. 5755, agrees that cause exists for discipline and hereby surrenders their Pharmacy Permit No.
4 PHY 45274 for the Board's formal acceptance.

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

7 CONTINGENCY

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

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

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

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

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ORDER

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2 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 45274, issued to Respondent
3 Bob's Greenley Pharmacy, Inc. dba Bob's Greenley Pharmacy, is surrendered and accepted by the
4 Board of Pharmacy. The effective date of the Decision shall be stayed for sixty (60) days after
5 the effective date of the Order adopting this Stipulated Surrender, at which time the pharmacy
6 shall be sold or closed.

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

11 2. Respondent shall lose all rights and privileges as a Pharmacy in California as of the
12 effective date of the Board's Decision and Order.

13 3. Respondent shall cause to be delivered to the Board its pocket license and, if one was
14 issued, its wall certificate on or before the effective date of the Decision and Order.

15 4. If Respondent ever files an application for licensure or a petition for reinstatement in
16 the State of California, the Board shall treat it as a new application for licensure. Respondent
17 must comply with all the laws, regulations and procedures for reinstatement of a revoked license
18 in effect at the time the petition is filed, and all of the charges and allegations contained in
19 Accusation No. 5755 shall be deemed to be true, correct and admitted by Respondent when the
20 Board determines whether to grant or deny the petition. Respondent is required to report this
21 surrender as disciplinary action.

22 5. Respondent shall pay the agency its costs of investigation and enforcement in the
23 amount of \$23,202.75, jointly and severally with Respondent John Robert Williams, prior to
24 issuance of a new or reinstated license.

25 6. If Respondent should ever apply or reapply for a new license or certification, or
26 petition for reinstatement of a license, by any other health care licensing agency in the State of
27 California, all of the charges and allegations contained in Accusation, No. 5755 shall be deemed
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1 to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any
2 other proceeding seeking to deny or restrict licensure.

3 7. In the event that Respondent is not sold within sixty (60) days of the effective date of
4 this Order adopting this Stipulated Surrender, Respondent shall, within ten (10) days of the stayed
5 effective date of the Board's Order, arrange for the destruction of, the transfer to, sale of or
6 storage in a facility licensed by the Board, of all controlled substances and dangerous drugs and
7 devices. Respondent shall further provide written proof of such disposition and submit a
8 complete Discontinuance of Business form according to Board guidelines.

9 8. In the event that Respondent is not sold within sixty (60) days of the effective date of
10 this Order adopting this Stipulated Surrender, Respondent shall, within ten (10) days of the stayed
11 effective date of the Board's Order, arrange for the continuation of care for ongoing patients of
12 the pharmacy, by a minimum, providing a written notice to ongoing patients that specifies the
13 anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable
14 of taking up the patients' care, and by cooperating as may be necessary in the transfer of record or
15 prescriptions for ongoing patients. Within five (5) days of satisfaction of this provision to the
16 pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the Board.
17 For the purposes of this provision, "ongoing patients" mean those patients for whom the
18 pharmacy has on file a prescription with one or more refills outstanding, or for whom the
19 pharmacy has filled a prescription within the preceding sixty (60) days.

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ACCEPTANCE


I have carefully read the Stipulated Surrender of License and Order. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. I attest that I am authorized to enter into this stipulation on behalf of Respondent Bob's Greenley Pharmacy and bind Respondent to the terms of this agreement.

DATED: 1/22/17 
BOB'S GREENLEY PHARMACY, INC. DBA
BOB'S GREENLEY PHARMACY
Respondent

ENDORSEMENT

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

Dated: 1/26/17

Respectfully submitted,
KATHLEEN A. KENEALY
Acting Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

STANTON W. LEE
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5755

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 STANTON W. LEE
Deputy Attorney General
4 State Bar No. 203563
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6 Telephone: (916) 445-9921
Facsimile: (916) 324-5567
7 *Attorneys for Complainant*

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16 **President/Pharmacist-in-Charge**
17 **ROBERT G. WILLIAMS, Secretary**
18 **800 Delnero Drive**
19 **Sonora, CA 95370**

A C C U S A T I O N

20 **Pharmacy Permit No. PHY 45274**

21 **and**

22 **JOHN ROBERT WILLIAMS**
23 **800 Delnero Drive**
24 **Sonora, CA 95370**

25 **Pharmacist License No. RPH 37271**

26 Respondents.

27 Complainant alleges:

28 **PARTIES**

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.
2. On or about July 20, 2001, the Board issued Pharmacy Permit Number PHY 45274 to Bob's Greenley Pharmacy, Inc. ("Respondent Bob's"), doing business as Bob's Greenley

1 Pharmacy, with John Williams, also known as John Robert Williams ("Respondent Williams"), as
2 president and pharmacist-in-charge and Robert G. Williams as secretary. The pharmacy permit
3 was in full force and effect at all times relevant to the charges brought herein and will expire on
4 July 1, 2017, unless renewed.

5 3. On or about June 30, 1984, the Board issued Pharmacist License Number RPH 37271
6 to Respondent Williams. The pharmacist license was in full force and effect at all times relevant
7 to the charges brought herein and will expire on June 30, 2018, unless renewed.

8 JURISDICTION

9 4. This Accusation is brought before the Board under the authority of the following
10 laws. All section references are to the Business and Professions Code ("Code") unless otherwise
11 indicated.

12 5. Section 4300 of the Code states, in pertinent part:

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

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

16 (1) Suspending judgment.

17 (2) Placing him or her upon probation.

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

20 (4) Revoking his or her license.

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

22 6. Section 4300.1 of the Code states:

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

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STATUTORY AND REGULATORY PROVISIONS

(Statutory Provisions)

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

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

....

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

.....

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

....

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

8. Section 4081 of the Code states, in pertinent part:

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

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

9. Section 4013, subdivision (a), of the Code states that "[a]ny facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal."

