# 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

Case No. 5755

AS TO RESPONDENT JOHN ROBERT WILLIAMS ONLY

Respondents.

#### **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 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	
2	KENT D. HARRIS Supervising Deputy Attorney General	
3	STANTON W. LEE  Deputy Attorney General	
	State Bar No. 203563	
4	1300 I Street, Suite 125 P.O. Box 944255	
5	Sacramento, CA 94244-2550 Telephone: (916) 445-9921	
6	Facsimile: (916) 324-5567 E-mail: Stanton.Lee@doj.ca.gov	
7	Attorneys for Complainant	
8	BEFORE T	
9	BOARD OF PHA DEPARTMENT OF CON	SUMER AFFAIRS
10	STATE OF CAL	IFORNIA
11	In the Matter of the Accusation Against: Ca	se No. 5755
12	BOB'S GREENLEY PHARMACY, INC.,	
	dba BOB'S GREENLEY PHARMACY ST	TIPULATED SETTLEMENT AND
13	aka JOHN ROBERT WILLIAMS, RI	SCIPLINARY ORDER AS TO ESPONDENT JOHN ROBERT
14	President/Pharmacist-in-Charge WILLIAMS, Secretary	ILLIAMS ONLY
15	800 Delnero Drive Sonora, CA 95370	
16	Pharmacy Permit No. PHY 45274	
17		
18	and	
19	JOHN ROBERT WILLIAMS 800 Delnero Drive	
20	Sonora, CA 95370	
21	Pharmacist License No. RPH 37271	
22	Respondents.	
23		
24		ED by and between the parties to the above-
25		
26		
27		xecutive Officer of the Board of Pharmacy
28	(Board). She brought this action solely in her offic	ial capacity and is represented in this matter by

4

3

5 6

7

8 9

10 11

12

13 14

15

16 17

18

19 20

21

22

23 24

25

26 27

28

///

#### **CULPABILITY**

- Respondent admits the truth of each and every charge and allegation in Accusation 9. No. 5755.
- Respondent agrees that his pharmacist license is subject to discipline and he agrees to .10. be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

#### CONTINGENCY

- This stipulation shall be subject to approval by the Board of Pharmacy. Respondent 11. understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- The parties understand and agree that Portable Document Format (PDF) and facsimile 12. copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- This Stipulated Settlement and Disciplinary Order is intended by the parties to be an 13. integrated writing representing the complete, final, and exclusive embodiment of his agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

#### DISCIPLINARY ORDER

IT IS HEREBY ORDERED that pharmacist license no. RPH 37271, issued to Respondent John Robert Williams is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

#### 1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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

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

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

## 2. Report to the Board

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

## 3.

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

## 4. Cooperate with Board Staff

Interview with the Board

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

## 5. Continuing Education

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

#### 6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5755 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5755, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5755 in advance

28 | ///

27 |

of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they has read the decision in case number 5755 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

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

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

#### 8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$23,202.75, jointly and severally with Respondent Bob's Greenley Pharmacy, Inc., dba Bob's Greenley Pharmacy. Respondent shall make said payments as according to a payment plan approved by the Board.

///

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

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

#### 9. Probation Monitoring Costs

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

#### 10. Status of License

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

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

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

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

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

Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

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

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

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

#### 13. Tolling of Probation

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

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

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

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

#### 14. Violation of Probation

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

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

## 15. Completion of Probation

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

#### 16. Remedial Education

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to prescription drug abuse and corresponding responsibility. The program of remedial education shall consist of at least 10 hours, which shall be completed in-person. Respondent shall complete at least 10 hours of remedial education prior to resuming practice as a pharmacist. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE)

courses used for license renewal purposes.

