

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

In the Matter of the Accusation and Petition to
Revoke Probation Against:

CAL-MEX SPECIAL SERVICES, INC.,
dba CAL-MEX PHARMACY
Pharmacy License No. PHY 50374

and

OLUGBENGA SOLOMON ODUYALE,
Pharmacist License No. 42719

Respondents.

Case No. 4724

OAH No. 2013080330

**DECISION AFTER RECONSIDERATION
(AS TO RESPONDENT CAL-MEX PHARMACY)
AND AFTER REMAND
(AS TO OLUGBENGA SOLOMON ODUYALE)**

This matter was heard on December 1 through 5, 2014; March 9 through 11; and March 13, 2015, by Susan J. Boyle, Administrative Law Judge (ALJ), Office of Administrative Hearings, in Calexico, El Centro and San Diego, California. Nicole R. Trama, Deputy Attorney General, Department of Justice, represented Virginia Herold (complainant), the Executive Officer of the California State Board of Pharmacy, Department of Consumer Affairs. Ronald S. Marks, Attorney at Law, represented respondents Cal-Mex Special Services, Inc., dba Cal-Mex Pharmacy (Respondent Cal-Mex) and Olugbenga Solomon Oduyale (Respondent Oduyale). Respondent Oduyale was present throughout the hearing.

Oral and documentary evidence was presented. The ALJ allowed the record to remain open until April 17, 2015, to allow the parties to file written closing statements. Both parties timely filed written closing statements, which were received in evidence as legal argument. On April 17, 2015, the record was closed, and the matter was submitted to the ALJ.

On June 29, 2015, the board issued an order adopting the ALJ's proposed decision with technical corrections and set the decision to become effective on July 29, 2015. The board's June 29, 2015, decision revoked, outright, Respondent Oduyale's pharmacist license and continued Respondent Cal-Mex's license on probation under terms and conditions for an additional four years.

Before the decision became effective, however, both parties petitioned for reconsideration. The effective date of the June 29, 2015, decision was stayed until 5 p.m. on August 10, 2015, to allow the board to consider the petitions. By board order dated August 6, 2015, the board agreed to reconsider the discipline against the pharmacy's license (Respondent Cal-Mex) and stayed that portion of the decision pending the board's final action. It denied the respondent's request to reconsider the revocation of Respondent Oduyale's pharmacist license. As a result, Respondent Oduyale's pharmacist license was revoked at 5 pm on August 10, 2015.

With respect to his pharmacist's license, Respondent Oduyale appealed the revocation to Superior Court for Imperial County (Imperial Court). In its case number ECU 08810, the Imperial Court granted the petition for a writ of mandate, in part, and remanded the matter back to the board with instructions to set aside its prior decision, and to reevaluate the penalty in light of the court's order. After receipt of the judgment regarding Respondent Oduyale's license, the board sought written argument, which was timely received from both parties.

With respect to the Respondent Cal-Mex's pharmacy license on reconsideration, both parties timely submitted written argument. After the Imperial Court's judgment issued as to Respondent Oduyale, the board invited additional written argument about whether and how the Imperial Court's decision might affect the board's decision on reconsideration of the pharmacy's license. In issuing this decision as to the reconsideration of Respondent Cal-Mex's license, to the extent that causes of action against Respondent Oduyale's pharmacist license were invalidated by the Imperial Court's decision¹ and the same causes of action had been charged against the pharmacy, the board extended the Imperial Court's reasoning to the pharmacy.

The board, having reviewed and considered the entire record, including the transcript, exhibits and written arguments on both reconsideration and remand, sets aside its prior decision and now issues this decision.

SUMMARY OF BACKGROUND AND CHARGES

Respondent Oduyale has been a pharmacist since 1989 (Pharmacist License Number 42719). The board took disciplinary action against his license in 2006, and his license was placed on probation for three years. He successfully completed probation, and his license was fully restored.

