

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

In the Matter of the Accusation Against:

**CALIFORNIA PHARMACY, INC., DBA
CALIFORNIA PHARMACY**
Pharmacy Permit No. PHY 46209,

and

MARTHA BRODBECK, CEO
Pharmacist-In-Charge
Pharmacist License No. RPH 32870,

Respondents.

Case No. 5615

OAH No. 2016020564

DECISION AFTER RECONSIDERATION

Administrative Law Judge (ALJ) Marilyn A. Woollard, Office of Administrative Hearings, heard this matter on June 20 and October 31, 2016, in Sacramento, California. The matter was submitted to the ALJ on January 16, 2017.

The ALJ issued her Proposed Decision on February 16, 2017, which proposed a stayed revocation, with probationary conditions for five years, for both Pharmacy License PHY 46209, issued to California Pharmacy, and Pharmacist License No 46209, issued to Martha Brodbeck. The Proposed Decision was submitted to the Board of Pharmacy ("Board"). After due consideration thereof, the Board adopted said Proposed Decision on March 21, 2017. Respondent timely requested reconsideration. On April 20, 2017, the Board granted Reconsideration of its March 21, 2017, staying the effective date until it rendered a decision on reconsideration.

On July 28, 2017, the Board issued an Order Fixing Date for Submission of Argument, requiring submissions by August 28, 2017. Written argument was timely received from both parties. In her petition for reconsideration, Respondent Brodbeck requests that the Board reconsider its decision and to modify the terms of her probation as a pharmacist.

The entire record, including written argument, the transcript and exhibits from the hearing having been read and considered, the Board, pursuant to Government Code section 11521, decides:

1. Legal Conclusion 2 on page 22 of the Proposed Decision dated February 16, 2017, is modified to read as follows:

2. *Burden and Standard of Proof*

a. In the part of this proceeding based on the accusation against a pharmacist, the burden of proof is on Complainant to establish alleged violations by “clear and convincing proof to a reasonable certainty.” (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) This means the burden rests on Complainant to establish the charging allegations against a pharmacist by proof that is clear, explicit and unequivocal - so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.)

b. In the part of this proceeding based on the accusation against a pharmacy, the burden of proof remains on Complainant, but the standard of proof is preponderance of the evidence. The pharmacy’s license is not a “professional” license in that there are not extensive education, training and testing requirements to obtain such licensure. (Bus. & Prof. Code § 4113; see also §§ 4101, 4305, 4329 and 4330.) Since it is a nonprofessional license, Complainant must establish cause for discipline against a pharmacy license by demonstrating cause for discipline by a preponderance of the evidence. (*Imports Performance v Dept. of Consumer Affairs, Bur. of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889.)

c. The distinction in the standards of proof between the two license types is unnecessary in this matter, however, because in this action, each violation found was proven by clear and convincing evidence.

2. Legal Conclusion 15 on page 27 of the Proposed Decision dated February 16, 2017, is modified to read as follows:

15. *Appropriate Discipline:*

a. In determining whether to discipline a license, the Board “shall give consideration to evidence of rehabilitation. However, public protection shall take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence.” (Bus. & Prof. Code, § 4313; see also Bus. & Prof. Code, § 4001.1.) Regulations under the Pharmacy Law require that the Board consider the Disciplinary Guidelines (Rev. 10/2007) (Guidelines) in reaching a decision on a disciplinary action under the adjudicatory provisions of the Administrative Procedure Act (Gov. Code § 11400, et seq.) and that deviation from those Guidelines “is appropriate where the Board in its sole discretion, determines that the facts of the particular case warrant such a

deviation – the presence of mitigating factors; the age of the case; evidentiary problems.” (Cal. Code Regs., tit. 16, § 1760.) The Guidelines have been reviewed and considered. When all the evidence is considered, respondents’ licenses shall be revoked, the revocation shall be stayed and the licenses placed on probation for a period of five years, subject to the terms and conditions.

b. Pursuant to Factual Findings 5, 26 through 34, and 41, a term and condition of Respondent Brodbeck’s probation shall include a medical evaluation. The administrative law judge personally heard and observed Respondent’s testimony and concluded that Respondent Brodbeck’s fitness should be evaluated. (Proposed Decision, p. 36, term 15.) Such evaluation is also consistent with Business and Professions Code section 822.

c. The model term from the Guidelines, Tolling of Suspension, is unnecessary since no suspension is ordered. (Proposed Decision, p. 39, term 21.)

d. Other model terms of probation from the Guidelines are appropriate to protect the public and deter Respondent Brodbeck from repeating the unprofessional conduct in the future.

ORDER

With the modifications identified above, the Board hereby adopts the Proposed Decision dated February 16, 2017, as its Decision and Order in this matter. Pharmacist License Number RPH 32870, issued to Martha Brodbeck, and Pharmacy License No. PHY 46209, issued to California Pharmacy, Inc., are hereby revoked, the revocations immediately stayed, and the licenses placed on probation for five (5) years, under the terms and conditions of probation as set forth in the Proposed Decision’s Order, except that Respondent Brodbeck will not be required to comply with proposed term 21 (on page 39) of the Proposed Decision, Tolling of Suspension.

This Decision shall become effective December 28, 2017.

IT IS SO ORDERED this 28th day of November, 2017.



By

Amarylis “Amy” Gutierrez, Pharm.D.
Board President
California State Board of Pharmacy

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

In the Matter of the Accusation Against:

CALIFORNIA PHARMACY,
Pharmacy Permit Number PHY 46209

MARTHA BRODBECK
Pharmacist License Number RPH 32870

Respondents.

Case No. 5615

OAH No. 2016020564

TO ALL PARTIES AND THEIR ATTORNEY OF RECORD:

ORDER SETTING DATE FOR SUBMISSION OF WRITTEN ARGUMENT

The administrative record of the hearing in the above-entitled matter having now become available, the parties are hereby notified of the opportunity to submit written arguments in accordance with the Order Granting Petition for Reconsideration and Stay of Execution of the Effective Date of Decision and Order dated April 20, 2017.

Written argument shall be filed with the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, California, on or before August 28, 2017. **No new evidence may be submitted.**

IT IS SO ORDERED this 28th day of July 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:

CALIFORNIA PHARMACY, INC. DBA
CALIFORNIA PHARMACY
Pharmacy Permit Number : PHY 46209

and

MARTHA BRODBECK, CED and PHARMACIST-
IN CHARGE
Pharmacist License Number RPH 32870

Respondents.

Case No. 5615

OAH No. 2016020564

**ORDER GRANTING
PETITION FOR RECONSIDERATION**

DECISION AND ORDER

Respondent having requested reconsideration of the decision in the above-entitled matter, and good cause appearing, IT IS HEREBY ORDERED:

- (1) That reconsideration be, and is, hereby granted, said reconsideration to be solely on whether to reject the decision and order;
- (2) That the parties will be notified of the date for submission of any oral or written arguments they may wish to submit when the transcript of the above-entitled matter becomes available; and;
- (3) The Decision of the Board in this matter issued on March 21, 2017, is hereby stayed until the Board renders its decision on reconsideration.

The board itself will decide the case upon the record, including the exhibits and oral and written arguments of the parties, without taking additional evidence.

IT IS SO ORDERED this 20th day of April 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation
Against:

CALIFORNIA PHARMACY, INC. DBA
CALIFORNIA PHARMACY

Pharmacy Permit Number: PHY 46209

And,

MARTHA BRODBECK, CEO and PHARMACIST-
IN-CHARGE,

Pharmacist License Number: RPH 32870

Respondent.

Case No. 5615

OAH No. 2016020564

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge 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 April 20, 2017.

It is so ORDERED on March 21, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:

CALIFORNIA PHARMACY, INC. DBA
CALIFORNIA PHARMACY,
Pharmacy Permit Number: PHY 46209

and,

MARTHA BRODBECK, CEO and
PHARMACIST-IN-CHARGE,
Pharmacist License Number: RPH 32870

Respondents.

Case No. 5615

OAH No. 2016020564

PROPOSED DECISION

A hearing convened before Administrative Law Judge Marilyn A. Woollard, Office of Administrative Hearings (OAH), State of California, on June 20, and October 31, 2016, in Sacramento, California.

Stanton W. Lee, Deputy Attorney General, Department of Justice, appeared on behalf of complainant, Virginia Herold, Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

John Edward Brooks, Attorney at Law, appeared on behalf of respondents California Pharmacy, Inc. dba California Pharmacy (Pharmacy) and Martha Brodbeck, Pharmacist-in-Charge (PIC) and Chief Executive Officer (CEO) (PIC Brodbeck).

Oral and documentary evidence was presented. At the conclusion of the evidentiary hearing, the record remained open for written closing arguments. The parties timely filed their closing arguments, which were marked for identification as complainant's Exhibit 29, and respondent's Exhibit L. Complainant did not file reply brief. On January 16, 2017, the record was closed and the matter was submitted for decision.

FACTUAL FINDINGS

1. On August 8, 1979, the Board issued Pharmacist License Number RPH 32870 to PIC Brodbeck. There has been no prior disciplinary action against her license, which is in full force and effect through August 31, 2017.

2. On January 10, 2003, the Board issued Permit Number 46209 to Pharmacy, located at 9550 Micron Avenue, Suite D, in Sacramento, California. PIC Brodbeck has been Pharmacy's CEO and PIC since that date. As PIC, she is "responsible for ensuring [Pharmacy's] compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (Bus. & Prof. Code, § 4036.5.) There has been no prior license discipline against Pharmacy. As of the last hearing date, Pharmacy's license was current through January 1, 2017.

On June 14, 2016, complainant signed a declaration certifying Pharmacy's license history with the Board. This certification reflects that, since January 10, 2003, PIC Brodbeck and two other individuals were each 33 percent shareholders of Pharmacy.

3. *Accusation:* On December 22, 2015, complainant signed an Accusation seeking to discipline respondents' licenses for unprofessional conduct based on their conduct of allegedly taking drugs returned for destruction and repackaging them for sale; acting as a reverse distributor without a license; failing to complete and maintain records as required by federal and state regulations; failing to properly label medications; failing to properly secure controlled substances; failing to properly identify pharmacy technicians (technicians); failing to properly equip the pharmacy with a dedicated sink; and failing to report a change in pharmacy ownership. These charges arose following the Board's random inspection of Pharmacy on November 13 and 14, 2013. Complainant also requested that respondents be ordered to pay the Board's reasonable costs for the investigation and enforcement of this matter.

Respondents filed a Notice of Defense and requested a hearing. The matter was then set for an evidentiary hearing before an Administrative Law Judge of the Office of Administrative Hearings, an independent adjudicative agency of the State of California, pursuant to Government Code section 11500, et seq.

4. At the hearing, respondents did not dispute some of the causes for discipline; i.e., that they had failed: to report change in ownership, to have technicians wear name tags, to equip the pharmacy with a sink; and to have a lock on the controlled substances cabinet. Respondents argued that they quickly remedied these violations. Respondents contest the causes for discipline alleging they engaged in unprofessional conduct by reselling returned medications, acted as an unlicensed reverse distributor for used medications, failed to properly label medications and failed to keep adequate records.

Complainant called Inspector Patricia Jane Peterson as a witness. PIC Brodbeck testified on respondents' behalf and called technicians Ly Minh Le and Judith Enriquez, and

care home manager Emilia Esguerra as witnesses. The testimony of these witnesses is a paraphrased as relevant below. At the conclusion of the hearing, complainant amended the Accusation at paragraphs 44 and 45, by changing the numbers reported in Inspector Peterson's audit as specifically described in Factual Finding 22 below.

5. *Beneficial Ownership:* After obtaining her license in 1979, PIC Brodbeck worked at several retail pharmacies. She was then employed as a pharmacist at Lodi Memorial Hospital (Lodi) and remained in this position over the next 30 years. In 2004, while still employed at Lodi, she became a part-owner of Pharmacy, with another pharmacist and a technician as co-owners.

In 2009, PIC Brodbeck was injured in an automobile accident and "lost blocks of memory." In 2010, after exhausting all of her sick leave, she ended her employment with Lodi and began working full-time at Pharmacy. Over the course of 2013, PIC Brodbeck became Pharmacy's sole owner, buying out her partners' interests in January and September.