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

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

#### 17. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his
supervisor submit notification to the board in writing stating that the supervisor has read the
decision in case number 5755 and is familiar with the required level of supervision as determined
by the board or its designee. It shall be the respondent's responsibility to ensure that his
employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the
board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely
acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that

his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 5755 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

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

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

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

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

## 18. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm,

6

11 12

10

13 14

16 17

15

18

19

20 21

22

23

24

25 26

27

28

partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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

#### **Ethics Course** 19.

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

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

/// ///

///

///

///

/// ///

///

#### ACCEPTANCE I have carefully read the Stipulated Settlement and Disciplinary Order. I understand the 2 stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplin try Order voluntarily, knowingly, and intelligently, and agree to be 4 bound by the Decision and Order of the Board of Pharmacy. 6 7 8 Respondent 9 ENDORSEMENT 10 The foregoing St pulated Settlement and Disciplinary Order is hereby respectfully 11 submitted for consider tion by the Board of Pharmacy. 12 13. Dated: 1/26/17 Respectfully submitted, 14 KATHLEEN A. KENEALY 15 Acting Attorney General of California KENT D. HAKRIS Supervising Deputy Attorney General 16 17 18 Deputy Attorney General 19 Attorneys for Complainant 20 21 22 SA2016100665 23 12554461.doc 24 25

262728

Exhibit A

Accusation No. 5755

		•
1 2 3 4 5	KAMALA D. HARRIS Attorney General of California KENT D. HARRIS Supervising Deputy Attorney General STANTON W. LEE Deputy Attorney General State Bar No. 203563 1300 I Street, Suite 125 P.O. Box 944255 Sacramento, CA 94244-2550 Telephone: (916) 445-9921 Facsimile: (916) 324-5567 Attorneys for Complainant	
8 9	BEFORE BOARD OF PI DEPARTMENT OF CO STATE OF CA	HARMACY ONSUMER AFFAIRS
11	In the Matter of the Accusation Against:	.Case No. 5755
12 13 14 15	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	ACCUSATION
17	Pharmacy Permit No. PHY 45274	
18	and	
19	JOHN ROBERT WILLIAMS 800 Delnero Drive Sonora, CA 95370	
20	Pharmacist License No. RPH 37271	
21 22	Respondents.	
23	Complainant alleges:	
24	·	TIES
25	III	ngs this Accusation solely in her official capacity
26	. 11	
27	Ÿ <b>\</b>	d issued Pharmacy Permit Number PHY 45274 to
29	Poble Greenley Pharmacy, Inc. ("Respondent Bo	b's"), doing husiness as Bob's Greenley

11	
	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	<u>JURISDICTION</u>
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 15	(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
16	(1) Suspending judgment.
17	(2) Placing him or her upon probation.
18	
19	year.
20	(4) Revoking his or her license.
2	(5) Taking any other action in relation to disciplining into the as the
2	Colorate Col
	license by operation of law or by order or decision of the board of a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.
	26
2	28 ///

## 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."

- 11

15.

.23

$_{1}\parallel$	10. Section 4104 of the Code states, in pertinent part:
.	
2	
3	(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or
1	self-use of dangerous drugs, among licensed individuals employed by or with the
	pharmacy.
5	(c) Every pharmacy shall report and provide to the board, within 14 days
6	of the receipt or development thereof, the following information with regard to any licensed individual employed by or with the pharmacy:
7	·
8	(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
	(2) Any admission by a licensed individual of theft, diversion, or self-use
9	of dangerous drugs.
10	(3) Any video or documentary evidence demonstrating chemical, mental,
11	or physical impairment of a licensed individual to the extent it affects his or her
	ability to practice.
12	(4) Any video or documentary evidence demonstrating theft, diversion, or
13	self-use of dangerous drugs by a licensed individual.
14	(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
15	
16	(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs
17	11. Section 4105 of the Code states, in pertinent part:
18	(a) All records or other documentation of the acquisition and disposition
	of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
19	be retained on the licensed premises in a readily retained as a second s
. 20	
21	(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.
22	
23	
24	shall be responsible for a pharmacy's compliance with all state and federal laws and regulations
25	pertaining to the practice of pharmacy.
26	
, 2	$\mathcal{T}^{(1)}$
2	3:    ///
: . <del></del> .	