In mid-2010, shortly after he completed probation, Respondent Oduyale and others applied for a pharmacy permit in the name of Respondent Cal-Mex. Respondent Oduyale planned to own the pharmacy and act as its pharmacist-in-charge.² The board denied Respondent Cal-Mex's application for a pharmacy permit based upon the prior discipline of Respondent Oduyale's license.

¹ The "Imperial Court decision" refers to the judgment and each of the court's orders leading up to that judgement, including the court's statement of decision.

² A pharmacist-in-charge has administrative and management responsibilities in a pharmacy and is responsible for ensuring that the pharmacy complies with state and federal regulations and, in larger chain pharmacies, internal policies and procedures. (Bus. & Prof. Code § 4113.)

Respondent Oduyale and Respondent Cal-Mex challenged the denial of the pharmacy permit. The board filed a Statement of Issues. In mid-2011, Respondent Oduyale signed a Stipulated Settlement, which the board approved, through which the board agreed to issue Respondent Cal-Mex a probationary pharmacy permit for 35 months and to allow Respondent Oduyale to act as Respondent Cal-Mex's pharmacist-in-charge. The board agreed to issue Respondent Cal-Mex an unrestricted permit if it successfully completed probation. The board issued the probationary pharmacy permit to Respondent Cal-Mex on August 19, 2011 (Pharmacy Permit Number 50374). Respondent Cal-Mex opened for business in April 2012.

In January 2013, board inspectors conducted a routine inspection at Respondent Cal-Mex. They found several discrepancies and requested additional information from Respondent Oduyale. Respondent Oduyale supplied some of the requested additional information; however, not all of the inspectors' questions were answered, and they were unable to reconcile the information provided with prior records received from Respondent Cal-Mex. The inspectors conducted a second inspection in March 2013. This inspection did not resolve the inspectors' questions and concerns.

In July 2014, complainant filed a First Amended Accusation and Petition to Revoke Probation (Accusation and Petition). The Accusation and Petition alleged that Respondent Oduyale and Respondent Cal-Mex engaged in conduct that violated the laws and regulations governing pharmacists and pharmacies. The Accusation and Petition asserted that this conduct warranted revocation of Respondent Cal-Mex's probation and revocation or suspension of Respondent Cal-Mex's pharmacy permit. The Accusation and Petition also called for the revocation or suspension of Respondent Oduyale's pharmacist license. The Accusation and Petition sought reimbursement for reasonable costs of the investigation and enforcement of the case.

The Accusation and Petition alleged that Respondent Oduyale and Respondent Cal-Mex engaged in the following unlawful conduct:

- a. Failed to maintain proper records of acquisition and disposition of hydrocodone/acetaminophen 10 mg/325 mg from May 1, 2012, through January 28, 2013. (First Cause for Discipline)
- b. Failed to report dispensed controlled substances on a weekly basis from March 21, 2012, to November 2013. (Third Cause for Discipline)
- c. Failed to properly dispense oxycodone when making a substitution in August 2012. (Fourth Cause for Discipline)
- d. Improperly deviated from the directions and requirements of five prescriptions without obtaining authorization. (Fifth Cause for Discipline)
- e. Improperly dispensed 24 prescriptions for controlled substances that were not written on required controlled substance forms. Each prescription was written on a preprinted, check-off, prescription blank that was not authorized for use in dispensing controlled substances. (Sixth, Seventh, and Tenth Causes for Discipline)

f. Improperly dispensed Testim, a controlled substance, before the prescription was written and without documenting that the prescriber was contacted to correct or verify the prescription. (Eighth and Tenth Causes for Discipline)

g. Failed to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions on 39 prescriptions. (Ninth and Tenth Cause for Discipline)

h. Improperly dispensed Motrin 600 mg to a customer without the authorization of the prescriber. (Eleventh Cause for Discipline)

i. Improperly dispensed a ninety day supply of oxycodone 30 mg in thirty days. (Twelfth Cause for Discipline)

j. Provided altered documents to an inspector that falsely represented the existence of certain facts. (Thirteenth Cause for Discipline)