1 10. Section 4104 of the Code states, in pertinent part:

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3 (b) Every pharmacy shall have written policies and procedures for
4 addressing chemical, mental, or physical impairment, as well as theft, diversion, or
5 self-use of dangerous drugs, among licensed individuals employed by or with the
6 pharmacy.

7 (c) Every pharmacy shall report and provide to the board, within 14 days
8 of the receipt or development thereof, the following information with regard to any
9 licensed individual employed by or with the pharmacy:

10 (1) Any admission by a licensed individual of chemical, mental, or
11 physical impairment affecting his or her ability to practice.

12 (2) Any admission by a licensed individual of theft, diversion, or self-use
13 of dangerous drugs.

14 (3) Any video or documentary evidence demonstrating chemical, mental,
15 or physical impairment of a licensed individual to the extent it affects his or her
16 ability to practice.

17 (4) Any video or documentary evidence demonstrating theft, diversion, or
18 self-use of dangerous drugs by a licensed individual.

19 (5) Any termination based on chemical, mental, or physical impairment
20 of a licensed individual to the extent it affects his or her ability to practice.

21 (6) Any termination of a licensed individual based on theft, diversion, or
22 self-use of dangerous drugs . . .

23 11. Section 4105 of the Code states, in pertinent part:

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

27

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

12. Section 4113, subdivision (c), of the Code states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

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13. Section 4342, subdivision (a), of the Code states:

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

14. Health and Safety Code section 11200 states, in pertinent part:

....

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply . . .

15. Health and Safety Code section 11153, subdivision (a), states:

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

(Regulatory Provisions)

16. Title 16, California Code of Regulations ("CCR"), section 1707.2 states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

1 (B) whenever a prescription drug not previously dispensed to a patient in
the same dosage form, strength or with the same written directions, is dispensed by
the pharmacy.

2 (2) When the patient or agent is not present (including but not limited to a
3 prescription drug that was shipped by mail) a pharmacy shall ensure that the patient
receives written notice:

4 (A) of his or her right to request consultation; and

5 (B) a telephone number from which the patient may obtain oral
6 consultation from a pharmacist who has ready access to the patient's record . . .

7 17. Title 16, CCR, section 1707.5 states, in pertinent part:

8 (a) Labels on drug containers dispensed to patients in California shall
conform to the following format:

9 (1) Each of the following items, and only these four items, shall be
10 clustered into one area of the label that comprises at least 50 percent of the label.
Each item shall be printed in at least a 12-point sans serif typeface, and listed in the
11 following order:

12

13 (B) Name of the drug and strength of the drug. For the purposes of this
14 section, "name of the drug" means either the manufacturer's trade name of the drug,
or the generic name and the name of the manufacturer . . .

15 18. Title 16, CCR, section 1711 states, in pertinent part:

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

19

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

22

23 (d) Each pharmacy shall use the findings of its quality assurance program
to develop pharmacy systems and workflow processes designed to prevent medication
24 errors . . .

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

28 ///

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

4 19. Title 16, CCR, section 1714, subdivision (b), states:

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

9 20. Title 16, CCR, section 1715.6 states that "[t]he owner shall report to the Board within
10 thirty (30) days of discovery of any loss of the controlled substances, including their amounts and
11 strengths."

12 21. Title 16, CCR, section 1718 states:

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

16 The controlled substances inventories required by Title 21, CFR, Section
17 1304 shall be available for inspection upon request for at least 3 years after the date of
18 the inventory.

19 22. Title 16, CCR, section 1735.2 states, in pertinent part:

20

21 (d) A drug product shall not be compounded until the pharmacy has first
22 prepared a written master formula record that includes at least the following elements:

23 (1) Active ingredients to be used.

24 (2) Equipment to be used.

25 (3) Expiration dating requirements.

26 (4) Inactive ingredients to be used.

27 (5) Process and/or procedure used to prepare the drug.

28 (6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

. . . .

(h) Every compounded drug product shall be given an expiration date
representing the date beyond which, in the professional judgment of the pharmacist
performing or supervising the compounding, it should not be used. This "beyond use
date" of the compounded drug product shall not exceed 180 days from preparation or

1 the shortest expiration date of any component in the compounded drug product,
2 unless a longer date is supported by stability studies of finished drugs or compounded
3 drug products using the same components and packaging. Shorter dating than set
4 forth in this subsection may be used if it is deemed appropriate in the professional
5 judgment of the responsible pharmacist.

6

7 (j) Prior to allowing any drug product to be compounded in a pharmacy,
8 the pharmacist-in-charge shall complete a self-assessment for compounding
9 pharmacies developed by the board. (Incorporated by reference is "Community
10 Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form
11 17M-39 Rev. 02/12.) That form contains a first section applicable to all
12 compounding, and a second section applicable to sterile injectable compounding. The
13 first section must be completed by the pharmacist-in-charge before any compounding
14 is performed in the pharmacy. The second section must be completed by the
15 pharmacist-in-charge before any sterile injectable compounding is performed in the
16 pharmacy. The applicable sections of the self-assessment shall subsequently be
17 completed before July 1 of each odd-numbered year, within 30 days of the start of a
18 new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy
19 license. The primary purpose of the self-assessment is to promote compliance through
20 self-examination and education.

21 23. Title 16, CCR, section 1735.3 states, in pertinent part:

22 (a) For each compounded drug product, the pharmacy records shall
23 include:

- 24 (1) The master formula record.
25 (2) The date the drug product was compounded.
26 (3) The identity of the pharmacy personnel who compounded the drug
27 product.
28 (4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug
product.
(6) The manufacturer, expiration date and lot number of each component .
If the manufacturer name is demonstrably unavailable, the name of the supplier may
be substituted . . .

(7) A pharmacy assigned reference or lot number for the compounded
drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

. . . .

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

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24. Title 16, CCR, section 1735.4 states, in pertinent part:

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

....