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). 5 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: ..10 A prescription for a controlled substance shall only be issued for a 11 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 12 dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. 13 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 14 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 15: 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 16 comfortable by maintaining customary use. 17 (Regulatory Provisions) 18 16. Title 16, California Code of Regulations ("CCR"), section 1707.2 states, in pertinent 19 part: 20 (a) A pharmacist shall provide oral consultation to his or her patient or the 21 patient's agent in all care settings: 22 -(1-)-upon-request; or-(2) whenever the pharmacist deems it warranted in the exercise of his or 24 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.
3	(2) When the patient or agent is not present (including but not limited to a 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 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:
10 11	(1) Each of the following items, and only these four items, shall be 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 following order:
12	
13 14	(B) Name of the drug and strength of the drug. For the purposes of this 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 17	pharmacy service and prevent errors.
19 20	(c)(1) Each quality assurance program shall be managed in accordance
2.	
2	in II
## <b>1,2</b>	to develop pharmacy systems and workflow processes designed to prevent medication errors
2	(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative
	7

11	1	·
1		(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created
::::::::::::::::::::::::::::::::::::::		19. Title 16, CCR, section 1714, subdivision (b), states:
5		Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
7	.	20. Title 16, CCR, section 1715.6 states that "[t]he owner shall report to the Board within
8	thirt	(30) days of discovery of any loss of the controlled substances, including their amounts and
9	strer	gths."
10		21. Title 16, CCR, section 1718 states:
11 12		"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
13 14		The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.
15	5	22. Title 16, CCR, section 1735.2 states, in pertinent part:
16	: :   5:    5:	••••
17	]]	(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
18		(1) Active ingredients to be used.
19		(2) Equipment to be used.
20	V	(3) Expiration dating requirements.
2	2	(4) Inactive ingredients to be used.
<del></del>	23	(5)-Process-and/or-procedure-used-to-prepare-the drug
	24	(6) Quality reviews required at each step in preparation of the drug.
	25	(7) Post-compounding process or procedures required, if any.
: 4 <sup>11</sup> .		· · · · · · · · · · · · · · · · · · ·
	26   27   28	(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
\$10 7724	·· ··	a

ii	
1 2	the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
	••••
5 6 7 8 9 10	(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
	23. Title 16, CCR, section 1735.3 states, in pertinent part:
12	
13	include:
14	(1) The master formula record.
15	(2) The date the drug product was compounded.
16	(3) The identity of the pharmacy personnel who compounded the drug
11	7 product.
1	(5) The quantity of each component used in compounding the drug
	product.
2	(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
2	(7) A pharmacy assigned reference or lot number for the compounded
2	drug product.
	(8) The expiration date of the final compounded drug product.
	(9) The quantity or amount of drug product compounded.
	26:
	(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.

1	24. Title 16, CCR, section 1735.4 states, in pertinent part:
3	(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).
4	••••
5	(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.
8	25. Title 16, CCR, section 1735.5, subdivision (a), states:
9 10 11	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.
12	26. Title 16, CCR, section 1735.7 states:
13 14 15	(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.
16 17	(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.
18 19	(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.
20	27. Title 16, CCR, section 1735.8, subdivision (a), states:
21 22	written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug
23	products.
24	28. Title 16, CCR, section 1761 states:
25 26 27	prescriber to obtain the information needed to validate the prescription.
28	

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose. COST RECOVERY Section 125.3 of the Code provides, in pertinent part, that a Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case. DRUG CLASSIFICATIONS "Norco", a brand name for hydrocodone/acetaminophen, is a Schedule III controlled 30. 9 substance pursuant to Health and Safety Code section 11056, subdivision (e)(5). Norco was 10 reclassified as a Schedule II controlled substance pursuant to Title 21, Code of Federal 11 Regulations ("CFR"), section 1308.12, subdivision (b)(1)(vi), effective October 6, 2014. Norco .12 is also a dangerous drug pursuant to Code section 4022 and is used to treat pain. 13 31. "Roxicodone", a brand name for oxycodone, is a Schedule II controlled substance 14 pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M). Roxicodone is also a 15 dangerous drug pursuant to Code section 4022 and is used to treat pain. 16 32. "Soma", a brand name for carisoprodol, is a Schedule IV Controlled Substance 17. pursuant to Title 21, CFR, section 1308.14, subdivision (c)(6). Soma is also a dangerous drug 18 pursuant to Code section 4022 and is used as a muscle relaxant. 19 33. "Ambien", a brand name for zolpidem, is a Schedule IV controlled substance 20 pursuant to Health and Safety Code section 11057, subdivision (d)(32). Ambien is also a 21 dangerous drug pursuant to Code section 4022 and is used to treat insomnia. 22 34. "Ativan", a brand name for lorazepam, is a Schedule IV controlled substance 23 pursuant to Health and Safety Code section 11057, subdivision (d)(16). Ativan is also a 24 dangerous drug pursuant to Code section 4022 and is used to treat anxiety. 25 "Restoril", a brand name for temazepam, is a Schedule IV controlled substance 26 pursuant to Health and Safety Code section 11057, subdivision (d)(29). Restoril is also a 27 dangerous drug pursuant to Code section 4022 and is used to treat insomnia. 28