The Accusation and Petition alleged that Respondent Oduyale engaged in the following unlawful conduct:

k. Failed to exercise his best professional judgment with regard to (a) through (j) above. (Fourteenth Cause for Discipline)

l. Improperly extended the expiration date of oxytocin and dispensed the medication for use by patients. (Fifteenth through Twentieth Cause for Discipline)

The Accusation and Petition sought to revoke Respondent Cal-Mex's probation and its pharmacy permit because it did not obey all state and federal laws and regulations (First Cause to Revoke Probation) and because it did not maintain a separate file of all records pertaining to the acquisition and disposition of all controlled substances (Second Cause to Revoke Probation).

PROTECTIVE ORDER

The names of the patients in this matter are subject to a protective order. No court reporter or transcription service shall transcribe the name of a patient but shall instead refer to the patient by his or her initials, which were identified during the administrative hearing, are listed in the Confidential Names List (Exhibit 109), and are used in this decision.

SEALING ORDER

Numerous exhibits were admitted into evidence that contain confidential medical information and patient names. It was not practical to delete this information from some of these exhibits. To protect privacy and confidential personal information from inappropriate disclosure, the ALJ issued a written Protective Order Sealing Confidential Records on December 3, 2014, and provided to the parties on the record. It has been marked and admitted as Exhibit 112. During and after the hearing, the parties identified exhibits that also require sealing. The ALJ determined that additional exhibits (HHH, JJJ and XXX) contained confidential information and

required sealing. The ALJ issued an Amended Protective Order Sealing Confidential Records on May 18, 2015. The Amended Protective Order lists all the exhibits that are ordered sealed. The order governs the release of documents to the public. A reviewing court, parties to this matter, their attorneys, and a government agency decision maker or designee under Government Code section 11517 may review the documents subject to this order, provided that such documents are protected from release to the public.

FACTUAL FINDINGS

1. a. On August 8, 1989, the board issued Original Pharmacist License Number RPH 42719 to respondent Olubenga Solomon Oduyale. His pharmacist's license was set to expire on October 31, 2016, unless renewed.

b. On August 19, 2011, the board issued Pharmacy Permit Number PHY 50374 to Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy, with Olubenga Solomon Oduyale as President, owner, and pharmacist-in-charge.

c. At all times relevant to the allegations in this matter, the above licenses were in full force and effect.

Prior Disciplinary History

2005 ACCUSATION AGAINST RESPONDENT ODUYALE

2. On April 29, 2005, the then executive officer of the board filed an Accusation, Case No. 2733 (2005 Accusation), against Respondent Oduyale. The 2005 Accusation alleged sixteen causes for discipline and sought the revocation or suspension of Respondent Oduyale's pharmacist license. The 2005 Accusation also sought the recovery of reasonable costs of the investigation and enforcement of the case pursuant to Business and Professions Code section 125.3. Nine of the causes for discipline related to an incident that occurred in December 2002; seven of the causes for discipline related to a 2004 pharmacy inspection.

2006 DECISION ON THE 2005 ACCUSATION

3. On February 6, 7, and 8, 2006, ALJ Greer D. Knopf conducted a hearing on the Accusation. On April 2, 2006, ALJ Knopf issued a proposed decision to revoke Respondent Oduyale's license, stay the revocation and place Respondent Oduyale on three years' probation with certain terms and conditions. The board adopted Judge Knopf's decision with the exception that it modified one of the 18 terms of probation. The decision became effective on December 21, 2006 (2006 Decision).

2006 FINDINGS RELATING TO POSSESSION OF UNLABELED MEDICATIONS

4. In the 2006 Decision, the board found the factual circumstances underlying the December 2002 incident to be as follows: Respondent Oduyale had been working as the pharmacist-in-charge of a Rite-Aid store in Calexico, California, since March 1997. On

December 31, 2002, just after midnight, a California Highway Patrol officer observed Respondent Oduyale driving erratically, drifting across the lanes. The officer pulled him over.

