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

In the Matter of the Petition for Early Termination of Probation by:

PACIFIC WEST PHARMACY, Petitioner

Case No. 5745

OAH No. 2020090404

DECISION

This matter was heard by video conference before a quorum of the Board of Pharmacy (Board) in Sacramento, California, on September 17, 2020. Marcie Larson, Administrative Law Judge, Office of Administrative Hearings (OAH), presided at the hearing.

Summer Haro, Deputy Attorney General, appeared pursuant to Government Code section 11522.

Nicholas Jurkowitz, Attorney at Law, represented petitioner Pacific West Pharmacy (Pacific or petitioner) and Arthur Whitney, President and Chief Executive Officer (CEO) of Pacific, who was present at the hearing. Evidence was received, the record was closed, and the matter was submitted for decision on September 17, 2020,

FACTUAL FINDINGS

Background and Procedural History

- 1. On December 16, 1994, the Board issued Pacific, Pharmacy Permit No. PHY 40592 (permit), with Mr. Whitney as president and 38 percent shareholder of Pacific. Pacific's permit is valid and will expire on December 1, 2020, unless renewed or revoked.
- 2. On July 30, 2016, complainant Virginia K. Herold, a former Executive Officer for the Board, issued an Accusation against petitioner, other officers of Pacific, and the pharmacist in charge (PIC) of Pacific. Complainant alleged that an inspection of Pacific conducted in October and November 2015 revealed petitioner engaged in violations of the Business and Professions Code sections 4301, subdivisions (j) and (o); 4115, subdivisions (a) and (f)(1); 4081, subdivision (a); and 4015, subdivision (o), for allowing unsupervised pharmacy technicians to fill prescriptions, compound sterile prescription preparations, and stock and pull drugs from stock for prescriptions. Complainant further alleged petitioner failed to properly maintain the facilities to comply with safety and security requirements which resulted in significant shortages and overages of controlled substances, and failed to maintain an accurate inventory of dangerous drugs and controlled substances.
- 3. On February 4, 2017, Mr. Whitney signed a Stipulated Settlement and Disciplinary Order (Stipulated Settlement) on behalf of Pacific. Mr. Whitney admitted to the truth of every charge and allegation in the Accusation. Petitioner's permit was

revoked. The revocation was stayed and placed on probation for five years, subject to various terms and conditions, including to obey all laws, submit quarterly reports, reimburse the Board \$8,398.69 for investigation and enforcement costs, complete remedial education on topics of inventory control and drug loss, and retain an independent consultant to review pharmacy operations on a monthly basis to ensure compliance with state and federal laws. The Board adopted the Stipulated Settlement, which was effective on September 6, 2017.

Petition for Early Termination of Probation

- 4. On August 22, 2019, petitioner signed and thereafter filed with the Board a Petition for Early Termination of Probation (Petition). Petitioner has not previously applied for termination of probation. In support of the petition, Mr. Whitney submitted detailed information and policies Pacific implemented concerning operational changes made to address the violations identified in the Accusation, and four letters of recommendation. In the Petition, and during testimony at hearing, Mr. Whitney explained the circumstances surrounding the events that gave rise to the discipline imposed on Pacific's permit and the steps he has taken to address those issues and prevent future violations.
- 5. Petitioner is currently in compliance with the terms and conditions of Board probation. Petitioner has completed approximately three years of probation, which is scheduled to end on or about September 6, 2022. The required remedial education has been completed. The investigation and enforcement costs have been paid.
- 6. Mr. Whitney explained that Pacific is a family-owned independent pharmacy he started in 1987. Pacific is a "closed door" pharmacy that only serves

skilled nursing facilities. As of 2015, Pacific had a PIC who had been employed at Pacific for many years. Mr. Whitney explained that during two days in late 2015, Board inspectors conducted an inspection of Pacific. The inspector identified many deficiencies and violations of the Boards laws and regulations. Mr. Whitney realized he had not been monitoring the PIC and assumed the PIC was ensuring Pacific was complying with all the applicable laws and regulation. Upon learning of the violations, Mr. Whitney immediately began making changes and implementing new policies and procedures to correct the violations.

7. The PIC was demoted, replaced, and eventually left Pacific. The pharmacy's current PIC is subject to a quarterly audit to ensure he is complying with his duties. Pharmacy technicians and input clerks' duties are put in writing and all staff were provided notice of their specific duties. Written schedules are created and posted to ensure proper ratios at all times. Mr. Whitney redesigned Pacific's facility to ensure that staff could be viewed and monitored at all times. Cameras were installed throughout the pharmacy so that all areas of the pharmacy can be viewed from the pharmacist station.