1

2

4.

6

:8

36. "Klonopin", a brand name for clonazepam, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(7). Klonopin is also a dangerous drug pursuant to Code section 4022, and is used to treat anxiety.  37. "Xanax", a brand name for alprazolam, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is also a dangerous drug pursuant to Code section 4022 and is used to treat anxiety.  38. "Valium", a brand name for diazepam, is a Schedule IV controlled substance pursuant to Code section 4022 and is used to treat anxiety.	
dangerous drug pursuant to Code section 4022, and is used to treat anxiety.  37. "Xanax", a brand name for alprazolam, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is also a dangerous drug pursuant to Code section 4022 and is used to treat anxiety.	
37. "Xanax", a brand name for alprazolam, is a Schedule IV controlled substance  pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is also a dangered drug pursuant to Code section 4022 and is used to treat anxiety.	- 1
pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is also a dangerod drug pursuant to Code section 4022 and is used to treat anxiety.	
drug pursuant to Code section 4022 and is used to treat anxiety.	
20	us
38. "Valium", a brand name for diazepam, is a Schedule IV controlled substance purs	
*	ant
8 to Health and Safety Code section 11057, subdivision (d)(9). Valium is also a dangerous drug	
pursuant to Code section 4022 and is used to treat anxiety.	
39. "Butrans", a brand name for buprenorphine, is a Schedule V controlled substance	
pursuant to Health and Safety Code section 11058, subdivision (d). Butrans is also a dangero	.s
drug pursuant to Code section 4022 and is used to treat pain.	
40. "Adderall", a brand name for amphetamine/dextroamphetamine, is a Schedule II	ļ
controlled substance pursuant to Health and Safety Code section 11055, subdivision (d)(1).	
Adderall is also a dangerous drug pursuant to Code section 4022 and is used to treat ADHD	
(Attention Deficit Hyperactivity Disorder).	
41. "Kadian", a brand name for morphine, is a Schedule II controlled substance pursu	ant
to Health and Safety Code section 11055, subdivision (b)(1)(L). Morphine is also a dangerou	3
drug pursuant to Code section 4022 and is used to treat pain.	
42. "Fioricet with codeine", a brand name for butalbital/acetaminophen/caffeine/cod	ine,
is a Schedule III controlled substance pursuant to Health and Safety Code section 11056,	
subdivision (e)(2). Fioricet with codeine is also a dangerous drug pursuant to Code section 4	)22
and is used to treat headache:	
43. "Tylenol with codeine #4", a brand name for acetaminophen with codeine, is a	
Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdiv	sion
(e)(2). Tylenol with codeine #4 is also a dangerous drug pursuant to Code section 4022 and	.S
used to treat pain.	
28 ///	

- 44. "Cymbalta", a brand name for duloxetine, is a dangerous drug pursuant to Code section 4022 and is used to treat depression.
- 45. "Wellbutrin", a brand name for bupropion, is a dangerous drug pursuant to Code section 4022 and is used to treat depression.
- 46. "Premarin", a brand name for conjugated estrogens, is a dangerous drug pursuant to Code section 4022 and is used to treat postmenopausal osteoporosis.
- 47. "Nuvigil", a brand name for armodafinil, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (f)(3). Nuvigil is also a dangerous drug pursuant to Code section 4022 and is used to treat narcolepsy.