(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

25. Title 16, CCR, section 1735.5, subdivision (a), states:

Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

26. Title 16, CCR, section 1735.7 states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

27. Title 16, CCR, section 1735.8, subdivision (a), states:

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.

28. Title 16, CCR, section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

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1 (b) Even after conferring with the prescriber, a pharmacist shall not
2 compound or dispense a controlled substance prescription where the pharmacist
3 knows or has objective reason to know that said prescription was not issued for a
4 legitimate medical purpose.

3 **COST RECOVERY**

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

8 **DRUG CLASSIFICATIONS**

9 30. "Norco", a brand name for hydrocodone/acetaminophen, is a Schedule III controlled
10 substance pursuant to Health and Safety Code section 11056, subdivision (e)(5). Norco was
11 reclassified as a Schedule II controlled substance pursuant to Title 21, Code of Federal
12 Regulations ("CFR"), section 1308.12, subdivision (b)(1)(vi), effective October 6, 2014. Norco
13 is also a dangerous drug pursuant to Code section 4022 and is used to treat pain.

14 31. "Roxicodone", a brand name for oxycodone, is a Schedule II controlled substance
15 pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M). Roxicodone is also a
16 dangerous drug pursuant to Code section 4022 and is used to treat pain.

17 32. "Soma", a brand name for carisoprodol, is a Schedule IV Controlled Substance
18 pursuant to Title 21, CFR, section 1308.14, subdivision (c)(6). Soma is also a dangerous drug
19 pursuant to Code section 4022 and is used as a muscle relaxant.

20 33. "Ambien", a brand name for zolpidem, is a Schedule IV controlled substance
21 pursuant to Health and Safety Code section 11057, subdivision (d)(32). Ambien is also a
22 dangerous drug pursuant to Code section 4022 and is used to treat insomnia.

23 34. "Ativan", a brand name for lorazepam, is a Schedule IV controlled substance
24 pursuant to Health and Safety Code section 11057, subdivision (d)(16). Ativan is also a
25 dangerous drug pursuant to Code section 4022 and is used to treat anxiety.

26 35. "Restoril", a brand name for temazepam, is a Schedule IV controlled substance
27 pursuant to Health and Safety Code section 11057, subdivision (d)(29). Restoril is also a
28 dangerous drug pursuant to Code section 4022 and is used to treat insomnia.

1 36. "Klonopin", a brand name for clonazepam, is a Schedule IV controlled substance
2 pursuant to Health and Safety Code section 11057, subdivision (d)(7). Klonopin is also a
3 dangerous drug pursuant to Code section 4022, and is used to treat anxiety.

4 37. "Xanax", a brand name for alprazolam, is a Schedule IV controlled substance
5 pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is also a dangerous
6 drug pursuant to Code section 4022 and is used to treat anxiety.

7 38. "Valium", a brand name for diazepam, is a Schedule IV controlled substance pursuant
8 to Health and Safety Code section 11057, subdivision (d)(9). Valium is also a dangerous drug
9 pursuant to Code section 4022 and is used to treat anxiety.

10 39. "Butrans", a brand name for buprenorphine, is a Schedule V controlled substance
11 pursuant to Health and Safety Code section 11058, subdivision (d). Butrans is also a dangerous
12 drug pursuant to Code section 4022 and is used to treat pain.

13 40. "Adderall", a brand name for amphetamine/dextroamphetamine, is a Schedule II
14 controlled substance pursuant to Health and Safety Code section 11055, subdivision (d)(1).
15 Adderall is also a dangerous drug pursuant to Code section 4022 and is used to treat ADHD
16 (Attention Deficit Hyperactivity Disorder).

17 41. "Kadian", a brand name for morphine, is a Schedule II controlled substance pursuant
18 to Health and Safety Code section 11055, subdivision (b)(1)(L). Morphine is also a dangerous
19 drug pursuant to Code section 4022 and is used to treat pain.

20 42. "Fioricet with codeine", a brand name for butalbital/acetaminophen/caffeine/codeine,
21 is a Schedule III controlled substance pursuant to Health and Safety Code section 11056,
22 subdivision (e)(2). Fioricet with codeine is also a dangerous drug pursuant to Code section 4022
23 and is used to treat headache :

24 43. "Tylenol with codeine #4", a brand name for acetaminophen with codeine, is a
25 Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision
26 (e)(2). Tylenol with codeine #4 is also a dangerous drug pursuant to Code section 4022 and is
27 used to treat pain.

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1 44. "Cymbalta", a brand name for duloxetine, is a dangerous drug pursuant to Code
2 section 4022 and is used to treat depression.

3 45. "Wellbutrin", a brand name for bupropion, is a dangerous drug pursuant to Code
4 section 4022 and is used to treat depression.

5 46. "Premarin", a brand name for conjugated estrogens, is a dangerous drug pursuant to
6 Code section 4022 and is used to treat postmenopausal osteoporosis.

7 47. "Nuvigil", a brand name for armodafinil, is a Schedule IV controlled substance
8 pursuant to Health and Safety Code section 11057, subdivision (f)(3). Nuvigil is also a dangerous
9 drug pursuant to Code section 4022 and is used to treat narcolepsy.

10 **FACTUAL ALLEGATIONS**

11 48. Board Inspector I.T. analyzed CURES (Controlled Substance Utilization Review and
12 Evaluation System) data for Bob's Greenley Pharmacy ("Bob's"), and found that multiple
13 patients had received early fills of their Schedule II to V controlled substance medications from
14 the pharmacy. Further, the pharmacy had refilled numerous prescriptions for Schedule III and IV
15 controlled substances more than five times and in an amount beyond the 120-day supply allowed
16 by law.