A "controlled cage" was installed directly in front of the pharmacist's desk. The cage can only be accessed through an identified card that records the name, time and date of every person who enters the cage. Only a pharmacist may remove any items from the cage, including filling prescriptions. There is also an overhead camera inside the cage that records all activity and can be viewed on a screen in the pharmacy and remotely by Mr. Whitney if he is not at Pacific.

8. Pacific also performs daily reconciliation of controlled substances and weekly inventory reconciliations of at least 15 of the top controlled medications. Yearly controlled inventory is also "reconciled against dispense logs, purchases, hard counts

and wasted documentation." Policies and Procedures were prepared and implemented to detail this process.

- 9. Mr. Whitney took full responsibility for the violations identified by the inspector and set forth in the Accusation. He hired the PIC and trusted he was doing his job. However, Mr. Whitney failed to verify the PIC's activities. Through this experience, Mr. Whitney learned that he must verify his employees are complying with the Boards laws and regulations.
- 10. Mr. Whitney is requesting early termination of Pacific's probation because of the finance loss it has sustained as a result of the probationary status. Within one year of probation, MedImpact, a pharmacy benefit manager (PBM), cancelled a contract with Pacific because of the probation status. At the time, Pacific had a contract with a skilled nursing home to provide services to all of their eligible clients. As a result, Pacific is still providing medication to MedImpact patients at the contracted facilities, even though Pacific is not reimbursed for the medications. This resulted in a \$18,000 loss per month since the contract was cancelled by MedImpact. Mr. Whitney is concerned that additional PBM's will cancel Pacific's contracts as well. If that occurs Pacific may not be able to stay in business.

Recommendations

11. Pursuant to Business and Professions Code section 4309, subdivision (b)¹ petitioner submitted two letters of recommendation from individuals licensed by the

The petition shall state any facts required by the Board, and the petition shall be accompanied by two or more verified

¹ Business and Professions Code section 4309, subdivision (b), provides:

Board and two letters of recommendation from private citizens. All of the authors are aware of the disciplined imposed on Pacific's permit. The authors of the letters describe Mr. Whitney as a dedicated businessman who cares for his customers and patients. For example, a letter written by Alex Cavalari, Pharm.D., who serves as the PIC consultant for Pacific, explains that since the discipline of Pacific's permit, Mr. Whitney has instituted significant changes and improvement to Pacific to address the violations identified by the Board. Dr. Cavalari opined that Pacific made the "necessary changes to ensure the safety of the public and to provide higher quality and better care to their patients."

Two letters are written by individuals who have known Mr. Whitney for over 40 years. They describe Mr. Whitney as a person who is passionate about his business, with a high level of integrity and commitment to his community. Harold Burton, M.D., wrote that Mr. Whitney is a "tremendous advocate for the patient and their overall health" and always strives to "do the right thing for the patient."

Analysis

12. Petitioner has completed three years of Board probation. Before Pacific's permit was placed on probation, Mr. Whitney undertook extensive changes to address the violations identified by Board inspectors. Many of the violations were addressed

recommendations from holders of licenses issued by the Board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the Board and the activities of the petitioner since the disciplinary penalty was imposed.

before Pacific's probation started in September 2017. The changes and improvements Mr. Whitney implemented have more than addressed the public safety concerns identified by the Board and went beyond the Board's expectation for ensuring compliance with the Board's laws and regulations.

13. When all the evidence is considered, no further public interest will be served by continuing petitioner on probation at this time. Mr. Whitney demonstrated that Pacific can operate as a pharmacy without restrictions, and without harm to the public.

LEGAL CONCLUSIONS

- 1. In a proceeding for reinstatement of a license, including early termination of probation, the burden at all times is on the petitioner to establish rehabilitation. (See *Flanzer v. Board of Dental Examiners* (1990) 220 Cal.App.3d 1392, 1398, citing *Housman v. Board of Medical Examiners* (1948) 84 Cal.App.2d 308, 315.) The standard of proof is clear and convincing evidence to a reasonable certainty. (*Hippard v. State Bar* (1989) 49 Cal.3d 1084, 1091-1092; *Feinstein v. State Bar* (1952) 39 Cal.2d 541.)
- 2. Business and Professions Code section 4309, subdivision (d), sets forth the following factors for consideration when the Board reviews a petition for early termination of probation:
 - (1) All the activities of the petitioner since the disciplinary action was taken.
 - (2) The offense for which the petitioner was disciplined.