## FACTUAL ALLEGATIONS

- 48. Board Inspector I.T. analyzed CURES (Controlled Substance Utilization Review and Evaluation System) data for Bob's Greenley Pharmacy ("Bob's"), and found that multiple patients had received early fills of their Schedule II to V controlled substance medications from the pharmacy. Further, the pharmacy had refilled numerous prescriptions for Schedule III and IV controlled substances more than five times and in an amount beyond the 120-day supply allowed by law.
- 49. On or about October 21, 2015, Board Inspectors I.T. and S.K. conducted an inspection at Bob's. Pharmacist N.R. met with the inspectors and told them that Respondent Williams ("Williams") was not working that day. Pharmacist N.R. also stated that Williams performs all of the pharmacy's compounding. Inspector I.T. asked Pharmacist N.R. for Bob's compounding self-assessment and DEA Biennial Controlled Substances Inventory. Pharmacist N.R. contacted Williams then told the inspectors that he had not completed a compounding self-assessment in 2015. Pharmacy Technician W. arrived at Bob's and located the biennial inventory. Inspector I.T. asked Pharmacy Technician W. to pull a sample of original hard copy prescriptions for the patients identified during the CURES data analysis, for the period from 2012 to 2015. Pharmacy Technician W. told the inspectors that only two years of hard copy prescription were stored at Bob's and that the prescriptions for the earlier years were stored at

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

- of all generic and brand name hydrocodone/acetaminophen (H/APAP) 10/325 mg, carisoprodol 350 mg and oxycodone 30 mg immediate-release (IR) tablets. Inspector I.T. then obtained a copy of a DEA 106 Report that Bob's had filed on January 22, 2015, following a burglary which occurred during the early morning hours on January 17, 2015. Pharmacy Technician W. stated that the burglars broke in through the vents on the roof, cut the alarm, telephone and computer wires, and stole both controlled and non-controlled medications. Inspector I.T. asked Pharmacy Technician W. if she or Williams reported the loss to the Board and she said "no." The inspectors asked Pharmacist N.R. to show them a random quality assurance report. Pharmacist N.R. stated that she did not know where they were kept and could not immediately retrieve them.
- dispense the most frequently filled medications. The inspectors asked to see the lot numbers and expiration dates of the drugs contained in the ADDS. Pharmacist N.R. stated that the actual lot numbers of the drugs were not kept in the computer system. Pharmacist N.R. explained that they would place the empty bottles which contained the drugs used to fill the ADDS on the shelf after the ADDS were replenished. Pharmacist N.R. claimed that this would allow them to identify the lot number and expiration date of the drugs if necessary. The inspectors expressed their concern that the lot numbers and expiration dates would be lost in the event the empty bottles were accidentally discarded.
- 52. During the inspection, patient H.L. arrived at Bob's to pick up a prescription for Wellbutrin XL 150 mg tablets. H.L. informed clerk Z.Y. that she had never taken the medication before and asked clerk Z.Y. if she could provide her with any paperwork explaining the potential side effects. Clerk Z.Y. did not call Pharmacist N.R. to perform an oral consultation with the patient. Later, patient T.M. picked up a prescription for Premarin 0.9 mg tablets. Clerk M.C. asked patient T.M. if she had any questions for the pharmacist. Patient T.M. stated that she had taken the medication before, but it was in a new strength. Clerk M.C. did not call Pharmacist

U

.7:

...10

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

53. The inspectors learned that Bob's delivered medications to patients who resided

...1

19.