PIC Brodbeck never reported the change in Pharmacy's ownership to the Board. She believed such a report was only required if the partners sold the pharmacy to another person. Because the sales transactions were between the original partners, no new owners were brought in, and she remained an owner throughout, PIC Brodbeck believed Pharmacy was not "sold" and that reporting an ownership change was not necessary. She filed a Statement of Information, reflecting this change, with the Secretary of State.

6. *Overview of Pharmacy:* Pharmacy is a closed-door pharmacy that solely services board-and-care homes (care homes). It is not open to the general public, there is no walk-through traffic, and only employees have access to the pharmacy. The front door is locked and visitors must ring a doorbell to gain entry. On entering, the first room (Room 1) is an office and storage area that runs the full length of the premise's storefront. There is a locked door between Room 1 and the back half of the premises, which contains a large "pharmacy area" in the middle and two smaller rooms on either end: Room 2 (to the left), where the technicians work and where controlled substances are stored; and a cove-like break room (to the right), which has a bathroom and an all-purpose sink. Although the back half of the premises (excluding Room 1) is considered by respondents to be the pharmacy, Pharmacy's license covers the entire premises. On May 16, 2003, and October 31, 2006, Pharmacy was inspected by Board Inspector Orlandella, who never raised any concerns about the sink in the break room.

November 13 and 14, 2013 Inspection

7. *Testimony of Patricia Jane Peterson:* Inspector Peterson has been an inspector with the Board for the past three and a half years. Her duties include inspecting pharmacies for compliance with state and federal laws and regulations, and investigating drug diversion and fraud as part of the drug diversion team. Prior to this position, Inspector Peterson was a practicing pharmacist for 30 years, which included 20 years of experience as a PIC. She worked in retail and hospital pharmacies and as a consultant to long-term care,

closed-door pharmacies that handled skilled nursing facilities. As an inspector, she has seen cases in which care homes send medications back to pharmacies, which then re-use and re-bill other patients for improperly stored and adulterated medications. In late 2013, Inspector Peterson was assigned to conduct a routine (non-complaint) inspection of Pharmacy.

8. On November 13, 2013, Inspector Peterson and Inspector Bob Ratcliff conducted an inspection at Pharmacy over the course of more than six hours. On November 14, 2013, Inspector Peterson and Inspector Joseph Wong returned to Pharmacy to conduct an “embargo” of the large quantities of returned and/or outdated over-the-counter (OTC) and dangerous drugs observed in Room 1 the previous day, by sealing and sequestering them to prevent their reuse. By the end of the inspection, there were 18 boxes of drugs sequestered from Room 1 for return to a “reverse distributor,” a licensed entity which receives, inventories, warehouses, and manages the disposition of outdated or nonsaleable dangerous drugs.¹ (Bus. & Prof. Code, § 4040.5.)

9. November 13, 2013: After ringing the bell, the inspectors were allowed into the premises by PIC Brodbeck. On entering, Inspector Peterson noted that Room 1 contained desks on the right and a couch on the left with a table in front of it. The table was stacked with papers and boxes. There were multiple stacks of cardboard boxes to the left of the couch, as well as many brown paper grocery bags. She could see blister cards (also referred to as bubble packs) of medications sticking out of some of the boxes. These are monthly packages of medications that can be punched out for use on a daily basis. PIC Brodbeck explained that Room 1 was her office and the storage room for drugs that were kept in boxes for destruction.

The inspectors next walked through an open doorway into a large room that PIC Brodbeck called the “pharmacy area.” In the breakroom to the right, Inspector Peterson noticed food items on the counter near the sink. When asked whether the breakroom was part of the pharmacy, PIC Brodbeck said it was not, and noted that the sink was used “for everything.” When asked if the pharmacy had a dedicated sink, PIC Brodbeck stated that she did not know this was required.

PIC Brodbeck introduced the inspectors to respondents’ two technicians: Ly Minh Le and Judith Enriquez, neither of whom was wearing a name tag identifying them as such. Inspector Peterson explained that such identification was required even in a closed pharmacy. Several hours later, she noticed the technicians had stickers on their shirts with their names written on them.

10. Inspector Peterson was told that Room 2 was designated as the filling room, where the technicians filled blister packs with medications for delivery to the residents of

¹ “A ‘dangerous drug’ means any drug unsafe for self-use in humans or animals, and includes the following: (a) Any drug that bears the legend: ‘Caution: federal law prohibits dispensing without prescription,’ ‘Rx only,’ or words of similar import.” (Bus. & Prof. Code, § 4022, subd. (a).)

care homes. Pharmacy received most of their prescriptions by fax from the prescribers, and delivered the filled prescriptions to the care homes.

In Room 2, Inspector Peterson observed an unlocked cabinet under the filling counter. PIC Brodbeck stated this was where she always stored Pharmacy's controlled substances, which were kept together, and that she did not order or keep any Schedule II controlled substances. Inside the cabinet, Peterson found two amber bottles/vials labeled as Temazepam 15 mg and Lunesta 2 mg, which are both Schedule III controlled substances. PIC Brodbeck said she did not know where the manufacturers' original stock bottles (stock bottles) for these drugs had gone. When asked to provide a report of Pharmacy's controlled substances prescription refills, which are required within 72 hours of such refill, PIC Brodbeck told Inspector Peterson that she had not been generating these reports. The last such report was dated July 2013, but was unsigned.

11. *Biennial Inventory*: PIC Brodbeck was asked to provide respondents' current biennial inventory of controlled substances. She gave Inspector Petersen a sheet dated July 30, 2012, which was not labeled or titled a "biennial inventory," did not indicate whether the inventory was completed at the open or at the close of business, and did not have a pharmacist's signature, as required by federal regulations. PIC Brodbeck indicated that she counted the drugs "throughout the day" rather than at Pharmacy's opening or closing. Inspector Peterson observed at least three people filling bubble packs at a time, which would make an accurate inventory count very difficult. PIC Brodbeck also indicated that she had completed the inventory and that, because she was the only pharmacist who worked there, she did not need to verify the document. Inspector Peterson later learned, from a license posted on the wall, that Pharmacist Lilly Lowe was employed by respondents on a part-time basis.

12. *CURES*: Inspector Peterson checked the California Controlled Substance Utilization Review and Evaluation System (CURES) from her laptop to see if Pharmacy was reporting its dispensing of Schedule II, III, and IV controlled substances each week as required. PIC Brodbeck reported she had been having problems with her CURES reporting for the past one-and-a-half years, and had contacted Atlantic Associates (Atlantic), the company through which these reports are transmitted, to see if they could give her proof of reporting. Due to these problems, PIC Brodbeck eventually purchased a second computer system for Pharmacy. PIC Brodbeck believed her last CURES transmission was February 28, 2013. She found a binder with these reports and gave it to Inspector Peterson. Its contents reflected that respondents' last CURES transmission was in 2009.

In Inspector Peterson's experience, Atlantic provides an email to the sender which either confirms an accurate CURES transmittal or provides an alert there is an error which needs to be fixed. Respondents did not have any documents from Atlantic. Inspector Peterson requested a CURES record of respondents' transmissions from the Department of Justice (DOJ). This report documented that respondents' last transmitted CURES report was sent on July 28, 2010.

13. *Self-Assessment*: When asked to produce the Self-Assessment PICs are to complete by July 1 of every other year, PIC Brodbeck could only produce a one-page face sheet of an inventory conducted in 2011. She could not find the rest of the Self-Assessment's approximately 33 pages.

14. *Photographs*: Inspector Peterson took numerous photographs of what she observed at Pharmacy during the inspection. Some of the items shown in these photographs include the following:

A. Room 1: This room contained dangerous drugs stored in multiple boxes that were not sealed or secured; numerous blister cards/bubble packs with dangerous drugs tucked back behind the boxes; and a large bag full of medications from Kaiser and other pharmacies, with a note which stated: "E.B.² back-up meds 7/20/13." PIC Brodbeck indicated that she repackaged medications for certain Kaiser patients, but that E.B. was not a Kaiser patient. (Finding 15.) Also depicted were:

- * a Folger's container full of loose pills, plastic bags filled with pills and stock bottles;
- * used blister packs with patient labels and care home names;
- * a large white plastic bag and multiple brown grocery bags full of used bubble packs for patients including M.M., E.B., E.R. and J.M., as well as many amber vials with unidentified tablets inside and incomplete labels. Five of the bags had the names of care homes on the outside of the bag. Only one bag said "return for disposal";
- * many expired OTC drugs, many in amber vials mixed with dangerous drugs, including controlled substances;
- * large containers of mixed pills marked for destruction with no indication where they came from;
- * a large box of empty labeled stock bottles from other pharmacies, which raised Inspector Peterson's concerns about where the medications went and whether they were mixed into Pharmacy's inventory for reuse; and,
- * drugs with dates after 2010, when PIC Brodbeck said she had stopped

² The exhibits in this matter are subject to the February 16, 2017 Protective Order. To protect privacy of patients/care home residents, their initials have been substituted for their full names, which are contained in the February 16, 2017 Order Re: Confidential Names and Confidential Names List.

taking returned medications.

B. Pharmacy Area/Room 2: Room 2 contained numerous unlabeled amber vials/bottles with loose pills in them. Some of the vials had paper wrapped around them; many others were rubber-banded to stock bottles. Inspector Peterson explained that any vials stored with stock bottles are considered to be there for re-use, rather than for destruction, like those in Room 1. If medication is in bottle, it needs to be labeled with the National Drug Code (NDC) which identifies the manufacturer, drug, strength, size of bottle, lot (corresponding to the original stock bottle), and expiration date. Many of the amber vials lacked complete labels. Some of the stock bottles contained pills of different colors, which increased the inspector's suspicion that the technicians were punching out returned pills into the stock bottles for reuse.

In the unlocked controlled substances cabinet, there was an improperly labeled vial of Lunesta and a properly labeled vial of Temazepam. There were no stock bottles to match these drugs, which added to Inspector Peterson's suspicion that they had been punched out from somewhere and put into the vials. There were many such vials in Room 1. On the counter, there was an amber vial with mixed drugs inside and two stock bottles with mixed drugs inside. One was marked "destroy." There were many used blister packs under the counter of the technicians' filling area. Inside the pharmacy area, there was a box that contained a plastic bag of clonazepam .5 mg. for resident V.H. (See Finding 15.)

15. *Repackaging of Medications*: At the request of a care home or resident, pharmacies are authorized to repackage previously dispensed medication for ease of use. (Bus. & Prof. Code, § 4052.7.) PIC Brodbeck showed Inspector Peterson two totes in respondents' pharmacy area which had medication for repackaging one resident's Kaiser prescriptions into blister packs. She did not indicate that respondents kept any medications for repackaging in Room 1. PIC Brodbeck provided respondents' Policies and Procedures (Policies) for repackaging. Respondent's Policies included an incomplete description of what was required to be placed on the label, by failing to include the original prescription number. The labels respondents used for repackaging medications appeared appropriate, except they did not include the name of the original pharmacy and the prescription number. Based on this review, Inspector Peterson concluded that PIC Brodbeck understood she had to log what she received from the original dispensing pharmacy, with the name, address and prescription number of that pharmacy. This constitutes the record of acquisition of the drug to be repackaged. However, when asked for such repackaging acquisition records, PIC Brodbeck stated she had not been completing this log.

There was evidence of inappropriate repackaging. Inspector Peterson saw a baggie of Clonazepam which PIC Brodbeck indicated a care home had asked her to repackage for V.H. PIC Brodbeck indicated that the care home had probably poured the pills into a bag and labeled them. She told Inspector Peterson that she planned to repackage these pills for Mr. H. Inspector Peterson told her that respondents could not take them back for repackaging, because the pills were not returned in their original stock bottle, the source was not identified

and they could not take back controlled substances. The pharmacy had no repackaging records for V.H.

16. *Reverse Distributors:* Inspector Peterson testified that, until 2003, retail pharmacies were allowed to take expired or unused medications back from patients for destruction. Effective 2005, a final Drug Enforcement Administration (DEA) rule required all controlled substances and all dangerous drugs be returned to licensed reverse distributors. Reverse distribution is typically a function performed by wholesalers, but the rule also includes pharmacies.

Pharmacy has never been licensed as a reverse distributor. Without such a license, it is not allowed to accept back medications after they are dispensed and leave the pharmacy. Based on what she observed in Room 1, Inspector Peterson asked PIC Brodbeck if she took return medications from patients. PIC Brodbeck stated that she "used to" accept such returns, but had stopped doing so sometime in 2010. She explained that they still had these returned medications stored in Room 1 for destruction, because the last time she sent medications back for this purpose was in 2005.