- (3) The petitioner's activities during the time the license was in good standing.
- (4) The petitioner's documented rehabilitative efforts.
- (5) The petitioner's general reputation for truth and professional ability.
- 3. When all the relevant rehabilitation criteria set forth in Business and Professions Code section 4309, subdivision (d), are considered, Mr. Whitney established that it would be consistent with the public health, safety and welfare to terminate Pacific's probation.

ORDER

The petition for early termination of probation of Pacific West Pharmacy, Pharmacy Permit No. PHY 40592, is GRANTED.

This Decision shall become effective at 5:00 p.m. on December 15, 2020. It is so ORDERED on January 14, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

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By

Greg Lippe Board President

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

In the Matter of the Accusation Against:

PACIFIC WEST PHARMACY, INC.
ARTHUR C. WHITNEY, PRESIDENT/SHAREHOLDER
HELEN S. WHITNEY, SEC./TREAS./SHAREHOLDER
HORIZON WEST, INC., SHAREHOLDER
TOM ROGERS aka THOMAS STEVEN ROGERS,
PHARMACIST-IN-CHARGE
4363 Pacific Street
Rocklin, CA 95677

Pharmacy Permit No. PHY 40592

Case No. 5745

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO PACIFIC WEST PHARMACY, INC.

Respondent.

DECISION AND ORDER

The attached Stipulated Settlement 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 September 6, 2017.

It is so ORDERED on August 7, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D.

Board President

1	XAVIER BECERRA Attorney General of California			
2	JANICE K. LACHMAN			
	Supervising Deputy Attorney General JEFFREY M. PHILLIPS			
3	Deputy Attorney General State Bar No. 154990			
4	1300 I Street, Suite 125 P.O. Box 944255			
5	Sacramento, CA 94244-2550			
6	Telephone: (916) 324-6292 Facsimile: (916) 327-8643			
7	Attorneys for Complainant	Attorneys for Complainant		
8	BEFORE THE			
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS			
-	STATE OF	CALIFORNIA		
10	In the Matter of the Accusation Against:	Case No. 5745		
11	PACIFIC WEST PHARMACY, INC.	STIPULATED SETTLEMENT AND		
12	ARTHUR C. WHITNEY, PRES./SHAREHOLDER	DISCIPLINARY ORDER AS TO		
13	HELEN S. WHITNEY, SEC./TREAS./SHAREHOLDER	PACIFIC WEST PHARMACY, INC.		
14	HORIZON WEST, INC., SHAREHOLDER TOM ROGERS aka THOMAS STEVEN	•		
15	ROGERS, PHARMACIST-IN-CHARGE			
16	4363 Pacific Street Rocklin, CA 95677			
17	Pharmacy Permit No. PHY 40592			
18	Respondent.	,		
19				
20	IT IS STIPULATED AND AGREED by	and between the parties to the above-entitled		
21	proceedings that the following matters are true:			
22	<u>PARTIES</u>			
23	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy			
24	(Board). She brought this action solely in her official capacity and is represented in this matter by			
25	Xavier Becerra, Attorney General of the State of California, by Jeffrey M. Phillips, Deputy			
26	Attorney General.			
27	2. Respondent Pacific West Pharmacy,	Inc. (Respondent) is represented in this		
28	proceeding by attorney Gregory Matzen, whose address is: 2104 Big Sandy Court, Gold River,			
]	•		

CA, 95670.

3. On or about December 16, 1994, the Board issued Pharmacy Permit No. PHY 40592 to Pacific West Pharmacy, Inc. (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5745, and will expire on December 1, 2017, unless renewed.

JURISDICTION

- 4. Accusation No. 5745 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on August 12, 2016. Respondent timely filed its Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 5745 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5745. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 5745.