- within approximately a ten mile radius of Sonora. The inspectors looked into a bag which contained medications for delivery to patient C.M. The bag did not contain a written notice of the patient's right to request an oral consultation and a telephone number to call to obtain the consultation. Clerks Z.Y. and M.C. confirmed with the inspectors that this notice was not sent out to patients who received deliveries of medications from the pharmacy.
- 54. Inspector I.T. asked Pharmacist N.R. and Pharmacy Technician W. for all records relating to compounding, including master formulas, compounding logs, compounding policies and procedures, a compounding quality assurance plan, and training records. The pharmacy did not have any of these records with the exception of compounding logs, which were kept electronically on-line for each patient. The inspectors obtained computer print outs of two patient compounding records and copies of prescription labels for patients S.D. and A.V. The compounding records did not show the date the drug products were compounded, the identity of the pharmacy personnel who compounded the drug products, the identity of the pharmacist reviewing the final drug products, the manufacturer, the expiration date, or the lot number of each component.
- show the strength of each drug used in the compounded medication. The prescription label for patient S.D. did not contain the complete name of one of the components used in the compounded medication; the drug lidocaine had been improperly abbreviated as "lido". Inspector I.T. also noted that the expiration dates for both compounded medications were one year from the date the prescriptions were written. Inspector I.T. asked Pharmacy Technician W. if Williams was signed up to receive email notifications from the Board, and she indicated that he was not.

27.

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

- 57. On or about October 27, 2015, Inspector I.T. sent wholesaler Cardinal Health a letter, requesting certified records of any brand and generic H/APAP 10/325 mg, oxycodone 30 mg IR, and carisoprodol 350 mg purchased by or returned from Bob's from February 5, 2015 to October 21, 2015. Cardinal Health provided the records on or about October 29, 2015.
- 58. On or about November 3, 2015, Inspector I.T. received copies of various documents from Williams, including the pharmacy's policy and procedure entitled "Impaired Pharmacist".
- 59. On or about November 5, 2015, Williams provided Inspector I.T. with the pharmacy's computer records of dispensed H/APAP 10/325 mg, oxycodone 30 mg IR, and carisoprodol 350 mg. Inspector I.T. determined based on the biennial inventory, the records from Cardinal Health, the pharmacy's dispensing records, and the count of the stock on hand conducted by Pharmacist N.R. that the pharmacy had a shortage of 182 carisoprodol 350 mg tablets for the period from February 6, 2015 to October 21, 2015. Inspector I.T. also found that the pharmacy had an overage of 125 H/APAP 10/325 mg tablets.
- 60. On and between November 13, 2015 and November 16, 2015, Inspector I.T. received several emails from QS1 Data System containing computer records of all of Bob's dispensed prescriptions from October 1, 2012 to October 21, 2015. Inspector I.T. found that based on the dispensing data and the information from CURES that the pharmacy had refilled and dispensed 105 prescriptions for Schedule III to IV controlled substances more than five times and in an amount, for all refills of each prescription taken together, exceeding the 120-day supply allowed

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

61. Inspector I.T. found in reviewing the CURES data, pharmacy dispensing data, and hard copy prescriptions that Bob's failed to fulfill its corresponding responsibility when it 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. Williams verified and dispensed early fills in 170 instances; Pharmacist C.L. verified and dispensed early fills in 79 instances, and Pharmacist N.R. verified and dispensed early fills in 42 instances.

## Causes for Discipline as to Respondent Bob's Greenley Pharmacy

#### FIRST CAUSE FOR DISCIPLINE

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

62. Respondent Bob's 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, CCR, section 1714, subdivision (b), resulting in a shortage of 182 carisoprodol 350 mg tablets.

## SECOND CAUSE FOR DISCIPLINE

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

- 63. Respondent Bob's is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated sections 4081, subdivision (a), and 4105, subdivisions (a) and (c), of the Code as follows:
- a. On and between February 6, 2015 and October 21, 2015, Respondent failed to maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in a shortage of 182 carisoprodol 350 mg tablets and an overage of 125 hydrocodone/acetaminophen 10/325 mg tablets.

.26

27

-28

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

#### THIRD CAUSE FOR DISCIPLINE

## (Failure to Provide Oral Consultation to Patients)

- 64. 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 1707.2, subdivisions (a)(1) and (2) and (b)(1)(A) and (B), as follows:
- a. On or about October 21, 2015, Respondent's licensed pharmacist, Pharmacist N.R. failed to provide oral consultations to patients H.L. and T.M., as set forth in paragraph 52 above.
- b. Respondent failed to provide patients, who received their medications by delivery service, with a written notice of their right to request an oral consultation from a pharmacist and a telephone number to call to obtain the consultation.