Inspector Peterson explained that pharmacies must maintain both acquisition and destruction records. Because respondents had no acquisition logs for the medications returned to them since 2005, there was no way to know what and how many medications had been returned to Pharmacy or to compare what had been returned with what remained of those drugs in November 2013 when they were embargoed for destruction.

17. *Alleged Reuse of Dispensed Medications - Technician's Sworn Statements:* On November 13, 2013, Inspector Peterson observed many unlabeled amber bottles/vials in Room 2. She asked Ms. Enriquez whether she was punching out pills from returned blister cards and putting them into these vials. Ms. Enriquez did not answer but looked at Ms. Le. Inspector Peterson opened a cabinet below the filling counter where she saw many used blister cards, some with prescription labels, some with the labels cut off. All of them appeared to have had the pills punched out. Ms. Peterson could not think of any reason to keep these used packs and became concerned that the technicians were punching out the pills for reuse. She asked them whether "there used to be drugs in these bubble packs?" and they both shook their heads "yes." She asked them if the blister/bubble packs were returned from care homes, and Ms. Enriquez shook her head "yes." She asked whether the technicians had "been taking back drugs from homes when they're not used and putting them in amber vials for reuse?" Ms. Lee answered "yes" and explained that Nicky, respondents' previous technician, had taught the new technicians to punch the pills out, put them in the amber vials and attach them to the stock bottle that matched the medication. Ms. Le said this is what she had been doing. When asked if she had been taught to do this as well, Ms. Enriquez also shook her head "yes."

18. November 14, 2013: On November 14, 2013, Inspector Peterson met with the technicians again. She asked if they would give her a statement about what they discussed the previous day. Ms. Le said she just did not know what to write; Ms. Enriquez, who tended

to defer to Ms. Le, nodded agreement when ask if she felt the same. Inspector Peterson asked them if she could write a statement and if they could review and sign it. They each agreed. Inspector Peterson had already prepared substantially identical draft statements (Statements) for them the night before, using notes from what they had discussed that day. She showed the technicians the draft Statements and asked them to review them. She testified:

I said, I have instructions. I want you to read this. And if there is anything in here that is not true what you said to me, scratch it out. If there is anything in here that you think doesn't sound right or doesn't sound like what you're doing, I want you to tell me and I will get rid of it. Or you can write on there things in your own words. I told them they could do whatever they wanted to.

Inspector Peterson testified that, after they read the Statements, both technicians said the Statements were fine, that they were willing to sign them, and that they did so. Ms. Le then asked Inspector Peterson if it was appropriate for the technicians to change a bubble pack before it leaves the pharmacy by removing a half tablet, placing it in an amber vial and then use the half tab for another patient. Inspector Peterson initially explained that this was fine, as long as the vial was properly labeled. She then sought further clarification from Ms. Le that this was different from what was described in the Statement. Ms. Le confirmed that it was. Ms. Enriquez also acknowledged that she understood Inspector Peterson's explanation. Inspector Peterson testified that, after this exchange, she asked Ms. Le to:

clarify again from the day before why they were punching out the medication. And she said it was explained to her that they were taking back the medication. And that if they didn't reuse it, it was just a waste of money because the pills would just be wasted. So it could be given to somebody else who would use it.

19. Inspector Peterson then gave the Statements to the technicians for review, correction as needed and signature. The technicians wrote the date on which they began working for respondents and dated and signed their respective Statements below the following notation: "I have read the foregoing statement and I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above statement." These Statements were admitted and are considered to the extent allowed by Government Code section 11513, subdivision (d).³ Each 8.5 x 11 inch, typewritten sworn Statement provided as follows:

³ Government Code section 11513, subdivision (d), provides in pertinent part that "hearsay evidence may be used for the purpose of supplementing or explaining other evidence but over timely objection shall not be sufficient in itself to support a finding unless it would be admissible over objection in civil actions"

1. We receive blister cards back from patients who are no longer taking their medications. These patients wanted to give us the medications because they don't need them anymore.
2. I punch out the medications and place in an amber vial.
3. These medications are labeled in the amber vial with the NDC and expiration date.
4. I then rubber band these amber vials with the stock bottle to be dispensed on a future prescription for another patient.
5. I understood I was punching out these medications and re-using them because these medications could be used for other people who needed them.

As discussed below (Factual Findings 23 and 24), both technicians disavowed the substance of these Statements in the testimony, and indicated they felt compelled by Inspector Peterson to sign them.

20. *Drug Audit:* Inspector Peterson selected nine dangerous drugs for audit, which included two Schedule III controlled substances, Temazepam (a benzodiazepine) and Lunesta (a sedative). She chose these particular drugs because she had repeatedly seen them in amber vials or in baggies or, for Temazepam, in amber vials with no corresponding stock bottles. To conduct an audit on these drugs, Inspector Peterson first had Ms. Enriquez help her pull all of the nine drugs that were in respondents' stock to obtain the "on-hand counts." Ms. Enriquez then counted the drugs and Inspector Peterson entered the quantities of each drug counted. PIC Brodbeck told her she had conducted an entire pharmacy inventory at the beginning of 2012. The actual inventory date was December 30, 2011, and Inspector Peterson selected this as the audit's beginning date. The audit's end date was originally November 13, 2013, the date of the on-hand counts, but was later changed to November 14, 2013, because the inspector audited another drug (Fluoxetine 10 mg) on that date.

At the end of the inspection, PIC Brodbeck was asked to provide all her records of acquisition and disposition (drug utilization review or DUR reports), which included all dispensing reports of drugs sold to patients, and all drugs received from respondents' single wholesaler, Cardinal Healthcare (Cardinal). She also requested all records of destruction, even though PIC Brodbeck already indicated she had not destroyed any drugs since 2005.

21. In response, on November 19, 2013, PIC Brodbeck faxed respondents' records of purchase and DURs, showing the number of prescriptions and quantity of tablets dispensed during the audit period. Inspector Peterson also request Cardinal's records of respondents' purchases and returns for the subject drugs during the audit period. Cardinal eventually provided purchase records for eight of the nine drugs audited. They indicated there were no returns of any of the drugs and that they did not sell the audited drug

Levetiracetam, 1,000 ml. to respondents during the audit period. After further inquiry and investigation, Inspector Peterson confirmed that Cardinal had sold respondents this drug, at this strength.

After completion of the audit, there were problems reconciling some of the numbers. Inspector Peterson again asked PIC Brodbeck if she had used any other wholesaler. PIC stated that she could not find any records to support this but that she “must have used somebody else . . .” She was advised to try to locate these records for inclusion in the audit.

22. Inspector Peterson testified that the results of her audit showed that, for six of the nine drugs, “there was a possibility” that respondents’ had sold more drugs than they had purchased. The negative variances determined from the audit indicate that the pharmacy sold more of a particular drug than they purchased from any source. A positive variance indicates that drugs are missing as either stolen or are unaccounted for.

On the last day of hearing, during her rebuttal testimony, Inspector Peterson testified that she had discovered a mathematical error and made corrections to the final audit numbers contained in Table 14 of her Report. These corrections are as follows and the Accusation was amended at Paragraphs 44 and 45 to reflect these corrections. The numbers or words in parenthesis reflect the contents as originally alleged in the Accusation.

A. Paragraph 44: Inspector Peterson prepared the following table reflecting the results of her audit of respondents’ inventory records pertaining to purchase and dispensing quantities:

Drug	Purchase Quantity Report 12/30/11 – 11/13/13	Dispensing Reported
Clozapine (100 mg)	16,200	17,363.5
Paroxetine (40 mg)	4,350 (Unknown)	4,622
Levetiracetam (1,000 mg)	1,380	1,486
Oxcarbazepine (150 mg)	2,600 (2,500)	2,048
Temazepam (15 mg)	2,900 (Unknown)	1,016
Lunesta (2 mg)	520 (500)	560
Clonazepam (.5 mg)	13,500 (26,700)	13,976
Oxcarbazepine (600 mg)	2,600 (2,600)	3,304
Fluoxetine (10 mg)	1,650 (100)	2,048 (1,350)

B. Paragraph 45: Of the nine drugs audited, Inspector Peterson found negative variances in three of the drugs.⁴ This negative variance allegedly indicates sales or billing in excess of the number of drugs actually purchased.

⁴ The Accusation alleges negative variances in six of these drugs; however, based on the amended figures, there were only three negative variances.

Drug	Variance
Clozapine (100 mg)	- 633 (-1,412)
Paroxetine (40 mg)	-441 (+4,791)
Levetiracetam (1,000 mg)	-237 (-247)
Lunesta (2 mg)	+1,870 (-50)
Oxcarbazepine (600 mg)	+376 (-54)
Fluoxetine (10 mg)	+120 (-1,019)

Respondent's Evidence

23. *Testimony of Ly Minh Le:* Ms. Le completed a pharmacy technician program at Consumnes River College (Consumnes) and received her license in 2012. She looked for a job for about a year and a half, and was hired into her first technician job by respondents on August 28, 2013. Ms. Le indicated it was difficult finding a job as a technician. When she arrived, Ms. Enriquez trained her to fill the bubble packs.

Ms. Le recalled meeting Inspector Peterson on November 13, 2013. Ms. Le was not wearing a nametag, and gave Inspector Peterson her name and license number. They did not discuss anything else, and Inspector Peterson did not ask her any questions. Ms. Le met with Inspector Peterson again on November 14, 2013, and she remembered signing a Statement that day. After reviewing her Statement on the witness stand, Ms. Le indicated that she did not write the Statement. She received it already typed up by Inspector Peterson, who asked her to sign it. Ms. Le testified that she did not read the Statement before she signed it. She felt she “was under a lot of pressure to sign” the Statement. She reiterated that “I don’t remember what I signed,” but agreed that the signature on the Statement looks like her signature.

Ms. Le disagreed with the contents of the Statement. She testified that, when patients want to give medications back to Pharmacy, “we tell them we can’t accept any medications.” She would provide them a piece of paper which gave the place and locations for medication “take backs.” From the time she began working for respondents through the end date of the inspection, Ms. Lee never saw any drugs being taken back from patients by anyone at Pharmacy. She denied punching out medications and placing them in amber vials, and clarified that “those vials were there before I got there.” She never personally did this; never personally rubber banded any such vials to stock bottles; and she has never taken medications out of the vials to dispense to a patient. She disagreed with Statement No. 5, because “we don’t reuse medications.”

Ms. Le agreed that Pharmacy does take medications from Kaiser for one patient and repackages that medication into blister packs. She is responsible for repackaging one patient’s medication, which is kept in a clear plastic tote in the pharmacy area, near the bathroom wall. Ms. Le has seen used blister packs within the pharmacy room. There have been times when medication is prepared in a blister pack and the medication changes before

it leaves the pharmacy. In those situations, she would reverse the original medication, cut open the back of the blister pack to remove the medication that is being changed, return it to its original bottle and then fill the blister pack with the correct medication prior to dispensing it. This procedure applies to whole or half tablets. She does not place the returned medication into amber vials.

24. *Testimony of Judith Enriquez:* Ms. Enriquez earned an Associates Degree in science (pharmacy technician program) from Consumnes in May 2012, became licensed the next month, and was hired as a technician by respondent in February 2013. PIC Brodbeck trained Ms. Enriquez in what Pharmacy does; essentially, by showing her how to fill prescriptions in blister packs. At the time of her hire, "Nicky" was another technician on staff. She left within a few months and was replaced by Ms. Le. Within a few months after Ms. Enriquez began, PIC Brodbeck hired a part-time pharmacist, Lilly Lowe, who worked on Thursdays and Fridays for a few months. Ms. Lowe was still employed at the time of the inspection.

Ms. Enriquez testified that, on November 13, 2013, Inspector Peterson came into Room 2 and asked her questions about the blister packs "and that was it." Ms. Le was there at the time, but she was facing the other way "working on her stuff." Ms. Enriquez recalled that Inspector Peterson was at Pharmacy for more than six hours that day, and that their conversation in Room 2 lasted less than five minutes. On November 14, 2013, Inspector Peterson called Ms. Enriquez aside for: "just like 30 seconds. Just basically for a signature and that was it." She did not recall what she signed. After reviewing her Statement at the hearing, Ms. Enriquez identified her signature, and the dates of employment and of execution on the Statement. Ms. Enriquez did not remember that what she signed was a "whole piece of paper." She believed it was half the paper that Inspector Peterson "just made me sign." Ms. Enriquez did not read the Statement before signing it because Inspector Peterson "basically just called—called me and then basically said sign and that was it." She then asked Ms. Enriquez to call Ms. Le over to sign.