17 49. On or about October 21, 2015, Board Inspectors I.T. and S.K. conducted an
18 inspection at Bob's. Pharmacist N.R. met with the inspectors and told them that Respondent
19 Williams ("Williams") was not working that day. Pharmacist N.R. also stated that Williams
20 performs all of the pharmacy's compounding. Inspector I.T. asked Pharmacist N.R. for Bob's
21 compounding self-assessment and DEA Biennial Controlled Substances Inventory. Pharmacist
22 N.R. contacted Williams then told the inspectors that he had not completed a compounding self-
23 assessment in 2015. Pharmacy Technician W. arrived at Bob's and located the biennial
24 inventory. Inspector I.T. asked Pharmacy Technician W. to pull a sample of original hard copy
25 prescriptions for the patients identified during the CURES data analysis, for the period from 2012
26 to 2015. Pharmacy Technician W. told the inspectors that only two years of hard copy
27 prescription were stored at Bob's and that the prescriptions for the earlier years were stored at

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1 Williams' home. Inspector I.T. asked Pharmacy Technician W. if the pharmacy had an off-site
2 storage waiver. Pharmacy Technician W. indicated that they did not.

3 50. Inspector I.T. had Pharmacist N.R. perform a count of the pharmacy's stock on hand
4 of all generic and brand name hydrocodone/acetaminophen (H/APAP) 10/325 mg, carisoprodol
5 350 mg and oxycodone 30 mg immediate-release (IR) tablets. Inspector I.T. then obtained a copy
6 of a DEA 106 Report that Bob's had filed on January 22, 2015, following a burglary which
7 occurred during the early morning hours on January 17, 2015. Pharmacy Technician W. stated
8 that the burglars broke in through the vents on the roof, cut the alarm, telephone and computer
9 wires, and stole both controlled and non-controlled medications. Inspector I.T. asked Pharmacy
10 Technician W. if she or Williams reported the loss to the Board and she said "no." The inspectors
11 asked Pharmacist N.R. to show them a random quality assurance report. Pharmacist N.R. stated
12 that she did not know where they were kept and could not immediately retrieve them.

13 51. Bob's had several Automated Drug Delivery Systems ("ADDS"), which were used to
14 dispense the most frequently filled medications. The inspectors asked to see the lot numbers and
15 expiration dates of the drugs contained in the ADDS. Pharmacist N.R. stated that the actual lot
16 numbers of the drugs were not kept in the computer system. Pharmacist N.R. explained that they
17 would place the empty bottles which contained the drugs used to fill the ADDS on the shelf after
18 the ADDS were replenished. Pharmacist N.R. claimed that this would allow them to identify the
19 lot number and expiration date of the drugs if necessary. The inspectors expressed their concern
20 that the lot numbers and expiration dates would be lost in the event the empty bottles were
21 accidentally discarded.

22 52. During the inspection, patient H.L. arrived at Bob's to pick up a prescription for
23 Wellbutrin XL 150 mg tablets. H.L. informed clerk Z.Y. that she had never taken the medication
24 before and asked clerk Z.Y. if she could provide her with any paperwork explaining the potential
25 side effects. Clerk Z.Y. did not call Pharmacist N.R. to perform an oral consultation with the
26 patient. Later, patient T.M. picked up a prescription for Premarin 0.9 mg tablets. Clerk M.C.
27 asked patient T.M. if she had any questions for the pharmacist. Patient T.M. stated that she had
28 taken the medication before, but it was in a new strength. Clerk M.C. did not call Pharmacist

1 N.R. to perform an oral consultation with the patient. Inspector I.T. obtained copies of the patient
2 profiles for the two patients, which confirmed that patient H.L. had not received Wellbutrin from
3 Bob's in the past and that the increased strength of Premarin had never been dispensed to patient
4 T.M.

5 53. The inspectors learned that Bob's delivered medications to patients who resided
6 within approximately a ten mile radius of Sonora. The inspectors looked into a bag which
7 contained medications for delivery to patient C.M. The bag did not contain a written notice of the
8 patient's right to request an oral consultation and a telephone number to call to obtain the
9 consultation. Clerks Z.Y. and M.C. confirmed with the inspectors that this notice was not sent
10 out to patients who received deliveries of medications from the pharmacy.

11 54. Inspector I.T. asked Pharmacist N.R. and Pharmacy Technician W. for all records
12 relating to compounding, including master formulas, compounding logs, compounding policies
13 and procedures, a compounding quality assurance plan, and training records. The pharmacy did
14 not have any of these records with the exception of compounding logs, which were kept
15 electronically on-line for each patient. The inspectors obtained computer print outs of two patient
16 compounding records and copies of prescription labels for patients S.D. and A.V. The
17 compounding records did not show the date the drug products were compounded, the identity of
18 the pharmacy personnel who compounded the drug products, the identity of the pharmacist
19 reviewing the final drug products, the manufacturer, the expiration date, or the lot number of each
20 component.

21 55. Inspector I.T. noted in reviewing the prescription label for patient A.V. that it did not
22 show the strength of each drug used in the compounded medication. The prescription label for
23 patient S.D. did not contain the complete name of one of the components used in the compounded
24 medication; the drug lidocaine had been improperly abbreviated as "lido". Inspector I.T. also
25 noted that the expiration dates for both compounded medications were one year from the date the
26 prescriptions were written. Inspector I.T. asked Pharmacy Technician W. if Williams was signed
27 up to receive email notifications from the Board, and she indicated that he was not.

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1 56. At the conclusion of the inspection, Inspector I.T. obtained a copy of the DEA
2 Biennial Controlled Substances Inventory. The biennial inventory showed that it had been
3 performed at the close of business on February 5, 2015. Inspector I.T. issued an inspection report
4 and requested Bob's computer records of dispensed brand and generic H/APAP 10/325 mg,
5 carisoprodol 350 mg, and oxycodone 30 mg IR prescriptions from February 6, 2015 to October
6 21, 2015, all records of acquisition and disposition for the three controlled substances (with the
7 exception of reverse distributor data) from February 6, 2015 to October 21, 2015, and computer
8 records of dispensed prescriptions for all patients and all drugs from October 1, 2012 to October
9 21, 2015.