## FOURTH CAUSE FOR DISCIPLINE

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

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

## FIFTH CAUSE FOR DISCIPLINE

## (Failure to Comply with Quality Assurance Program)

66. 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 1711, as follows: Respondent failed to have immediately available for inspection, the pharmacy's quality assurance review records.

///

1	maintaining training records and an on-going competency evaluation process for pharmacy	i
2	personnel involved in compounding.	
3	NINTH CAUSE FOR DISCIPLINE	
4	(Compounding of Drug Products without Master Formula Records 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.	
41	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	1 4 the let 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	Respondent failed to join the Board's e-mail notification	n
: 2	list.	
2		
2	3" ///	
2	4 ///	
7	11/ <sub>25</sub> ///	
	26. ///	
	27 . ///	
	28 ///	
• · · •	$\Pi$	

1		
2.		
3		
4	1	pι
. 2		S
1 2 3 4 5 6 7 8 9 10 11 12 14 15 15 15 20 20 20 20 20 20 20 20 20 20 20 20 20		
7		la
Q	$\ $	la tl
0	.	
9 .:::-::	.	
10		p
11		C
12	╢	
12	·	
13		
14		
15		]
16	;	,
17		;
	7 3	
Τζ	5	
19	)	
20	5	
2 2	1	
2	2	
2	~ 	
2	<u>ح</u>	
2	4	
2 2 2 2 2 2	1 2 3 4 .5	
. 2	6	
2 2	7	-
	· (	

#### ELEVENTH CAUSE FOR DISCIPLINE

## (Improper Labeling of Compounded Drug Products)

- 72. 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, sections 1707.5 and 1735.4 regarding the labeling of drug products, as follows:
- a. <u>Section 1707.5, subdivision (a)(1)(B)</u>: Respondent failed to list on the prescription label for the drug product compounded for patient A.V. the strengths of each component used in the compounded medication, as set forth in paragraph 55 above.
- b. <u>Section 1735.4</u>: Respondent failed to list on the prescription label for the drug product compounded for patient S.D. the full name of one of the ingredients used in the compounded medication and used an abbreviation instead, as set forth in paragraph 55 above.

## TWELFTH CAUSE FOR DISCIPLINE

## (Failure to Maintain Written Quality Assurance Plan)

73. 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 1735.8, as follows: Respondent failed to maintain a written quality assurance plan for compounded prescriptions.

## THIRTEENTH CAUSE FOR DISCIPLINE

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

74. 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 1735.5, as follows: Respondent failed to maintain a written policy and procedure manual for compounding.

## FOURTEENTH CAUSE FOR DISCIPLINE

## (Failure to Report Loss of Controlled Substances)

75. 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 1715.6, as follows: Respondent failed to report to the Board the burglary or theft of

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

## FIFTEENTH CAUSE FOR DISCIPLINE

## (Failure to Comply with Restrictions on Dispensing or Refilling)

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

Drug/Strength	Excess Dosage Units Supplied
zolpidem 10 mg	570
lorazepam 2 mg	60
temazepam 30 mg	270
carisoprodol 350 mg	1,080
clonazepam 1 mg	90
zolpidem 5 mg	150
alprazolam 0.5 mg	720
lorazepam 0.5 mg	60
temazepam 15 mg	120
hydrocodone/APAP 10/325 mg	3,030
clonazepam 2 mg	120
lorazepam 1 mg	270
diazepam 5 mg	90
hydrocodone/APAP 5/325 mg	420
alprazolam 1 mg .	780

	ı
	ľ
	l
-1	l
•	
2	١
2	١
٥	1
.4	l
. :-	
5	
. نه .	
. 6	
7	
· · '	•
8	
:	
. 9	
10	
. 10	٠
. 11.	:
12	
	:
13	•
. 14	:
	:
16	
17	7
di. Hiligiy	:
18	5
:10	`
. 13	7
···· 2(	)
2	l
	:
2.	2
n	2
1 2 3 4 5 6 7 8 9 10 11 14 15 16 20 2 2 2 2 2	ر
2	4
2( 2 2 2	

.26

27.