10. Respondent agrees that its Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

RESERVATION

11. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

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

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15. 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 ORDERED that Pharmacy Permit No. PHY 40592 issued to Respondent Pacific West Pharmacy, Inc. is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

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

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

- an arrest or issuance of a criminal complaint for violation of any provision of the

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

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

2. Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of

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delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

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

4. Cooperate with Board Staff

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

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of \$8,398.69. Respondent owner may make said payments in a payment plan approved by the Board. There shall be no deviation from the payment plan absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

6. Probation Monitoring Costs

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

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. License Surrender While on Probation

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

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

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

those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

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

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

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements

under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

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

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

13. Completion of Probation

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

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14. Remedial Education

Respondent shall provide an appropriate program of remedial education to all pharmacist employees consisting of six (6) hours on the topics of inventory control and drug losses. This program shall be approved by the Board prior to its implementation. The program of remedial education shall consist of at six (6) hours total, for each pharmacist employees, which shall be completed at respondent's own expense and completed for all employees within the first three (3) months of probation. 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.

15. Consultant Pharmacist Review of Pharmacy Operations

During the period of probation, respondent shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

<u>ACCEPTANCE</u>

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

1	Board of Pharmacy.		
2			
3	DATED: 2/4/17 authorities		
4	PACIFIC WEST PHARMACY, INC. Respondent		
5			
6	I have read and fully discussed with Respondent Pacific West Pharmacy, Inc. the terms and		
7	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order		
8	I approve its form and content.		
9	11 / AAT/		
10	DATED: 2/3/17		
11	GREGORY MATZEN /		
12			
13	ENDORSEMENT		
14	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully		
15.	submitted for consideration by the Board of Pharmacy.		
16			
17	Dated: 2/6/17 Respectfully submitted,		
18	XAVIER BECERRA		
19	Attorney General of California JANICE K. LACHMAN		
20	Supervising Deputy Attorney General		
21	Der franches		
22	JEFFREY M. PHILLIPS Deputy Attorney General		
23	Attorneys for Complainant		
24			
25			
26	SA2016100465 Stipulation.rtf		
27			
28			
11			

Exhibit A

Accusation No. 5745

1	KAMALA D. HARRIS		
2	Attorney General of California JANICE K. LACHMAN		
3	Supervising Deputy Attorney General JEFFREY M. PHILLIPS		
4	Deputy Attorney General State Bar No. 154990		
5	1300 I Street, Suite 125 P.O. Box 944255 Sacramento, CA 94244-2550		
6	Telephone: (916) 324-6292 Facsimile: (916) 327-8643		
7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 5745	
12	PACIFIC WEST PHARMACY, INC. ARTHUR C. WHITNEY, PRES./SHAREHOLDER		
13	HELEN S. WHITNEY, SEC./TREAS./SHAREHOLDER HORIZON WEST, INC., SHAREHOLDER	ACCUSATION	
14	TOM ROGERS aka THOMAS STEVEN ROGERS, PHARMACIST-IN-CHARGE		
15	4363 Pacific Street Rocklin, CA 95677		
16	Pharmacy Permit No. PHY 40592		
17	and		
18	THOMAS STEVEN ROGERS		
19	20291 Rim Rock Court Foresthill, CA 95631		
20 21	Pharmacist License No. RPH 30137		
22	Respondents.		
23	Complainant alleges:		
24	PARTIES		
25	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity		
26	as the Executive Officer of the Board of Pharmacy ("Board"),	Department of Consumer Affairs.	
27	2. On or about December 16, 1994, the Board issued	Pharmacy Permit Number PHY	
28	40592 to Pacific West Pharmacy, Inc. ("Respondent Pacific W	est Pharmacy" or "Pacific West	
	1		
ļ	(PACIFIC WI	EST PHARMACY, INC.) ACCUSATION	

STATUTORY AND REGULATORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part: 2 3 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 4 not limited to, any of the following: 5 6 (i) The violation of any of the statutes of this state, or any other state, or 7 of the United States regulating controlled substances and dangerous drugs. 8 9

- (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 4115 of the Code states:
- (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
- 9. Section 4023.5 of the Code states that "direct supervision and control' means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist."
- 10. Title 16, California Code of Regulations, section 1793.2 defines "nondiscretionary tasks," as used in Business and Professions Code section 4115, as:
 - (a) removing the drug or drugs from stock;
 - (b) counting, pouring, or mixing pharmaceuticals;
 - (c) placing the product into a container;
 - (d) affixing the label or labels to the container;
 - (e) packaging and repackaging.

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11. 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 . . .

12. Section 4105, subdivision (a), of the Code states:

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.

- 13. 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."
 - 14. Section 4115 of the Code states, in pertinent part:
 - (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
 - (d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
 - (f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an

inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

- (2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117 . . .
- 15. Title 16, California Code of Regulations ("CCR"), section 1714 states, in part:
- (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy...
- 16. Title 16, CCR, section 1718 states:

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

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

- 17. Title 16, CCR, section 1793.7 states, in pertinent part:
- (a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
- (b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
- (e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients . . .

COST RECOVERY

18. Section 125.3 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

- 19. "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 used to treat anxiety.
- 20. "Soma", a brand name for carisoprodol, is a Schedule IV Controlled Substance pursuant to Title 21, Code of Federal Regulations ("CFR"), section 1308.14, subdivision (c)(6). Soma is used as a muscle relaxant.
- 21. "Norco", a brand name for hydrocodone/acetaminophen (APAP), was a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e). Norco was reclassified as a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12, effective October 6, 2014. Norco is used to treat pain.
- 22. "Dilaudid," a brand name for hydromorphone, is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(J). Dilaudid is used to treat pain.
- 23. "Ativan," a brand name for lorazepam, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(16). Ativan is used to treat anxiety.
- 24. "Dolophine", a brand name for methadone, is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c)(14). Dolophine is used to treat pain.
- 25. "Roxanol", a brand name for morphine sulfate, is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(L). Roxanol is used to treat pain.

- 26. "Percolone" and "Roxicodone" are brand names for oxycodone. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M). Percolone and Roxicodone are used to treat pain.
 - 27. All of the above controlled substances are dangerous drugs pursuant to section 4022.

STATEMENT OF FACTS

- 28. On or about October 15, 2015, Board Inspector S. K. went to Pacific West Pharmacy to conduct an inspection. The pharmacy was not open for walk-in retail business as it provided services to skilled nursing and assisted living facilities. The pharmacy maintained Talyst Automated Drug Delivery Systems (ADDS) and emergency kits (E-kits) in some of the facilities they serviced. Upon arrival, there was only one pharmacist on duty and in the building, Respondent Thomas Rogers, the pharmacist-in-charge (PIC). Pharmacist K. D. arrived later during the inspection. There was a closed door labeled "IV Room" near the front of the pharmacy. Inspector S. K. opened the door and observed pharmacy technician (TCH) C. Y. filling and compounding sterile prescription preparations in the room. There was no one else in the room, and there were no unobstructed windows on the walls nor a window in the door.
- 29. Inspector S. K. went to the main pharmacy area and observed: TCH P. P. filling and labeling prescriptions, TCH Y. Y. filling prescriptions, TCH K. B. pulling drugs from stock for prescriptions and filling prescriptions, and TCH D. L. handling controlled substances and other drugs. D. L. was organizing controlled substances and putting them away on the drug stock shelves. PIC Rogers was in the main pharmacy area during the inspection.
- 30. Inspector S. K. went into an open, separate room in the rear of the main filling area and observed TCH R. B. filling cells with drugs for the ADDS. There was no one else in the room. There was no door on this room.
- 31. PIC Rogers provided various documents to Inspector S. K., including inventories of controlled substances conducted by the pharmacy on October 1, 2015 through October 5, 2015. Inspector S. K. reviewed the pharmacy's invoices and found that they purchased controlled substances from Cardinal Health ("Cardinal"), ParMed, and ANDA, Inc. ("ANDA").

- 32. Upon completion of the inspection, Inspector S. K. issued an inspection report and provided PIC Rogers with a copy. Inspector S. K. requested that PIC Rogers provide complete records of all acquisitions and dispositions of all controlled substances from December 13, 2013 to October 4, 2015, other than from Cardinal, ParMed, and ANDA. The 2013 and 2014 controlled substance inventories did not include a count of controlled substances in the ADDS and E-kits. PIC Rogers stated that these controlled substances were stored at the off site facilities in the ADDS and E-kits in order to provide emergency access to medications needed by patients. Inspector S. K. requested an accounting of all controlled substances which were not on the premises during the previous inventories.
- 33. On or about October 21, 2015, Inspector S. K. received the pharmacy's dispensing data and the 2013 and 2014 offsite inventory information.
- 34. On or about October 22, 2015, Inspector S. K. sent Cardinal/ParMed and ANDA letters, requesting records of all Schedule II to V controlled substances sold to Pacific West Pharmacy from December 13, 2013 to October 4, 2015, including all credits. ANDA and Cardinal/ParMed provided the information to Inspector S. K. on October 26, 2015 and November 10, 2015, respectively.
- 35. Inspector S. K. conducted an audit based on the 2013 inventory, 2015 inventory, disposition data from Pacific West Pharmacy, and acquisition and credit data from Cardinal/ParMed and ANDA. Inspector S. K. found that the pharmacy had significant shortages and overages of controlled substances from December 13, 2014 to October 4, 2015, as set forth below.
- 36. On or about November 18, 2015, Board Inspector S. K. returned to the pharmacy with Board Inspector J. H. to conduct an inspection and follow up on the audit results. Inspector S. K. found that PIC Rogers was the only pharmacist on duty and in the building. Inspector S. K. observed TCH A. M. pulling drugs for prescriptions from stock and filling prescriptions, TCH's P. P. and Y. Y. filling and labeling prescriptions, and TCH C. Y. compounding sterile prescription preparations.