10 57. On or about October 27, 2015, Inspector I.T. sent wholesaler Cardinal Health a letter,
11 requesting certified records of any brand and generic H/APAP 10/325 mg, oxycodone 30 mg IR,
12 and carisoprodol 350 mg purchased by or returned from Bob's from February 5, 2015 to October
13 21, 2015. Cardinal Health provided the records on or about October 29, 2015.

14 58. On or about November 3, 2015, Inspector I.T. received copies of various documents
15 from Williams, including the pharmacy's policy and procedure entitled "Impaired Pharmacist".

16 59. On or about November 5, 2015, Williams provided Inspector I.T. with the
17 pharmacy's computer records of dispensed H/APAP 10/325 mg, oxycodone 30 mg IR, and
18 carisoprodol 350 mg. Inspector I.T. determined based on the biennial inventory, the records from
19 Cardinal Health, the pharmacy's dispensing records, and the count of the stock on hand
20 conducted by Pharmacist N.R. that the pharmacy had a shortage of 182 carisoprodol 350 mg
21 tablets for the period from February 6, 2015 to October 21, 2015. Inspector I.T. also found that
22 the pharmacy had an overage of 125 H/APAP 10/325 mg tablets.

23 60. On and between November 13, 2015 and November 16, 2015, Inspector I.T. received
24 several emails from QS1 Data System containing computer records of all of Bob's dispensed
25 prescriptions from October 1, 2012 to October 21, 2015. Inspector I.T. found that based on the
26 dispensing data and the information from CURES that the pharmacy had refilled and dispensed
27 105 prescriptions for Schedule III to IV controlled substances more than five times and in an
28 amount, for all refills of each prescription taken together, exceeding the 120-day supply allowed

1 by law. 5,040 excess dosage units had been supplied by Williams, 2,580 excess dosage units had
2 been supplied by licensed pharmacist C.L., and 630 excess dosage units had been supplied by
3 Pharmacist N.R., for a total of 8,250 dosage units, as set forth in paragraph 76 below.

4 61. Inspector I.T. found in reviewing the CURES data, pharmacy dispensing data, and
5 hard copy prescriptions that Bob's failed to fulfill its corresponding responsibility when it verified
6 and dispensed prescriptions for Schedule II to V controlled substances more than five (5) days
7 before a previously dispensed supply of medication was exhausted, in 291 instances. Williams
8 verified and dispensed early fills in 170 instances; Pharmacist C.L. verified and dispensed early
9 fills in 79 instances, and Pharmacist N.R. verified and dispensed early fills in 42 instances.

10 **Causes for Discipline as to Respondent Bob's Greenley Pharmacy**

11 **FIRST CAUSE FOR DISCIPLINE**

12 **(Failure to Maintain Pharmacy, Fixtures, and Equipment**
13 **so that Drugs Were Safely and Properly Secured)**

14 62. Respondent Bob's is subject to disciplinary action for unprofessional conduct
15 pursuant to section 4301, subdivisions (o) and (j), of the Code in that on and between February 6,
16 2015 and October 21, 2015, Respondent failed to maintain the pharmacy and its facilities, space,
17 fixtures and/or equipment so that drugs were safely and properly secured, in violation of Title 16,
18 CCR, section 1714, subdivision (b), resulting in a shortage of 182 carisoprodol 350 mg tablets.

19 **SECOND CAUSE FOR DISCIPLINE**

20 **(Failure to Maintain a Current Inventory of All Dangerous Drugs)**

21 63. Respondent Bob's is subject to disciplinary action for unprofessional conduct
22 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated sections 4081,
23 subdivision (a), and 4105, subdivisions (a) and (c), of the Code as follows:

24 a. On and between February 6, 2015 and October 21, 2015, Respondent failed to
25 maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in a
26 shortage of 182 carisoprodol 350 mg tablets and an overage of 125 hydrocodone/acetaminophen
27 10/325 mg tablets.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Information Regarding Lot Numbers of Drugs**
3 **Stored in the Automated Drug Delivery Systems)**

4 67. Respondent Bob's is subject to disciplinary action for unprofessional conduct
5 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated section 4342 of
6 the Code, as follows: Respondent failed to enter into the computer system the actual lot numbers
7 of the drugs stored in the pharmacy's Automated Drug Delivery System. As such, the lot
8 numbers could only be obtained from the labels on the empty bottles of drugs that were placed on
9 the pharmacy shelf after the ADD's were replenished.

10 **SEVENTH CAUSE FOR DISCIPLINE**

11 **(Compounding of Drug Products Without Master Formula Records;**
12 **Failure to Complete Compounding Self-Assessment)**

13 68. Respondent Bob's is subject to disciplinary action for unprofessional conduct
14 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated provisions of
15 Title 16, CCR, section 1735.2, as follows:

- 16 a. **Subdivision (d)**: Respondent performed compounding of drug products without
17 preparing written master formula records.
- 18 b. **Subdivision (h)**: Respondent assigned all compounded drug products an expiration
19 date of one year rather than 180 days from the date the drug products were prepared.
- 20 c. **Subdivision (j)**: Respondent failed to complete or have available at the pharmacy a
21 compounding self assessment.

22 **EIGHTH CAUSE FOR DISCIPLINE**

23 **(Failure to Maintain Training Records of**
24 **Pharmacy Personnel Involved in Compounding)**

25 69. Respondent Bob's is subject to disciplinary action for unprofessional conduct
26 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
27 section 1735.7, as follows: Respondent performed compounding of drug products without

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1 maintaining training records and an on-going competency evaluation process for pharmacy
2 personnel involved in compounding.