28

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,

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

1

27

28

any individual employed by the pharmacy, within 30 days of the receipt or development of the information when, in fact, the information was to be reported within 14 days as required by law.

## TWENTY-SECOND CAUSE FOR DISCIPLINE

## (Failure to Comply with Quality Assurance Program)

83. Respondent Williams 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 1711, as follows: Respondent failed to have immediately available for inspection, the pharmacy's quality assurance review records.

## TWENTY-THIRD CAUSE FOR DISCIPLINE

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

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

## TWENTY-FOURTH CAUSE FOR DISCIPLINE

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

- 85. Respondent Williams is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated provisions of Title 16, CCR, section 1735.2, as follows:
- a. <u>Subdivision (d)</u>: Respondent performed compounding of drug products without preparing written master formula records.
- b. <u>Subdivision (h)</u>: Respondent assigned all compounded drug products an expiration date of one year rather than 180 days from the date the drug products were prepared.

,	compounding self assessment.		
	TWENTY-FIFTH CAUSE FOR DISCIPLINE		
,    1	(Failure to Maintain Training Records of Pharmacy Personnel Involved in Compounding)		
5	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		
0	personnel involved in compounding.		
1			
2	TWENTY-SIXTH CAUSE FOR DISCIPLINE		
13	(Compounding of Drug 1 route to whether the control of the control		
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			
19	and a second sec		
20	A.V. in that the computer records did not include the dates the drug products for each patient		
21			
22	the identity of the pharmacist reviewing the final drug products, the manufacturer, the expiration		
2.	date, or the lot number of each component.		
2	.		
2	T. D. J. F. Moil Notification List)		
2	88. Respondent Williams is subject to disciplinary action for unprofessional conduct		
. 2	pursuant to section 4013, subdivision (o), of the Code in that Respondent violated section 4103,		
2	28 ///		

Subdivision (j): Respondent failed to complete or have available at the pharmacy a

c.

subdivision (a), of the Code, as follows: Respondent failed to join the Board's e-mail notification list. TWENTY-EIGHTH CAUSE FOR DISCIPLINE (Improper Labeling of Compounded Drug Products) Respondent Williams is subject to disciplinary action for unprofessional conduct 5 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated Title 16, CCR, sections 1707.5 and 1735.4 regarding the labeling of drug products, as follows: Section 1707.5, subdivision (a)(1)(B): Respondent failed to list on the prescription 8 label for the drug product compounded for patient A. V. the strengths of each component used in the compounded medication, as set forth in paragraph 55 above. 10 Section 1735.4: Respondent failed to list on the prescription label for the drug 11 product compounded for patient S. D. the full name of one of the ingredients used in the 12 compounded medication and used an abbreviation instead, as set forth in paragraph 55 above. 13 TWENTY-NINTH CAUSE FOR DISCIPLINE 14 (Failure to Maintain Written Quality Assurance Plan) 15 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 1735.8, as follows: Respondent failed to maintain a written quality assurance plan for 18 compounded prescriptions. 19 THIRTIETH CAUSE FOR DISCIPLINE 20 (Failure to Maintain a Written Policy and Procedure Manual for Compounding) 21 Respondent Williams is subject to disciplinary action for unprofessional conduct 22 pursuant to section 4301; subdivision (o), of the Code in that Respondent violated Title 16, CCR, 23 section 1735.5, as follows: Respondent failed to maintain a written policy and procedure manual 24 25 for compounding. THIRTY-FIRST CAUSE FOR DISCIPLINE 26 (Failure to Report Loss of Controlled Substances) 27 Respondent Williams is subject to disciplinary action for unprofessional conduct 28 92.

26

27

28

///-

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

## THIRTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Comply with Restrictions on Dispensing or Refilling)

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

## THIRTY-THIRD CAUSE FOR DISCIPLINE

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

94. Respondent Williams 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 dispensed prescriptions for Schedule II to V controlled substances more than five (5) days before a previously dispensed supply of medication was exhausted, in 170 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.

## THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

95. Respondent Williams 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 94 above.

SA2016100665

25

26

27

1

2

6