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FIRST CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law/Pharmacy Technician to Pharmacist Ratio)

37. Respondent Pacific West Pharmacy is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated section 4115, subdivisions (a) and (f)(1), of the Code and Title 16, CCR, section 1793.7, subdivision (b), as follows: On or about October 15, 2015, and November 18, 2015, Respondent authorized or allowed at least four pharmacy technicians to fill prescriptions, compound sterile prescription preparations, stock ADDS', or pull drugs from stock for prescriptions, as set forth in paragraphs 28 - 36, above, when, in fact, Respondent Rogers was the only pharmacist on duty and in the building. Further, Respondent Rogers was not in a position to directly supervise, and/or was not fully aware of, all of the activities of the technicians, who were preparing and dispensing medications.

SECOND CAUSE FOR DISCIPLINE

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

38. Re	spondent Pacific West Pharmacy is subject to disciplinary action for
unprofessional	conduct pursuant to section 4301, subdivisions (o) and (j), of the Code in that on
and between D	December 13, 2013 and October 4, 2015, Respondent failed to maintain the
pharmacy and	its facilities, space, fixtures and/or equipment so that drugs were safely and
properly secure	ed, in violation of title 16, CCR, section 1714, subdivision (b), resulting in
significant sho	rtages and overages of controlled substances, as follows:

Drug	Shortage or Overage
alprazolam 2 mg	-908
carisoprodol 350 mg	-94
hydrocodone/APAP 10/325 mg	-27,980
hydrocodone/APAP 5/325 mg	-10,400
hydrocodone/APAP 7.5/325 mg	-945
hydromorphone 2 mg	-544
lorazepam 0.5 mg	-8,216
lorazepam 1 mg	2,862
methadone 10 mg	507
methadone 5 mg	104
morphine 100 mg/5 ml sol.	-324
oxycodone 10 mg	-715
oxycodone 30 mg	-638
oxycodone 5 mg	-356
oxycodone/APAP 10/325 mg	-2,454
oxycodone/APAP 5/325 mg	-398
Total units unaccounted for by the pharmacy	57,445

THIRD CAUSE FOR DISCIPLINE

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

39. Respondent Pacific West Pharmacy 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, subdivision (o), of the Code as follows: Respondent failed to maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in significant shortages and overages of controlled substances, as set forth in paragraph 38, above.

FOURTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law/Pharmacy Technician to Pharmacist Ratio)

40. Respondent Rogers is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated section 4115, subdivisions (a) and (f)(1), of the Code and Title 16, CCR, section 1793.7, subdivision (b), as follows: On or about October 15, 2015, and November 18, 2015, Respondent authorized or allowed at least four pharmacy technicians to fill prescriptions, compound sterile prescription preparations, stock ADDS', or pull drugs from stock for prescriptions, as set forth in paragraphs 28 - 36, above. Respondent Rogers was the only pharmacist on duty and in the building. Further, Respondent Rogers was not in a position to directly supervise and/or was not fully aware of all of the activities of the technicians, who were preparing and dispensing medications.

FIFTH CAUSE FOR DISCIPLINE

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

41. Respondent Rogers is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivisions (o) and (j), of the Code in that on and between December 13, 2013 and October 4, 2015, Respondent failed to maintain Pacific West Pharmacy, Inc. 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 significant shortages and overages of controlled substances, as set the paragraph 38 above.

SIXTH CAUSE FOR DISCIPLINE

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

42. Respondent Rogers 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, subdivision (o), of the Code as follows: Respondent failed to maintain an accurate or current inventory of all dangerous drugs in Pacific West Pharmacy, Inc., resulting in significant shortages and overages of controlled substances, as set forth in paragraph 38 above.