Ms. Enriquez testified that she felt "forced" to sign the Statement. On the first day of the inspection, Inspector Peterson was using a very loud voice. Ms. Enriquez thought she "was screaming" and she was accusing PIC Brodbeck. The next day, Ms. Enriquez was "kind of scared." When told to sign the paper, Ms. Enriquez was concerned about her own license and did not know what to expect. Ms. Enriquez still works for respondents. She admitted she was nervous about giving any testimony that would show respondents in a bad light. Ms. Enriquez acknowledged that she and Ms. Le had discussed their recollections of the inspection before testifying.

Ms. Enriquez disagreed with the contents of the Statement. She testified that it was not true that they received bubble/blister packs of unused medications from patients, and she did not recall talking to Inspector Peterson about punching out returned medications for re-dispensing. She explained to Inspector Peterson that they do punch out medications from bubble packs, but do not accept bubble packs in return "because we know it's a rule against the pharmacy . . ." She described situations where medications would be punched out of

blister packs. This occurs frequently with psychiatric patients who often have changes in medication dosage. Before the medications leave the pharmacy, the technicians punch the medications out and return them to their stock bottles. This never occurs after the medications leave the pharmacy. Ms. Enriquez denied saying anything to Inspector Peterson about No. 2 through 4 in her Statement, regarding amber vials. She explained that Inspector Peterson was just looking around in the pharmacy and saw those vials with the stock bottles.

Ms. Enriquez clarified that the technicians actually do not “punch” the medications out – they cut the back of the blister packs and often use tweezers to extract the pills which can be small. They then place a white sticker over the cut out portion with their name, so it is clear who corrected the medication in the blister pack. She recognized photographs of blister packs that were used and partially destroyed which were kept in a cabinet under the technician’s filling station in Room 2. On rare occasions, the technicians would cut an unused strip from these blister packs, fill it with a patient’s current medications, seal it and tape the newly filled blister strip to the original blister packs for dispensing. This was often done just to add several days to a medication cycle. Ms. Enriquez did not know where the used blister packs came from. She agreed that the technicians kept a bottle of (antipsychotic) Clozapine in the cabinet under her filling station because it is a “fast mover.” The bottle she kept was similar to a photograph taken during the inspection of an amber vial banded to a Clozapine stock bottle.

Ms. Enriquez agreed that the technicians punch out medications and place them in amber vials, but only because the medications in the vials are from a different manufacturer and cannot be mixed with medications in the stock bottle. They would label the vials with the name of medication, the NDC and lot number. Since the inspection, respondents try to buy from the same manufacturer “so we have a stock bottle.” She agreed that the medications in the vials could be dispensed in the future, but only if they had not previously been billed for and dispensed. She disagreed with Statement No. 5, about “re-using” medications; this would only occur if the medications had never left the pharmacy.

25. *Testimony of Emilia Esguerra:* Ms. Esguerra has known PIC Brodbeck since 2009, when she worked at the Sean Suh Care Home (Sean Suh) and Selena So’s Care Home (Selena So’s), which are adult residential facilities. She left these jobs the following year. In November 2012, Ms. Esguerra was hired back as house manager at Selena So’s, where both she and her daughter Maria (Kit) Montiel work as caregivers. Their duties include administering prescription medications to residents.

Ms. Esguerra testified that when she returned to work in November 2012, there was “a lot of chaos” because her employer had closed three of his five care homes. Prior staff did not do anything with the residents’ old medications. She and her daughter cleaned out all of the old medications from these homes. Ms. Esguerra was trained by her employer to take expired or unused medications to Pharmacy, after recording that they had been destroyed in the care homes’ centrally stored medication records. When Ms. Esguerra worked at the care homes in 2010, PIC Brodbeck accepted returned medications that were in bubble packs on several occasions, “because they were sealed.”

On June 1, 2016, Ms. Esguerra and Ms. Montiel signed the following letter under penalty of perjury:

Around 9:30 am, September 7, 2013, Me (Emila Esguerra) and my daughter (Maria Montiel) went to California Pharmacy to destruct [*sic*] all unused medications from Selena So & Sean Suh's Care Homes. We met Martha (Pharmacist from Ca Pharmacy) and talked to her regarding these medications. We were all trained to destruct [*sic*] unused or expired medications by returning them to the Pharmacy because we cannot throw them anywhere nor flush them down in the toilet bowl.

We took them there because we believed that it was the right thing to do but Martha said she couldn't take them and she gave us a phone number to call for unused and expired medication disposal. Unfortunately we forgot to take the medications we brought for disposal back with us when we left.

Soon after that, Martha called us that she was cited for the unused medications we forgot to bring back to the care home. . .

In 2013, Ms. Esguerra went to Pharmacy multiple times a month as necessary for her clients when there was a change in prescriptions or a need to pick up a prescription quickly. She recalled telling PIC Brodbeck in September 2013, that "there are several medications here that I need to return. And that she refused to take them . . ." The types of medications returned were antipsychotic medications, mainly from Kaiser which did not, in her experience, take unused medications. During her testimony, Ms. Esguerra indicated that PIC Brodbeck called her a week or so after she dropped the medications off. Ms. Esguerra apologized for forgetting to take them and said she did not want "to put [her] in trouble because of those medications . . ." After the call, Ms. Esguerra didn't get a chance" to get these medications from Pharmacy. She then explained that PIC Brodbeck called her three times about the returned medications: initially, about a week after Ms. Esguerra dropped off them off (September 7, 2013); a second time; and then a third time after the November 13, 2013, inspection.

During her testimony, Ms. Esguerra reviewed a number of photographs of medications in plastic baggies that were found in Room 1 during the November 13, 2013 inspection. She quickly recognized a large white bag containing multiple zip-lock baggies full of medications, with some of her handwriting, as being the bag of medications she left at Pharmacy as described in the letter. She described this bag as being able to fill a banker box with some overlap.⁵ She recognized unused medications in baggies and vials as belonging to

⁵ The parties stipulated that the box she described is 15 inches in length by 12 inches width by 10 in height.

the residents in her homes. She did this, for example, by recognizing: her handwriting on zip-lock medication bags containing Clonazepam from Kaiser, with the initials of the client to whom it belonged; her daughter's handwriting on two of nine unlabeled amber vials; and the initials of certain residents in combination with medications she knew they had taken.

Ms. Esguerra also claimed to recognize unlabeled vials with no identifying handwriting or resident initials as medications she dropped off from her care homes. She explained she could recognize the medications in some of them, and knew they were the same medications taken by some of her residents. For example, after reviewing a photograph of two bottles Adderall and Adderall XR (Schedule II controlled substances), Ms. Esguerra recognized them as leftover medications from one of Sean Suh's residents that she dropped off at Pharmacy. She identified two pills in a vial as being Tylenol from a specific resident which she had personally placed in the vial for destruction. She specifically recognized medications in a Dixie cup with label Loratidine 10 mg, because it was grouped with Lorazepam, Adderall and Clonazepam and one of their clients is taking these medications. When asked if she could remember every pill she had dropped off at Pharmacy, Ms. Esguerra replied "if I see them, yes."

Ms. Esguerra testified that she had created a log of the names of residents whose medications she had dropped off, as well as a log of most of the medications she was returning. When she brought the medications to Pharmacy, she gave PIC Brodbeck a copy of the log, but PIC Brodbeck did not sign it because she refused to take the medication back. These destruction records are at the care homes.

26. *Testimony of PIC Brodbeck:* PIC Brodbeck testified that the name tag requirement for the closed-door pharmacy seemed "almost redundant" because there is only one pharmacist and two technicians and "we know who we are." She described the areas of non-compliance observed during the inspection and noted that she had promptly resolved many of these matters by: having the technicians wear name tags; having the wall between the breakroom and the pharmacy area cut out to make an accessible sink for the pharmacy; and amending the Repackaging Policies. The previous Board inspector had not mentioned either problems with the sink or the controlled substances container. She explained ongoing problems understanding whether CURES reports were transmitted, and her decision to purchase a second computer system in an effort to fix this. She noted her change in practices to prepare and sign the mandated biennial controlled substances inventory. She has changed her previous practice of maintaining a printable report of all combined medications dispensed. Currently, Pharmacy now splits this report into two lists: one for controlled substances and one for all other medications. She explained that she did not update the Board with her ownership status for the reasons expressed above, and because Inspector Peterson told her not to do so during the investigation.

27. PIC Brodbeck testified that 99 percent of respondents' narcotics are in Room 2.⁶ The cabinet has two shelves; the narcotics are placed on the lower shelf or in one of the

⁶ There is a small shelf with narcotic liquids and inhalers in the pharmacy area.

trays inside the cabinet. Most of the narcotics were in their stock bottles; however, there were two amber vials with handwritten labels containing Lunesta and Temazepam.⁷ Shortly after the November 2013 inspection, she put a lock on the narcotics cabinet and she is the only one with a key. While Inspector Peterson thought she could not properly supervise the technicians working near the controlled substances unless she was in Room 2's doorway, PIC Brodbeck testified there is a window between Room 1 into Room 2 which allows her to do so.

28. On November 13, 2013, PIC Brodbeck was asked for but could not locate and provide her self-assessment form completed by July 1, 2013. She felt that Inspector Peterson was accusing her of recycling drugs and was already seeing her as "guilty" shortly after she came into the pharmacy. PIC Brodbeck found the situation to be very intimidating and she was very nervous. She could not locate her current self-assessment and said that she would redo it and she did so. PIC Brodbeck did find the first page of a self-assessment inventory that she had signed on January 7, 2011, during the previous reporting period. She did not recall why she could not locate the remaining 30-some pages of this assessment. Since the inspection, PIC Brodbeck has completed self-assessment, with the most recent period in 2015.

29. PIC Brodbeck agreed that respondents have never been licensed as a reverse distributor at any time. Prior to the inspection in 2013, the last time respondents sent any medications in for destruction was "around 2005." She explained that, in order to return the medications that had accumulated after 2005, she would have had to do an actual inventory of them for destruction. She did not do so because she did not have the time. She had to inventory respondents' active medications. Then in 2009, she had the car accident and afterwards, things "just kind of accumulated." Now, an inventory is not a prerequisite for disposal. Respondents now use Interlink, a reverse distributor which has a disposal service. Every three months, they pick things up, count the medications and provide respondents with a destruction report.

PIC Brodbeck offered photographs showing Room 1's current, well-organized appearance, with boxes placed on shelving. Whereas prior to the inspection, she simply left the expired medications in their stock bottles and other items in Room 1, respondents now use the Interlink automatic process for destroying such medications, which was last completed in October 2016.

30. Regarding repackaging medications, PIC Brodbeck testified that respondents stopped repackaging medications for Sean Suh patients, where V.H. lived in 2012 and had returned all patient medications to this care home. She believed that this bag of medications, which included Clonazepam was then returned to Pharmacy by Ms. Esquerra in September

⁷ PIC Brodbeck explained that these pills were not in the stock bottle because a prescription package had been prepared for a patient, but the dose changed. The stock bottle had been thrown out as empty, so the pills were put into an amber vial for return to stock.

2013. At the time of the inspection, respondents never received Clonazepam and were only repackaging medications for a single patient (A.M.K.) who lived at a different care home. Respondents kept his medication in a separate tub in the pharmacy area to ensure they were not mixed with other patients' medications. Once a month, respondents take his Kaiser medications out of their stock bottles and put them into a bubble pack, with an appropriate and complete label, before returning them to the home for delivery to A.M.K.

31. PIC Brodbeck agreed that a substantial quantity of medication was found in Room 1 for destruction. She testified that, prior to 2010, unused medications could be returned to pharmacies for disposal after a patient died or a medication was no longer necessary. Records of individual drugs were not required as long as the medications were marked "for destruction." The law changed in 2010 and respondents were no longer able to take such medications back. PIC Brodbeck asserted that the medications found by the inspectors in November 2013, had been left there by Ms. Esguerra, even though she was told that respondents could not take them back. These medications were from 2012 and 2013. In addition to these more recently returned medications, the majority of the medications in the 18 embargoed boxes were from respondents' own expired medications.