3 **NINTH CAUSE FOR DISCIPLINE**

4 **(Compounding of Drug Products without Master Formula Records**
5 **and Other Information Required by Law)**

6 70. Respondent Bob's is subject to disciplinary action for unprofessional conduct
7 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
8 section 1735.3, subdivision (a), as follows:

9 a. Respondent performed compounding of drug products without maintaining master
10 formula records or written compounding logs.

11 b. Respondent failed to maintain complete compounding records for patients S.D. and
12 A.V. in that the computer records did not include the dates the drug products for each patient
13 were compounded, the identity of the pharmacy personnel who compounded the drug products,
14 the identity of the pharmacist reviewing the final drug products, the manufacturer, expiration
15 date, or the lot number of each component.

16 **TENTH CAUSE FOR DISCIPLINE**

17 **(Failure to Join Board's E-Mail Notification List)**

18 71. Respondent Bob's is subject to disciplinary action for unprofessional conduct
19 pursuant to section 4013, subdivision (o), of the Code in that Respondent violated section 4103,
20 subdivision (a), of the Code, as follows: Respondent failed to join the Board's e-mail notification
21 list.

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1 **ELEVENTH CAUSE FOR DISCIPLINE**

2 **(Improper Labeling of Compounded Drug Products)**

3 72. Respondent Bob's is subject to disciplinary action for unprofessional conduct
4 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
5 sections 1707.5 and 1735.4 regarding the labeling of drug products, as follows:

6 a. **Section 1707.5, subdivision (a)(1)(B)**: Respondent failed to list on the prescription
7 label for the drug product compounded for patient A.V. the strengths of each component used in
8 the compounded medication, as set forth in paragraph 55 above.

9 b. **Section 1735.4**: Respondent failed to list on the prescription label for the drug
10 product compounded for patient S.D. the full name of one of the ingredients used in the
11 compounded medication and used an abbreviation instead, as set forth in paragraph 55 above.

12 **TWELFTH CAUSE FOR DISCIPLINE**

13 **(Failure to Maintain Written Quality Assurance Plan)**

14 73. Respondent Bob's is subject to disciplinary action for unprofessional conduct
15 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
16 section 1735.8, as follows: Respondent failed to maintain a written quality assurance plan for
17 compounded prescriptions.

18 **THIRTEENTH CAUSE FOR DISCIPLINE**

19 **(Failure to Maintain a Written Policy and Procedure Manual for Compounding)**

20 74. Respondent Bob's is subject to disciplinary action for unprofessional conduct
21 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
22 section 1735.5, as follows: Respondent failed to maintain a written policy and procedure manual
23 for compounding.

24 **FOURTEENTH CAUSE FOR DISCIPLINE**

25 **(Failure to Report Loss of Controlled Substances)**

26 75. Respondent Bob's is subject to disciplinary action for unprofessional conduct
27 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
28 section 1715.6, as follows: Respondent failed to report to the Board the burglary or theft of

1 controlled substances from the pharmacy on January 17, 2015, as set forth in paragraph 50 above,
2 within 30 days of the theft.

3 **FIFTEENTH CAUSE FOR DISCIPLINE**

4 **(Failure to Comply with Restrictions on Dispensing or Refilling)**

5 76. Respondent Bob's is subject to disciplinary action for unprofessional conduct
6 pursuant to section 4301, subdivision (j), of the Code in that Respondent violated Health and
7 Safety Code section 11200, subdivision (b), as follows: On and between October 1, 2012 and
8 October 21, 2015, Respondent refilled and dispensed 105 prescriptions for Schedule III to IV
9 controlled substances more than five times or in an amount, for all refills of each prescription
10 taken together, exceeding the 120-day supply allowed by law, as set forth below and in paragraph
11 60 above.

12 Drug/Strength	13 Excess Dosage Units Supplied
14 zolpidem 10 mg	570
15 lorazepam 2 mg	60
16 temazepam 30 mg	270
17 carisoprodol 350 mg	1,080
18 clonazepam 1 mg	90
19 zolpidem 5 mg	150
20 alprazolam 0.5 mg	720
21 lorazepam 0.5 mg	60
22 temazepam 15 mg	120
23 hydrocodone/APAP 10/325 mg	3,030
24 clonazepam 2 mg	120
25 lorazepam 1 mg	270
26 diazepam 5 mg	90
27 hydrocodone/APAP 5/325 mg	420
28 alprazolam 1 mg	780

Drug/Strength	Excess Dosage Units Supplied
hydrocodone/APAP 7.5/500 mg	120
clonazepam 0.5 mg	90
Ambien CR/zolpidem ER 12.5 mg	60
Nuvigil 250 mg	150
Total	8,250

SIXTEENTH CAUSE FOR DISCIPLINE

(Dispensing Prescriptions Containing Significant Errors, Omissions, Irregularities, etc.)

77. Respondent Bob's is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR, section 1761, as follows: Respondent verified and dispensed prescriptions for Schedule II to V controlled substances more than five (5) days before a previously dispensed supply of medication was exhausted, in 291 instances, as set forth in paragraph 61 above. As a result, multiple patients received early fills of their medications and an excess amount of controlled substances.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

78. Respondent Bob's is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (d), of the Code in that Respondent clearly excessively furnished Schedule II to V controlled substances to patients, as set forth in paragraph 77 above.

Causes for Discipline as to Respondent John Robert Williams

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy, Fixtures, and Equipment so that Drugs Were Safely and Properly Secured)

79. Respondent Williams is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivisions (o) and (j), of the Code in that on and between February 6, 2015 and October 21, 2015, Respondent failed to maintain the pharmacy and its facilities, space, fixtures and/or equipment so that drugs were safely and properly secured, in violation of Title 16,

1 CCR, section 1714, subdivision (b), resulting in a shortage of 182 carisoprodol 350 mg tablets.

2 **NINETEENTH CAUSE FOR DISCIPLINE**

3 **(Failure to Maintain a Current Inventory of All Dangerous Drugs)**

4 80. Respondent Williams is subject to disciplinary action for unprofessional conduct
5 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated sections 4081,
6 subdivision (a), and 4105, subdivision (a) and (c), of the Code as follows:

7 a. On and between February 6, 2015 and October 21, 2015, Respondent failed to
8 maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in a
9 shortage of 182 carisoprodol 350 mg tablets and an overage of 125 hydrocodone/acetaminophen
10 10/325 mg tablets.

11 b. Respondent stored only two years of records of disposition in the pharmacy and
12 stored older records at his home without an off-site storage waiver approved by the Board.

13 **TWENTIETH CAUSE FOR DISCIPLINE**

14 **(Failure to Provide Oral Consultation to Patients)**

15 81. Respondent Williams is subject to disciplinary action for unprofessional conduct
16 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
17 section 1707.2, subdivision (b)(2)(A) and (B), as follows: Respondent failed to provide patients,
18 who received their medications by delivery service, with a written notice of their right to request
19 an oral consultation from a pharmacist and a telephone number to call to obtain the consultation.

20 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

21 **(Improper Policy and Procedure Re: Chemical/Mental/Physical Impairment,
22 Theft, Diversion, or Self-Use of Dangerous Drugs by Licensed Individuals/Employees)**

23 82. Respondent Williams is subject to disciplinary action for unprofessional conduct
24 pursuant to section 4301, subdivisions (o) and (j), of the Code in that the pharmacy's policy and
25 procedure entitled "Impaired Pharmacist" was not in compliance with section 4104 of the Code,
26 as follows: The policy stated that the pharmacy shall report to the Board information regarding
27 the chemical, mental or physical impairment, theft, diversion, or self-use of dangerous drugs by
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1 any individual employed by the pharmacy, within 30 days of the receipt or development of the
2 information when, in fact, the information was to be reported within 14 days as required by law.

3 **TWENTY-SECOND CAUSE FOR DISCIPLINE**

4 **(Failure to Comply with Quality Assurance Program)**

5 83. Respondent Williams is subject to disciplinary action for unprofessional conduct
6 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
7 section 1711, as follows: Respondent failed to have immediately available for inspection, the
8 pharmacy's quality assurance review records.

9 **TWENTY-THIRD CAUSE FOR DISCIPLINE**

10 **(Failure to Maintain Information Regarding Lot Numbers of Drugs
11 Stored in the Automated Drug Delivery Systems)**

12 84. Respondent Williams is subject to disciplinary action for unprofessional conduct
13 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated section 4342 of
14 the Code, as follows: Respondent failed to enter into the computer system the actual lot numbers
15 of the drugs stored in the pharmacy's Automated Drug Delivery System. As such, the lot
16 numbers could only be obtained from the labels on the empty bottles of drugs that were placed on
17 the pharmacy shelf after the ADD's were replenished.

18 **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

19 **(Compounding of Drug Products Without Master Formula Records;
20 Failure to Complete Compounding Self-Assessment)**

21 85. Respondent Williams is subject to disciplinary action for unprofessional conduct
22 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated provisions of
23 Title 16, CCR, section 1735.2, as follows:

24 a. **Subdivision (d)**: Respondent performed compounding of drug products without
25 preparing written master formula records.

26 b. **Subdivision (h)**: Respondent assigned all compounded drug products an expiration
27 date of one year rather than 180 days from the date the drug products were prepared.

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1 c. Subdivision (j): Respondent failed to complete or have available at the pharmacy a
2 compounding self assessment.

3 **TWENTY-FIFTH CAUSE FOR DISCIPLINE**

4 **(Failure to Maintain Training Records of
5 Pharmacy Personnel Involved in Compounding)**

6 86. Respondent Williams is subject to disciplinary action for unprofessional conduct
7 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
8 section 1735.7, as follows: Respondent performed compounding of drug products without
9 maintaining training records and an on-going competency evaluation process for pharmacy
10 personnel involved in compounding.

11 **TWENTY-SIXTH CAUSE FOR DISCIPLINE**

12 **(Compounding of Drug Products without Master Formula Records
13 and Other Information Required by Law)**

14 87. Respondent Williams is subject to disciplinary action for unprofessional conduct
15 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
16 section 1735.3, subdivision (a), as follows:

17 a. Respondent performed compounding of drug products without maintaining master
18 formula records or written compounding logs.

19 b. Respondent failed to maintain complete compounding records for patients S.D. and
20 A.V. in that the computer records did not include the dates the drug products for each patient
21 were compounded, the identity of the pharmacy personnel who compounded the drug products,
22 the identity of the pharmacist reviewing the final drug products, the manufacturer, the expiration
23 date, or the lot number of each component.

24 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE**

25 **(Failure to Join Board's E-Mail Notification List)**

26 88. Respondent Williams is subject to disciplinary action for unprofessional conduct
27 pursuant to section 4013, subdivision (o), of the Code in that Respondent violated section 4103,
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1 subdivision (a), of the Code, as follows: Respondent failed to join the Board's e-mail notification
2 list.

3 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE**

4 **(Improper Labeling of Compounded Drug Products)**

5 89. Respondent Williams is subject to disciplinary action for unprofessional conduct
6 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
7 sections 1707.5 and 1735.4 regarding the labeling of drug products, as follows:

8 a. **Section 1707.5, subdivision (a)(1)(B)**: Respondent failed to list on the prescription
9 label for the drug product compounded for patient A. V. the strengths of each component used in
10 the compounded medication, as set forth in paragraph 55 above.

11 b. **Section 1735.4**: Respondent failed to list on the prescription label for the drug
12 product compounded for patient S. D. the full name of one of the ingredients used in the
13 compounded medication and used an abbreviation instead, as set forth in paragraph 55 above.

14 **TWENTY-NINTH CAUSE FOR DISCIPLINE**

15 **(Failure to Maintain Written Quality Assurance Plan)**

16 90. Respondent Williams is subject to disciplinary action for unprofessional conduct
17 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
18 section 1735.8, as follows: Respondent failed to maintain a written quality assurance plan for
19 compounded prescriptions.