32. PIC Brodbeck offered the following explanations for some of the items observed by Inspector Peterson that caused her to suspect respondents of reusing medications:

- Respondents keep boxes of empty stock bottles, because they have been broken into twice. As a result, they do not put anything into the trash that identifies the premises as a pharmacy. They will wait until an hour before trash/recycle to put such items in the trash. In addition, there are some "really huge" stock bottles they save to use as a mini- garbage can for pharmaceutical waste for destruction.
- Respondents only use amber vials when the original stock bottles are gone. She agreed that some of the vials had incomplete labels.
- She agreed that the quantity of blister packs found under the counter in Room 2 and photographed was "excessive" and might cause someone to conclude that the pharmacy was recycling medications. The technicians do not do this anymore. The reason for keeping these partially used blister packs is that, "maybe once a month," respondents are asked to make "mini-blister packs" for a resident containing a two-to-three day supply of medications. This might occur if the resident is spending an overnight visit away from the care home or perhaps a longer weekend. Oftentimes, the care homes do not want residents to take all their medications with them on these trips.
- Reviewing larger amber bottles rubber banded to smaller stock bottles of Levetiracetam 1,000 mg tablets, a psychiatric medication, PIC Brodbeck

denied that respondents were recycling these medications. She explained that respondents were just "holding on to" medications prepared for care home patients who suddenly leave, move, go into hospital, or die before the medications are dispensed. Respondents typically hold on to these patients' medications "for a while" to see if the patient surfaces somewhere else in another home. These medications have not been "dispensed" and remain part of respondents' inventory after they reverse the charges. If the stock bottles are gone when this change occurs, the medications are put in a non-stock bottle with a label that is rubber banded to the stock bottle.

- PIC Brodbeck testified that, because respondents do not stock any schedule II drugs, the Adderall in the pictures must have been in the medications returned for disposal by Ms. Esguerra. She only ordered Adderall once for one patient at Sean Suh during respondents' first few months of operation, but never ordered it again.
- Respondents do not stock Dixie cups. The medications found in Dixie cups were also from the medications returned for disposal, which had been placed into the cups for individual patients.

33. PIC Brodbeck questioned the accuracy of Inspector Peterson's audit. Because respondents pre-pack significant numbers of blister packs prior to distribution to care homes, the numbers cannot be accurately counted. Once respondents' computer prints a label for a pre-pack, all of the drugs in that pre-pack are reported as having been dispensed that day, even if the drugs are still in the pharmacy for several more weeks and might change before actually being dispensed. The result is that respondents' inventory appears to be lower than it actually is. She testified that the inventory changes when the label is generated and the client is billed for the medication. She believed Inspector Peterson did not account for the prescriptions that were earmarked as filled and provided photographs of stacks of pre-packed blister cards as an example of how this could affect the count.

34. PIC Brodbeck described her plans for the pharmacy. She is 66 years old and has developed physical problems, which may require double knee replacements. On November 14, 2015, she decided to put Pharmacy up for sale. She entered into a contract with a pharmacy broker for this purpose, and did so one month before she received notice of the Accusation, which was filed in December 2015. If she does not have a pharmacy license, she cannot sell anything. She plans to retire when she turns 67 next year and draw Social Security.

35. *Character References:* PIC Brodbeck submitted nine character reference letters that were admitted and considered to the extent permitted by Government Code section 11513, subdivision (d) (Footnote 3). These letters uniformly describe PIC Brodbeck as a devout woman of good ethics and moral character, who is closely connected to both her church and synagogue and actively engaged in volunteer work, prayer and helping others.

Discussion

36. As discussed above, respondents concede that certain lapses were found during the inspection, which have since been corrected. The critical issue is whether there is clear and convincing evidence that respondents were engaged in a pattern of “dishonesty, fraud, deceit, or corruption” by taking back used medications as an unlicensed reverse distributor and repackaging them for sale to other consumers. Such practice, if true, is a serious violation of the Pharmacy Law that creates a great risk to consumers. A determination of this issue is largely predicated on the credibility of witnesses.

37. Inspector Peterson’s testimony about her discussions with respondents’ technicians Ms. Lee and Ms. Enriquez during the inspection is substantially more credible than that of either of these witnesses. Both technicians were given an opportunity to review their written Statements signed at the time of the inspection. These prior inconsistent statements, signed under penalty of perjury, directly contradict the truthfulness of their testimony. (Evid. Code, § 780.) The testimony of both witnesses was defensive and evasive. Both Ms. Le and Ms. Enriquez testified that they signed these Statements without even reviewing them. While they may well have felt concern when interviewed by an enforcement representative from their own licensing board, their testimony denying that they read the Statements before signing them was not believable. Their denial of the conversation on which the Statements were based and cautionary instructions testified to by Inspector Peterson was similarly not credible. Both witnesses have much to lose: they remain employed by respondents upon whom they rely both for current sustenance and good references for future jobs. By contrast, Inspector Peterson is a peace officer who has no reason to lie about the nature of their encounter. When all the evidence is considered, the sworn Statements signed by these witnesses are more believable than their hearing testimony and fully corroborate Inspector Peterson’s testimony about respondents’ practice of having the technicians punch out used medication for reuse.

Inspector Peterson’s testimony was further supported by the large quantity of drugs maintained in Room 1 for which respondents had no inventory records; the numerous drug bottles from other pharmacies for which respondents’ had no legitimate repackaging purpose; the extensive number of used bubble packs in the Room 2 drawer where the technicians filled prescriptions; the quantity of empty stock bottles which could be used for repackaging; and respondents’ acceptance of returned drugs from Ms. Esguerra as recently as September 2013.

38. The record establishes that a significant quantity of medications (sequestered in 18 boxes) was found in Room 1, and that these medications were completely unaccounted for by acquisition or disposition records created or maintained by respondents. These included medications dated after 2010, when respondents admitted they had stopped their previous practice of accepting medications for destruction from care homes. These post-2010 medications were not persuasively explained by Ms. Esguerra’s testimony that she inadvertently left a single banker’s box full of medication from her employers with

respondents. Ms. Esguerra's testimony was notable for her efforts to protect PIC Brodbeck: by expanding on the number of calls PIC Brodbeck purportedly made to her about the forgotten medication, beyond the single call referenced in her letter; and by identifying all loose, unlabeled or improperly stored medications as part of what she returned, despite the absence of any potentially identifying characteristics. Her testimony in this regard was not credible. On an even more fundamental level, the assertion that Ms. Esguerra accidentally "forgot" and left a large box of used medications inside the closed door pharmacy, whose entry and exit is controlled by respondents, is not credible.⁸

39. It was established by clear and convincing evidence that respondents acted as unlicensed reverse distributors and accepted previously dispensed medications for the purpose of reusing those medications. The extent to which respondents engaged in this unprofessional conduct was not established by clear and convincing evidence. Investigator Peterson's audit figures, both as initially pled in the Accusation and as Amended, do not establish a specific negative variance by clear and convincing evidence. As confirmed in Inspector Peterson's own testimony, the audit results demonstrated "a possibility" that respondents had sold more drugs than they had purchased, in three of the nine drugs audited.

40. Respondents contend that this is, at worse, a case of a disorganized pharmacy which PIC Brodbeck has worked to substantially improve since the inspection, rather than that of willful unprofessional misconduct, and that any discipline must consider the respondents' lack of previous discipline and PIC Brodbeck's positive character references.

41. There are numerous causes for discipline established that are of a lesser severity and which are considered Category I (failure to properly label medications and properly equip pharmacy) or Category II offenses (failure to secure controlled substances and identify technicians). In determining the appropriate discipline, these must be considered with the more serious causes for discipline established, which are considered Category II (unprofessional conduct and unlicensed activity) and Category III (failure to maintain proper records) offenses. PIC Brodbeck has a 30-plus year history of licensure without prior discipline, and there is no prior discipline for Pharmacy. Although she did not raise this as a specific defense, it is noteworthy that PIC Brodbeck apparently suffered injuries during a 2009 accident that left her with significant memory issues. The conditions discovered during the inspection reflected a widespread failure to comply with fundamental record keeping practices, including destruction records, which made it difficult to ascertain the extent of the unprofessional conduct that was established. When all the evidence is considered, respondents' licenses must be revoked, and subject to probationary conditions set forth below. These conditions include that PIC Brodbeck cannot function in the capacity of a pharmacist-in-charge.

⁸ Her testimony that PIC Brodbeck accepted returned medications in bubble packs on several occasions in 2010 "because they were sealed" supports a conclusion that such medications were being reused at that time.

Costs

42. Pursuant to Business and Professions Code section 125.3, subdivision (a), the Board may request an order directing a licensee “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.” A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative “shall be prima facie evidence of reasonable costs of investigation and prosecution of the case.” (Bus. & Prof. Code, § 125.3, subd. (c).)

In support of its request for costs, complainant submitted: (1) her Certification of Costs of Investigation, signed June 14, 2016, reflecting total investigative costs of \$5,913.25; (2) the June 14, 2016, Declaration of Patricia Peterson providing a breakdown of the tasks involved in the 56.25 investigator hours expended in this matter; and (3) the June 14, 2016, Certification of Prosecution Costs: Declaration of Stanton W. Lee. Mr. Lee declared that, as reflected in the DOJ’s “Matter Time Activity by Professional Type,” the DOJ has billed the Board a total of \$11,577.50 for time spent by legal staff on this matter. For the 2015 fiscal year, this reflects a total of 67.75 attorney hours and .5 paralegal hours on the enforcement of this matter.

Based on these documents, complainant’s request for an order for respondents to reimburse the Board a total of \$17,490.75 for its costs of investigative and enforcement is reasonable.

LEGAL CONCLUSIONS

1. The California State Board of Pharmacy is charged with the administration and enforcement of the Pharmacy Law, Business and Professions Code section 4000, et seq. (Bus. & Prof. Code, § 4001.) In exercising its licensing, regulatory, and disciplinary functions, the Board’s highest priority is protection of the public. “Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.” (Bus. & Prof. Code, § 4001.1.)

2. *Burden and Standard of Proof*: In this action to discipline respondents’ licenses, complainant bears the burden of proof on the charges alleged in the Accusation. The standard of proof is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-856.) Clear and convincing evidence means the evidence is “so clear as to leave no substantial doubt” and is “sufficiently strong to command the unhesitating assent of every reasonable mind.” (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co.* (1992) 4 Cal.App.4th 306, 332-333].) If the Board meets its burden, respondents bear the burden of establishing any affirmative defense, including proving rehabilitation. (*Whetstone v. Board of Dental Examiners* (1927) 87 Cal.App. 156, 164.)

As explained below, complainant has met her burden as to all causes for discipline.

3. Business and Professions Code section 4105 provides, in pertinent part, that: (a) “[a]ll 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 (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.” Further, a PIC must, at all times of operation, “be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically” (Bus. & Prof. Code, § 4105, subd. (d)(1).)

4. *First Cause for Discipline - Unprofessional Conduct:* Under Business and Professions Code section 4301, subdivision (f), the Board is required to take disciplinary action against any licensee guilty of “unprofessional conduct,” which includes:

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

When considering specified conduct as a basis for license suspension or revocation, the act must be “substantially related to the qualifications, function or duties of a licensee.” California Code of Regulations, title 16, section 1770, provides that: “a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.”

5. Complainant alleges that respondents engaged in such unprofessional conduct by taking drugs returned for destruction and repackaging them for resale. This conduct, if proved, is substantially related to the qualifications, functions or duties of pharmacy licensees. As set forth in the Factual Findings and Legal Conclusions as a whole, while the exact quantity involved was not established, complainant established that respondents engaged in the repackaging of returned medications for resale by clear and convincing evidence.

6. *Second Cause for Discipline - Unlicensed Reverse Distributors:* A “reverse distributor” means “every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.” (Bus. & Prof. Code, § 4040.5.) “Wholesaler” means and includes a person who acts as a . . . reverse distributor, . . . , who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022 [dangerous drugs].” (Bus. & Prof. Code, § 4043.) A “person shall not act as a wholesaler or third-party logistics provider

of any dangerous drug or dangerous device unless he or she has obtained a license from the board.” (Bus. & Prof. Code, § 4160, (subd. (a).)

7. As set forth in the Factual Findings as a whole, and particularly in Factual Finding 16, complainant met her burden of establishing, by clear and convincing evidence that respondents acted as unlicensed reverse distributors by accepting return medications from board and care homes without a license.

8. *Third Cause for Discipline - Failure to Complete and Maintain Records:*

A. Biennial Inventory: Pursuant to Business and Professions Code section 4081, subdivision (a), “[a]ll records of manufacture and of sale, acquisition, receipt, shipment, 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, third-party logistics provider, pharmacy . . .” The owner of a pharmacy “shall be jointly responsible, with the pharmacist-in-charge . . . for maintaining the records and inventory described in this section.” (Bus. & Prof. Code, § 4081, subd. (b).)

The general requirements for such inventories are itemized in the Code of Federal Regulations. “The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.” (21 C.F.R. § 1304.11, subd. (a).) “After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.” (21 C.F.R. § 1304.11, subd. (c).)

As set forth in Factual Finding 11, on November 13, 2013, respondents had not completed an accurate controlled substances biennial inventory, because the inventory presented did not identify itself as an inventory or identify the contents of the report and it lacked the signature of the pharmacist who completed it. In addition, controlled substance Adderall was observed in the pharmacy but was not listed on the inventory. Complainant established respondents’ violation of Business and Professions Code section 4081 and Code of Federal Regulations, title 21, section 1304.11, by clear and convincing evidence.

B. CURES Reports: The CURES reporting system was established: “for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.” (Health & Saf. Code, § 11165, subd. (a).) For “each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance . . . the dispensing pharmacy . . . shall report” specifically identified information to the Department of Justice “as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice . . .” (Health & Saf. Code, § 11165, subd. (d).)

As set forth in Factual Finding 12, respondents had not submitted any CURES report for transactions between July 28, 2010 and December 31, 2014. Complainant established by clear and convincing evidence that respondents failed to comply with the report requirements of Health and Safety Code Section 11165.

C. Records of Schedule III and IV refills: Pursuant to Code of Federal Regulations, title 21, section 1306.22, subdivision (f)(3), respondents are required to have records of Schedule III and Schedule IV drug refills that are signed, printed and readily retrievable to document such refills within 72 hours. “This printout of the day’s controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill is dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing . . .” (*Ibid.*)

As set forth in Factual Finding 10, respondents were unable to produce a controlled substances print out and PIC Brodbeck admitted she had not generated such a report since July 2013. Complainant established that respondents violated Code of Federal Regulations, title 21, section 1306.22, subdivision (f)(3), by clear and convincing evidence.

D. Self-Assessment by PIC: California Code of Regulations, title 16, section 1715, requires that “the pharmacist-in-charge of each pharmacy . . . shall complete a self-assessment of the pharmacy’s compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.” Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

As set forth in Factual Finding 13, respondents were unable to produce a complete self-assessment form for 2013. Complainant established respondents’ violated California Code of Regulations, title 16, section 1715, by clear and convincing evidence.

9. *Fourth Cause for Discipline – Failure to Properly Label Repackaged Medications*: Business and Professions Code section 4052.7 provides pharmacies with authority to “repackage a drug previously dispensed to the patient or to the patient’s agent pursuant to a prescription.” In order to do so, the pharmacy must have policies and procedures in place for repackaging the prescription, and must label the repackaged prescription container with: “(1) All the information required by Section 4076 [and] (2) [t]he name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.”

Under Business and Professions Code section 4076, each prescription must be correctly labeled with the manufacturer’s trade name of the drug or the generic name and the name of the manufacturer; directions for use; the name of the patient; the name of the prescriber; the date of issue; the names and address of the pharmacy and prescription number; the strength and quantity of the drugs dispensed; the expiration date; the condition

or purpose for which the drug was prescribed; and certain identifying physical descriptions (color, shape or identifying code).

As set forth in Factual Findings 15, repackaged medication discovered during the inspection did not include the name of the original pharmacy and original prescription number. Complainant established that respondents' violated Business and Professions Code section 4052.7, by clear and convincing evidence.

10. *Fifth Cause for Discipline – Failure to Properly Secure Controlled Substances:* California Code of Regulations, title 16, section 1714, subdivision (d), sets forth operational standards and security requirements for pharmacies. It provides that: “[e]ach pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

The federal regulations provide stricter standards for securing controlled substances.

Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. (16 C.F.R. § 1301.75, subd. (b).)

As set forth in Factual Findings 10, respondents failed to securely store their controlled substances by keeping them collected together in an unlocked cabinet. Complainant established respondents' violated California Code of Regulations, title 16, section 1714, subdivision (d), and 16 Code of Federal Regulations, section 1301.75, subdivision (b), by clear and convincing evidence.

11. *Sixth Cause for Discipline – Failure to Properly Identify Technicians:* A pharmacy technician is required to “wear identification clearly identifying him or her as a pharmacy technician.” (Cal. Code Regs., tit. 16, § 1793.7, subd. (c).) As set forth in Factual Finding 9, respondents failed to ensure that their technicians wore identification that clearly identified them as pharmacy technicians. There is no exception for close-door pharmacies. Complainant established that respondents' violated California Code of Regulations, title 16, section 1793.7, subdivision (c), by clear and convincing evidence.

12. *Seventh Cause for Discipline: Failure to Equip Pharmacy with Sink:* “The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.” (Cal. Code Regs., tit. 16, § 1714, subd. (c).)

As set forth in Factual Finding 9, respondents failed to ensure that their pharmacy was equipped with an accessible sink for pharmaceutical purposes. Complainant established that respondents' violated California Code of Regulations, title 16, sections 1714, subdivision (c), by clear and convincing evidence.

13. *Eighth Cause for Discipline: Failure to Report Change in Beneficial Ownership:* Business and Professions Code section 4201, subdivision (j), provides that "any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board."

As set forth in Factual Findings 2 and 5, respondents failed to report a change in PIC Brodbeck's beneficial ownership of Pharmacy. Complainant established that respondents violated Business and Professions Code section 4201, subdivision (j), by clear and convincing evidence.

14. *Laches:* Respondents argue there has been an unreasonable delay in initiating this proceeding, which has caused them prejudice, and that the doctrine of laches applies. (*Gates v. Dept. of Motor Vehicles* (1979) 94 Cal.App.2d 921, 925; *Brown v. California State Personnel Board* (1985) 166 Cal.App.3d 1151.) Laches is established by an unreasonable delay in bringing an action resulting in prejudice to the other party in presenting a defense. (*Id.*) The party asserting laches bears the burden of establishing prejudice; prejudice is never presumed. (*Conti v. Board of Civil Service Commissioners* (1969) 1 Cal.3d 351, 362.)

In this matter, nearly two years elapsed between the inspections (November 13-14, 2013) and the filing of the Accusation (December 22, 2015). Respondents failed to establish that any inordinate or unreasonable delay occurred that would trigger laches.

15. *Appropriate Discipline:* In determining whether to discipline a license, the Board "shall give consideration to evidence of rehabilitation. However, public protection shall take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence." (Bus. & Prof. Code, § 4313.) Regulations under the Pharmacy Law require that the Board consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 10/2007) (Guidelines) in reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.), and that deviation from these guidelines "is appropriate where the Board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems." (Cal. Code Regs., tit. 16, § 1760.) These Guidelines have been reviewed and considered. When all the evidence is considered, respondents' licenses shall be revoked, the revocation shall be stayed and the licenses placed on probation for a period of five years, subject to the terms and conditions set forth below.

16. *Costs:* Pursuant to *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, various factors must be considered in determining the amount of costs to be assessed. The Board must not assess the full costs of investigation and prosecution when to

do so will unfairly penalize a licensee who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed. The Board must consider the licensee's subjective good faith belief in the merits of his or her position, as well as whether the licensee has raised a colorable challenge to the proposed discipline. The Board must determine that the licensee will be financially able to make later payments. Finally, the Board may not assess the full costs of investigation and prosecution when it has conducted a disproportionately large investigation to prove that a licensee engaged in relatively innocuous misconduct.

As discussed in Factual Finding 42, complainant's request that respondent reimburse the Board \$17,490.75 for its costs to investigate and enforce this matter is reasonable. Respondents provided no evidence of any basis to reduce these costs, for which they are jointly and severally liable. Respondents shall be ordered to pay the Board's costs in the total amount of it \$17,490.75, within three years of the effective date of this decision, pursuant to a payment plan approved by the Board.

ORDER

License number RPH 32870, issued to respondent Martha Brodbeck, and Permit Number PHY 46209, issued to respondent California Pharmacy, are hereby REVOKED; however, the revocation is stayed and respondents are placed on probation for five (5) years upon the following terms and conditions:

A. **RESPONDENT CALIFORNIA PHARMACY** is placed on the following standard 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 contendere 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 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 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 Boards monitoring and investigation of respondent's compliance with the terms and conditions of his or her 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 \$17,490.75. Respondent owner shall make said payments as follows: within 3 years of the effective date of this Decision, pursuant to a reasonably payment plan agreed to 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. **RESPONDENT CALIFORNIA PHARMACY IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT BRODBECK, PURSUANT TO ORDER B. 8.**

The filing of bankruptcy by respondent owner shall not relieve respondent of his or her 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 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's license shall be subject to all terms and conditions of this probation not previously satisfied.

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

B. **RESPONDENT MARTHA BRODBECK** is placed on the following standard 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 contendere 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 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. **Interview with the Board:** 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:** 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 or her 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 OAH case number 2016020564 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 or her 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 OAH case number 2016020564, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her 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 or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in OAH case number 2016020564 in advance 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 or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in OAH case number 2016020564 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her 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 \$17,490.75. Respondent shall make said payments as follows: within 3 years of the effective date of this Decision, pursuant to a reasonably payment plan agreed to by the Board. **RESPONDENT BRODBECK IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT CALIFORNIA PHARMACY PURSUANT TO ORDER A.5.**

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 or her 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 or her 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 or her 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. **Medical Evaluation:** Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a pharmacist, the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

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 he or she 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.

16. **Community Services Program:** Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 30 hours per quarter for the first three years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

17. **Remedial Education:** Within sixty (60) 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 Pharmacy Law and recordkeeping. The program of remedial education shall consist of at least 40 hours, which shall be completed within 1 year at respondent's own expense. 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 or her 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.

18. **No Supervision of Ancillary Personnel:** During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.

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

19. **No New Ownership of Licensed Premises:** 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.

20. **Separate File of Records (For pharmacist owners and pharmacists-in-charge):** Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

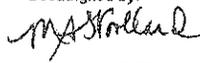
21. **Tolling of Suspension:** During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover,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

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

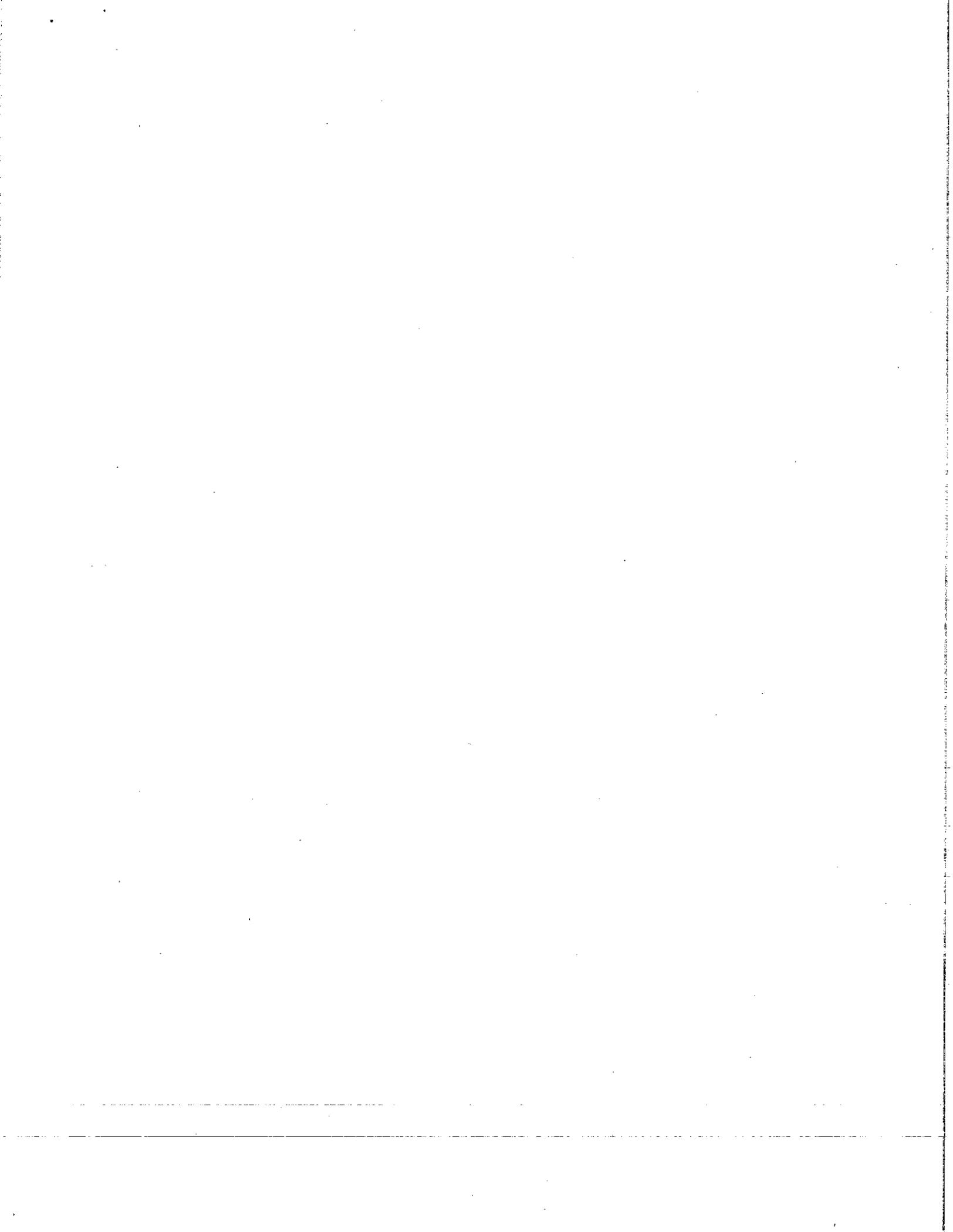
22. **Ethics Course:** Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within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