20 **THIRTIETH CAUSE FOR DISCIPLINE**

21 **(Failure to Maintain a Written Policy and Procedure Manual for Compounding)**

22 91. Respondent Williams is subject to disciplinary action for unprofessional conduct
23 pursuant to section 4301; subdivision (o), of the Code in that Respondent violated Title 16, CCR,
24 section 1735.5, as follows: Respondent failed to maintain a written policy and procedure manual
25 for compounding.

26 **THIRTY-FIRST CAUSE FOR DISCIPLINE**

27 **(Failure to Report Loss of Controlled Substances)**

28 92. Respondent Williams is subject to disciplinary action for unprofessional conduct

1 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
2 section 1715.6, as follows: Respondent failed to report to the Board the burglary or theft of
3 controlled substances from the pharmacy on January 17, 2015, as set forth in paragraph 50 above,
4 within 30 days of the theft.

5 **THIRTY-SECOND CAUSE FOR DISCIPLINE**

6 **(Failure to Comply with Restrictions on Dispensing or Refilling)**

7 93. Respondent Williams is subject to disciplinary action for unprofessional conduct
8 pursuant to section 4301, subdivision (j), of the Code in that Respondent violated Health and
9 Safety Code section 11200, as follows: On and between October 1, 2012 and October 21, 2015,
10 Respondent refilled and dispensed prescriptions for Schedule III to IV controlled substances more
11 than five times or in an amount, for all refills of each prescription taken together, exceeding the
12 120-day supply allowed by law, as set forth in paragraphs 60 and 76 above. As such,
13 Respondent dispensed a total of 5,040 excess dosage units of Schedule III and IV controlled
14 substances to patients.

15 **THIRTY-THIRD CAUSE FOR DISCIPLINE**

16 **(Dispensing Prescriptions Containing Significant Errors, Omissions, Irregularities, etc.)**

17 94. Respondent Williams is subject to disciplinary action for unprofessional conduct
18 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR,
19 section 1761, as follows: Respondent dispensed prescriptions for Schedule II to V controlled
20 substances more than five (5) days before a previously dispensed supply of medication was
21 exhausted, in 170 instances, as set forth in paragraph 61 above. As a result, multiple patients
22 received early fills of their medications and an excess amount of controlled substances.

23 **THIRTY-FOURTH CAUSE FOR DISCIPLINE**

24 **(Excessive Furnishing of Controlled Substances)**

25 95. Respondent Williams is subject to disciplinary action for unprofessional conduct
26 pursuant to section 4301, subdivision (d), of the Code in that Respondent clearly excessively
27 furnished Schedule II to V controlled substances to patients, as set forth in paragraph 94 above.

28 ///

MATTERS IN AGGRAVATION

1
2 96. To determine the degree of discipline to be assessed against Respondents Bob's and
3 Williams, if any, Complainant alleges that on or about September 6, 2012, Inspector W.Y.
4 conducted an inspection of Bob's and found multiple violations of the California Code of
5 Regulations, title 16, and thereafter on or about April 17, 2013, the Board issued the following
6 citations and fines:

7 **Citation and Fine No. CI 2011 52780, issued to Respondent Bob's for violations of:**

8 1. Section 1716 (Respondent deviated from the requirements of a prescription
9 without the prior consent of the prescriber when on or about May 29, 2012, Respondent filled RX
10 #7201699 with hydralazine 25 mg instead of hydroxyzine 25 mg, as prescribed for patient A.L.);

11 2. Section 1711(e) (failure to maintain a quality assurance records for the above
12 medication error);

13 3. Section 1707.2 (failure to provide oral consultation to patient A.L. for a drug that
14 had not been previously dispensed to the patient); and

15 4. Section 1715(a) (failure to complete a Community Pharmacy Self-Assessment).

16 The Board ordered Respondent to pay a fine of \$3,250 by May 17, 2013. Respondent complied
17 with the citation.

18 **Citation and Fine No. CI 2012 56229 issued to Respondent Williams for violations of:**

19 1. Sections 1716 (Respondent deviated from the requirements of a prescription
20 without the prior consent of the prescriber when on or about May 29, 2012, Respondent filled RX
21 #7201699 with hydralazine 25 mg instead of hydroxyzine 25 mg, as prescribed for patient A.L.);

22 2. Section 1711(e) (failure to maintain a quality assurance records for the above
23 medication error);

24 3. Section 1707.2 (failure to provide oral consultation to patient A.L. for a drug that
25 had not been previously dispensed to the patient); and

26 4. Section 1715(a) (failure to complete a Community Pharmacy Self-Assessment).

27 The Board ordered Respondent to pay a fine of \$3,250 by May 17, 2013. Respondent complied
28 with the citation.

PRAYER

1
2 **WHEREFORE**, Complainant requests that a hearing be held on the matters herein alleged,
3 and that following the hearing, the Board of Pharmacy issue a decision:

4 1. Revoking or suspending Pharmacy Permit Number PHY 45272, issued to Bob's
5 Greenley Pharmacy, Inc., doing business as Bob's Greenley Pharmacy;

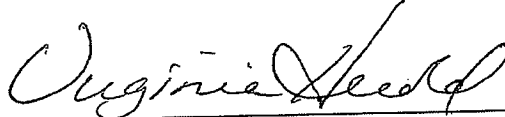
6 2. Revoking or suspending Pharmacist License Number RPH 37271, issued to John
7 Williams, also known as John Robert Williams;

8 3. Ordering Bob's Greenley Pharmacy, Inc., doing business as Bob's Greenley
9 Pharmacy, and John Williams, also known as John Robert Williams, to pay the Board of
10 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
11 Business and Professions Code section 125.3; and

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

13
14 DATED: _____

9/27/16



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

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