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

DATED: February 16, 2017

DocuSigned by:

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MARILYN A. WOOLLARD
Administrative Law Judge
Office of Administrative Hearings



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

11 In the Matter of the Accusation Against:

Case No. 5615

12 **CALIFORNIA PHARMACY**
13 **9550 Micron Ave., Ste. D**
14 **Sacramento, CA 95827**

A C C U S A T I O N

15 **Pharmacy Permit Number: PHY 46209**

16 **and**

17 **MARTHA BRODBECK**
18 **3003 Heirloom Way**
Sacramento, CA 95826
Pharmacist-In-Charge

19 **Pharmacist License Number: RPH 32870**

20 Respondents.

21
22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about January 10, 2003, the Board of Pharmacy issued Pharmacy Permit
27 Number PHY.46209 to California Pharmacy, Inc. dba California Pharmacy (the Pharmacy). On
28

1 or about January 10, 2003, Martha Brodbeck, co-owner of the Pharmacy, became the pharmacist-
2 in-charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges
3 brought herein and will expire on January 1, 2016, unless renewed.

4 3. On or about August 8, 1979, the board issued Pharmacist License Number RPH
5 32870 to Brodbeck. The license was in full force and effect at all times relevant to the charges
6 brought herein and will expire on August 31, 2017, unless renewed.

7 **JURISDICTION**

8 4. This Accusation is brought before the Board under the authority of the following
9 laws.

10 **BUSINESS AND PROFESSIONS CODE**

11 5. Section 4006 of the Code states in pertinent part:

12 The board may adopt regulations . . . limiting or restricting the furnishing of
13 a particular drug upon a finding that the otherwise unrestricted retail sale of the drug
14 . . . is dangerous to the public health or safety.

15 6. Section 4022 of the Code states in pertinent part:

16 "Dangerous drug" or "dangerous device" means any drug or device unsafe
17 for self-use in humans or animals, and includes the following:

18

19 (c) Any other drug or device that by federal or state law can be lawfully
20 dispensed only on prescription or furnished pursuant to Section 4006.

21 7. Section 4040.5 of the Code states:

22 "Reverse distributor" mean every person who acts as an agent for
23 pharmacies, drug wholesalers, manufacturers, and other entities by receiving,
24 inventorying, and managing the disposition of outdated or nonsalable dangerous
25 drugs.

26 8. Section 4043 of the Code states, in pertinent part:

27 "Wholesaler" means and includes a person who acts as a wholesale merchant
28 . . . reverse distributor . . . who sells for resale, or negotiates for distribution, or takes
29 possession of, any drug or device included in Section 4022. Unless otherwise
30 authorized by law, a wholesaler may not store, warehouse, or authorize the storage or
31 warehousing of drugs with any person or at any location not licensed by the board.

32 9. Section 4052.7 of the Code states in pertinent part:

33

1 (b) Any pharmacy providing repackaging services shall have in place
2 policies and procedures for repacking these drugs and shall label the repackaged
3 prescription container with the following:

4 (1) All the information required by Section 4076.

5 (2) The name and address of the pharmacy repackaging the drug and the
6 name and address of the pharmacy that initially dispensed the drug to the patient.

7

8 10. Section 4076 of the Code states in pertinent part:

9

10 (5) The date of issue.

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

13

14 11. Section 4081 of the Code states in pertinent part:

15 (a) All records of manufacture and of sale, acquisition, or disposition of
16 dangerous drugs or dangerous devices shall be at all times during business hours
17 open to inspection by authorized officers of the law, and shall be preserved for at
18 least three years from the date of making . . .

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

23

24 12. Section 4160 of the Code states, in pertinent part:

25 (a) A person may not act as a wholesaler of any dangerous drug or
26 dangerous device unless he or she has obtained a license from the board.

27 13. Section 4201 of the Code states in pertinent part:

28

(f) Notwithstanding any other law, the pharmacy license shall authorize the
holder to conduct a pharmacy. The license shall be renewed annually and shall not be
transferrable.

. . . .

(j) For licenses referred to in subdivisions (f) . . . any change in the proposed
beneficial ownership interest shall be reported to the board within 30 days thereafter
upon a form to be furnished by the board.

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14. Section 4300 of the Code states:

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

(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:

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

15. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or 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.

16. 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:

....

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

....

(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

1 pharmacy, including regulations established by the board or by any other state or
federal regulatory agency.

2 (p) Actions or conduct that would have warranted denial of a license.

3

4 17. Section 4332 of the Code states:

5 Any person who fails, neglects, or refuses to maintain the records required
6 by Section 4081 or who, when called upon by an authorized officer or a member of
7 the board, fails, neglects, or refuses to produce or provide the records within a
reasonable time, or who willfully produces or furnishes records that are false, is guilty
of a misdemeanor.

8 18. Section 4342 of the Code states in pertinent part:

9 (a) The board may institute any action or actions as may be provided by law
10 and that, in its discretion, are necessary, to prevent the sale of pharmaceutical
11 preparations and drugs that do not conform to the standard and tests as to quality and
12 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.

13

14 **HEALTH AND SAFETY CODE**

15 19. Section 11165 of the Code states in pertinent part:

16

17 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV
18 controlled substance . . . the dispensing pharmacy, clinic, or other dispenser shall
19 report the following information to the Department of Justice as soon as reasonably
possible, but not more than seven days after the date a controlled substance is
dispensed, in a format specific by the Department of Justice:

20 (1) Full name, address, and, if available, telephone number of the ultimate
21 user or research subject, or contact information as determined by the Secretary of the
United States Department of Health and Human Services, and the gender, and date of
birth of the ultimate user.

22 (2) The prescriber's category of licensure, license number, national provider
23 identifier (NPI) number, if applicable, the federal controlled substance registration
24 number, and the state medical license number of any prescriber using the federal
controlled substance registration number of a government-exempt facility.

25 (3) Pharmacy prescription number, license number, NPI number, and federal
controlled substance registration number.

26 (4) National Drug Code (NDC) number of the controlled substance
27 dispensed.

28 (5) Quantity of the controlled substance dispensed

1 (6) International Statistical Classification of Diseases, 9th revision (ICD-9)
or 10th revision (ICD-10) Code, if available.

2 (7) Number of refills ordered.

3 (8) Whether the drug was dispensed as a refill of a prescription or as a first-
4 time request.

5 (9) Date of origin of the prescription.

6 (10) Date of dispensing of the prescription.

7 20. Section 111395 of the Code states in pertinent part:

8 Any drug is misbranded in any of the following cases:

9

10 (c) The contents of the original package have been, wholly or partly,
removed and replaced with other material in the package.

11 **CALIFORNIA CODE OF REGULATIONS**¹

12 21. Section 1714 of the State Regulations state in pertinent part²:

13

14 (b) Each pharmacy licensed by the board shall maintain its facilities, space,
15 fixtures, and equipment s 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 (c) The pharmacy and fixtures and equipment shall be maintained in a clean
17 and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents
and insects, and properly lighted. The pharmacy shall be equipped with a sink with
18 hot and cold running water for pharmaceutical purposes.

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

22

23 22. Section 1715 of the State Regulations state in pertinent part:

24 (a) The pharmacist-in-charge of each pharmacy as defined under section
25 4029 or section 4037 of the Business and Professions Code shall complete a self-
assessment of the pharmacy's compliance with federal and state pharmacy law. The
26 assessment shall be performed before July 1 of every odd-numbered year. The
primary purpose of the self-assessment is to promote compliance through self-

27 ¹ Hereinafter referred to as "State Regulations."

28 ² All references to the State Regulations are to title 16 unless otherwise noted.

examination and education.

23. Section 1718 of the State Regulations 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 4331. 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.

24. Section 1793.7 of the State Regulations state in pertinent part:

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

CODE OF FEDERAL REGULATIONS³

25. Section 1301.75 of the Federal Regulations state in pertinent part⁴:

(b) Controlled substances listed in Schedule II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of controlled substances.

26. Section 1304.11 of the Federal Regulations state in pertinent part:

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location . . .

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances . . .

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is

³ Hereinafter referred to as “Federal Regulations.”

⁴ All references to the Federal Regulations are to title 21 unless otherwise noted.

1 within two years of the previous biennial inventory date.

2

3 27. Section 1306.22 of the Federal Regulations state in pertinent part:

4

5 (f) As an alternative to the procedures provided by paragraphs (a) through
6 (e) of this section, a computer application may be used for the storage and retrieval of
7 refill information for original paper prescription orders for controlled substances in
8 Schedule III and IV, subject to the following conditions:

9

10 (3) Documentation of the fact that the refill information entered into the
11 computer each time a pharmacist refills an original paper, fax, or oral prescription
12 order for a Schedule III or IV controlled substance is correct must be provided by the
13 individual pharmacist who makes use of such an application. If such an application
14 provides a hard-copy printout of each day's controlled substance prescription order
15 refill data, that printout shall be verified, dated, and signed by the individual
16 pharmacist who refilled such a prescription order. The individual pharmacist must
17 verify that the data indicated are correct and then sign this document in the same
18 manner as he would sign a check or legal documents . . . [t]his document shall be
19 maintained in a separate file at that pharmacy for a period of two years from the
20 dispensing date. This printout of the day's controlled substance prescription order
21 refill data must be provided to each pharmacy using such a computerized application
22 within 72 hours of the date on which the refill was dispensed. It must be verified and
23 signed by each pharmacist who is involved with such dispensing. In lieu of such a
24 printout, the pharmacy shall maintain a bound log book, or separate file, in which
25 each individual pharmacist involved in such dispensing shall sign a statement . . .
26 each day, attesting to the fact hat the refill information entered into the computer that
27 day has been reviewed by him and is correct as shown. Such a book or file must be
28 maintained at the pharmacy employing such an application for a period of two years
after the date of dispensing the appropriately authorized refill.

. . . .

COST RECOVERY

28 28. Business and Professions Code 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.

CONTROLLED SUBSTANCES

1 29. "Restoril," a brand of temazepam, is a Schedule IV controlled substance as designated
2 by Health and Safety Code section 11057, subdivision (d) and Code of Federal Regulations, title
3 21, section 1308.14.

4 30. "Lunesta," a brand of eszopiclone, an isomer of the drug zopiclone, is a Schedule IV
5 controlled substance under Code of Federal Regulations, title 21, section 1308.14.

6 31. "Klonopin," a brand of clonazepam, is a Schedule IV controlled substance as
7 designated by Health and Safety Code section 11057, subdivision (d) and Code of Federal
8 Regulations, title 21, section 1308.14.

BACKGROUND

9
10 32. On November 13, 2013, the California State Board of Pharmacy (Board) conducted a
11 routine inspection of Respondent California Pharmacy (Pharmacy). The inspection was carried
12 out by Board Inspector P.P. who was assisted by Board Inspector B.R. Pharmacist-in-Charge,
13 Respondent Martha Brodbeck (Brodbeck), guided the Board inspectors through their inspection.

14 33. Upon initiation of the inspection, Inspector P.P. entered a room filled with multiple
15 stacks of cardboard boxes. The room was used as an office, storage area for supplies, and for
16 storing medications intended for destruction. Although Brodbeck stated that the Pharmacy
17 stopped taking back medication from patients in 2010, the inspection revealed medication
18 returned to the Pharmacy as recent as 2012 and 2013.

19 34. The Pharmacy had one sink in an employee break room area and it was used for all
20 purposes. The Pharmacy did not have a sink dedicated only for pharmacy use.

21 35. Brodbeck was asked to provide the current biennial inventory of controlled substances
22 for inspection. A form dated July 20, 2012, was produced by Brodbeck but it was not titled or
23 labeled as a biennial inventory, and it did not have a pharmacist's signature on it, nor was there
24 any indication of whether the inventory was taken at the beginning or end of business. Brodbeck
25 indicated that she inventoried the Pharmacy's controlled substances throughout the day and did
26 not verify the inventory because she was the only pharmacist that worked for the Pharmacy.
27

1 During the inspection, Investigator P.P. determined that the Pharmacy also employed a second
2 pharmacist, L.L. on Thursdays and Fridays.

3 36. Inspector P.P. requested to review documentation of the Pharmacy's reporting to the
4 California Controlled Substance Utilization Review and Evaluation System (CURES) and
5 Inspector P.P determined that the Pharmacy and Brobeck had not submitted a CURES report
6 since July 28, 2010.

7 37. Inspector P.P asked Brobeck to produce a record or log to show the drugs taken back
8 from patients. Brobeck admitted to not having any such records claiming she had stopped taking
9 back any drugs in 2010.

10 38. The Pharmacy and Brobeck stored all controlled substance in an unlocked and
11 unsecured cabinet. Inside the cabinet were two amber bottles with the controlled substances
12 temazepam and Lunesta. Brobeck did not know where the stock bottles for the drugs were
13 located and was unable to produce a print out of controlled substances for the Pharmacy.
14 Brobeck admitted she had not generated a controlled substances report since July 2013.

15 39. The Pharmacy and Brobeck stored dangerous drugs in boxes that were neither sealed
16 nor stored in a secured location. Inspector P.P. observed a plastic bag with the drug clonazepam
17 (a schedule IV controlled substance) inside one of the boxes and labeled with the patient name
18 V.H. Brobeck indicated the drugs were to be repackage for the patient, but there were no records
19 or vials indicating patient V.H. was scheduled to have any drugs repacked by the Pharmacy.

20 40. Brobeck was asked to produce a copy of the Pharmacy's self-assessment and she
21 could not produce a self-assessment for 2013.

22 41. Inspector P.P identified medication that was repackaged by the Pharmacy and which
23 did not include the name of the originating pharmacy, lot, identifier, or expiration date. The
24 Pharmacy and Brobeck stored drugs in desk drawers along with partial and halved blister pack
25 cards. Some cards had medication labels while some were had no labels. Pharmacy technicians
26 J.E. and L.L., who lacked proper identification name tags, admitted they were trained by
27 Brobeck to punch out returned medications from bubble and blister packs and to place them in
28 amber vials for subsequent re-sale of the returned medications. During the inspection, multiple

1 stock bottles were observed with a mixture of medications inside as well as multiple empty stock
2 bottles.

3 42. On November 14, 2013, Inspector P.P. and Inspector J.W. returned to Respondent
4 Pharmacy for the purpose of seizing boxes of medications being stored by the Pharmacy in order
5 to prevent the Pharmacy from dispensing returned and outdated dangerous drugs to patients.
6 Inspectors P.P and J.W. observed open Dixie cups with various mixed drugs inside. Inspectors
7 P.P. and J.W. identified a large box of controlled substances and Adderall XR, that the Pharmacy
8 had received as returns, which were not identified in any inventory.

9 43. During the inspection, Inspectors P.P and J.W. observed two bottles of Schedule II
10 drugs that were not on Brodbeck's DEA inventory; amber vials containing a mixture of drugs,
11 some without labels; and a mixture of dangerous drugs being stored in baggies and a Folgers
12 coffee canister.

13 44. Inspector P.P. requested inventory records on nine drugs from Brodbeck which
14 revealed the following purchase and dispensing quantities:

<u>Drug</u>	<u>Purchase Quantity Report for 12/30/11 – 11/13/13</u>	<u>Dispensing Reported</u>
Clozapine (100mg)	16200	17363.5
Paroxetine (40mg)	Unknown	4622
Levetiracetam (1000mg)	1380	1486
Oxcarbazepine (150mg)	2500	2048
Temazepam (15mg)	Unknown	1016
Lunesta (2mg)	500	560
Clonazepam (.5mg)	26700	13976
Oxcarbazepine (600mg)	3100	3304
Fluoxetine (10mg)	100	1350

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1 45. Nine drugs dispensed by the Pharmacy were audited. Of the nine drugs, six drugs had
2 a negative variance, indicating sales/billings in excess of the number of drugs actually purchased.

3 Those drugs included:

<u>Drug</u>	<u>Variance</u>
Clozapine (100mg)	-1412
Paroxetine (40mg)	-4791
Levetiracetam (1000mg)	-247
Lunesta (2mg)	-50
Oxcarbazepine (600mg)	-54
Fluoxetine (10mg)	-1019

11 46. Cardinal Health, a supplier of drugs was contacted and sales and return records of the
12 Pharmacy were requested. Using Cardinal Health records as the baseline for drugs purchased by
13 the Pharmacy, it was determined that the Pharmacy had a significantly high variance of more
14 drugs sold and billed than purchased.

15 47. On November 13, 2013, Brodbeck identified herself as the sole owner of the
16 Pharmacy. Brodbeck produced records to Inspector P.P. demonstrating that ownership interest in
17 the Pharmacy by E.B. and L.S. were sold to Brodbeck in January and September 2013,
18 respectively. Brodbeck failed to report the Board of any changes in ownership.

19 **FIRST CAUSE FOR DISCIPLINE**
20 **(Unprofessional Conduct)**

21 48. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
22 pharmacist license are subject to disciplinary action pursuant to Business and Professions Code
23 section 4301(f) for unprofessional conduct when Respondents took drugs returned for destruction
24 and repackaged them for resale.

25 49. On November 13, 2013 and November 14, 2013, Respondents were found with
26 unlabeled drugs in stock that were not accounted for in purchase records and an audit of
27 Respondent California Pharmacy records resulted in multiple drugs having positive variances

1 indicating more drugs were sold by Respondents than were purchased by Respondent California
2 Pharmacy as described in paragraphs 44-45.

3 50. Pharmacy Technicians J.E. and L.L. admitted to being trained by Respondent
4 Brodbeck to punch out returned medications from bubble and blister packs so the drugs could be
5 resold as described in paragraph 41.

6 51. On November 13, 2013 and November 14, 2013, Board inspectors P.P., B.R., and
7 J.W. observed open and mixed containers of returned drugs, including controlled substances and
8 dangerous drugs, not accounted for in any inventory. These drugs were returned to Respondents
9 for disposal, but Respondents had established a dishonest, fraudulent, and deceitful practice of re-
10 packaging and re-selling the returned drugs to patients rather than properly disposing of them as
11 described in paragraphs 33, 39, and 41-46.

12 **SECOND CAUSE FOR DISCIPLINE**
13 **(Unlicensed Activity)**

14 52. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
15 pharmacist license are subject to disciplinary action pursuant to Business and Professions Code
16 sections 4040.5, 4043(a), and 4160(a) in that on November 13, 2013 and November 14, 2013,
17 Respondents were acting as a reverse distributor without a license by taking back drugs, including
18 controlled substances, that were previously dispensed to patients as described in paragraphs 33,
19 and 41-46.

20 **THIRD CAUSE FOR DISCIPLINE**
21 **(Failure to Complete and Maintain Records Under**
22 **Federal and State Regulations Governing Pharmacy)**

23 53. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
24 pharmacist license are subject to disciplinary action pursuant to Business and Professions Code
25 sections 4081 and 4332 and title 21 of the Code of Federal Regulations section 1304 in that on
26 November 13, 2013, they had not completed an accurate controlled substance biennial inventory.
27 The document presented by Respondent Brodbeck as the controlled substance biennial inventory
28 lacked an identifying title for the document, lacked a pharmacist signature, and did not identify

1 the contents of the report. Controlled substances were observed in stock in the pharmacy and
2 were not listed in the document provided as described in paragraph 35.

3 54. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
4 pharmacist license are subject to disciplinary action pursuant to Health and Safety Code section
5 11165 in that Respondents failed to provide a review of CURES information for the period
6 between January 1, 2009 through December 31, 2013, and had not submitted a CURES report for
7 any transaction between August 1, 2010 and December 31, 2014 as described in paragraph 36.

8 55. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
9 pharmacist license are subject to disciplinary action pursuant to title 16 of the Code of Federal
10 Regulations section 1306.22(f)(3) in that on November 13, 2014, Respondents did not have
11 records of Schedule III and Schedule IV drug refills that were signed, printed, and readily
12 retrievable documenting such refills every 72 hours as described in paragraph 38.

13 56. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
14 pharmacist license are subject to disciplinary action pursuant to title 16 of the California Code of
15 Regulations section 1715(a) in that a pharmacist-in-charge must complete a self-assessment of the
16 pharmacy's compliance with federal and state pharmacy law before July 1 of every odd-numbered
17 year and on November 13, 2014, Respondents did not have a completed Community Pharmacy
18 Self-Assessment form by July 1, 2013, as described in paragraph 40.

19
20 **FOURTH CAUSE FOR DISCIPLINE**
(Failure to Properly Label Medications)

21 57. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
22 pharmacist license are subject to disciplinary action pursuant to Business and Professions Code
23 4052.7 in that Respondents's repackaging of a patient's own medications lacked the date,
24 prescription number, and other means of identifying the prescription as described in paragraph 41.

25
26 **FIFTH CAUSE FOR DISCIPLINE**
(Failure to Properly Secure Controlled Substances)

27 58. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
28 pharmacist license are subject to disciplinary action pursuant to California Code of Regulations

1 section 1714(b) and title 16 of the Code of Federal Regulations section 1301.75(b) in that
2 Respondents' storage of controlled substances was not in a securely locked or substantially
3 constructed cabinet, nor were the controlled substances dispersed throughout the stock of non-
4 controlled substances so as to obstruct theft or diversion as described in paragraph 38.

5 **SIXTH CASE FOR DISCIPLINE**
6 **(Failure to Properly Identify Pharmacy Technicians)**

7 59. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
8 pharmacist license are subject to disciplinary action pursuant to title 16 of the California Code of
9 Regulations section 1793.7(c) in that pharmacy technicians J.E. and L.L. were allowed to work
10 without wearing proper identification clearly identifying each as a pharmacy technician as
11 described in paragraph 41.

12 **SEVENTH CASE FOR DISCIPLINE**
13 **(Failure to Properly Equip Pharmacy)**

14 60. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
15 pharmacist license are subject to disciplinary action pursuant to title 16 of the California Code of
16 Regulations section 1714(c) in that on November 13, 2013, Respondents did not have a sink
17 dedicated for pharmacy purposes as described in paragraph 34.

18 **EIGHTH CASE FOR DISCIPLINE**
19 **(Failure to Report Change in Pharmacy Ownership)**

20 61. Respondent California Pharmacy's pharmacy permit and Respondent Brodbeck's
21 pharmacist license are subject to disciplinary action pursuant to Business and Professions Code
22 4201 in that after the beneficial ownership interest in Respondent California Pharmacy changed,
23 neither Respondents reported such change to the California Board of Pharmacy within 30-days of
24 the change in ownership interest as described in paragraph 47.

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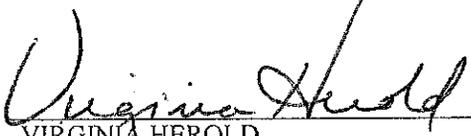
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PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 46209, issued to California Pharmacy, Inc. dba California Pharmacy;
2. Revoking or suspending Pharmacist License Number RPH 32870, issued to Martha Brodbeck;
3. Ordering that Respondents California Pharmacy and Martha Brodbeck pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
4. Taking such other and further action as deemed necessary and proper.

DATED: 12/22/15



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

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