During the stop, the officer observed a wooden Billy club on the floor of the vehicle. When Respondent Oduyale opened his car door, the officer saw two brown prescription bottles in the driver's door pouch. The officer retrieved the weapon and the prescription bottles. The prescription bottles did not have any prescription labels on them but had tops with the Rite-Aid name printed on them. Respondent Oduyale told the officer that he was a pharmacist at the Calexico Rite-Aid, that one of the bottles contained Vicodin and the other contained Xanax, and that he was delivering the drugs to a customer in Yuma. The officer opened the medication bottles and observed that one of the bottles had more than one type of pill in it. Respondent Oduyale then told the officer that the bottle contained Xanax as well as Viagra, an antibiotic, and Claritin. The officer asked Respondent Oduyale if he had a prescription for these medications and he said he did not but that his customer did. Respondent Oduyale told the officer that the customer contacted him because she was having trouble obtaining the medication she needed. Respondent Oduyale claimed he had called the customer's physician for authorization to fill the prescription. Respondent Oduyale said he was delivering the medication as a favor.

The officer arrested Respondent Oduyale for possession of controlled substances and possession of a dangerous weapon. The officer conducted a body search of Respondent Oduyale after his arrest and found more pills, identified as Viagra, Floxin, and naproxen, loose in Respondent Oduyale's pocket. In addition, the officer found an unopened bottle of Viagra, a prescription bottle with no label on it containing more Viagra, two opened bottles of naproxen, and two foil wrapped cards with unidentified pills in the rear floor boards of Respondent Oduyale's car. In the trunk of the car, the officer found another prescription bottle of 51 Vicodin tablets labeled for a person in Coachella, California. Respondent Oduyale told the officer he was delivering Vicodin to a tenant at his trailer park who also worked for him. Respondent Oduyale told the officer that his tenant had serious arthritis and was unable to have his prescription filled in the Rite-Aid in Yuma and asked Respondent Oduyale for help. Respondent Oduyale found his tenant's prescription in the Rite-Aid computer and transferred it to the Calexico Rite-Aid where he was the pharmacist-in-charge. Respondent Oduyale said his employer did not know he had taken the medications for his customer and client.

Respondent also stated that some of the medications in his possession were for his own personal use although he did not have prescriptions for them. Respondent Oduyale stated that he did not print a label for the Vicodin he was delivering to his tenant because the printer jammed; however, he could have cleared the printer or hand-written a label. The board found that Respondent Oduyale "cut corners" and "failed to follow proper pharmaceutical protocol for dangerous drugs;" however, the board also found "[t]here was insufficient evidence to establish that respondent illegally possessed, furnished, or transported the Vicodin or acted fraudulently to create a prescription for [his tenant]."

As related to his customer, the board found that Respondent Oduyale often helped by delivering medications to her. The board did not find evidence that Respondent Oduyale "illegally possessed, furnished, or transported the Xanax or acted fraudulently to obtain the Xanax," but the board found that Respondent Oduyale's practices relating to dangerous drugs,

including possessing medications not properly labeled and in a bottle mixed with his own personal medications, “were at the very least sloppy.”

2006 FINDINGS RELATING TO THE 2004 INSPECTION

5. Respondent Oduyale was employed as the pharmacist-in-charge at Palo Verde Hospital (PVH) pharmacy from January 2003 to March 2005. In 2004, the board conducted an inspection of that pharmacy. In the 2006 Decision, the board made the following findings of fact relating to the inspection:

Respondent worked hard to cooperate and he made every effort to comply with [the inspector’s] multiple requests for records. However, respondent was not able to provide all records requested and some of the records produced had errors. Some of the records for the period of January through March 2004 regarding acquisition and disposition of drugs were found to contain crossouts, corrections, and omissions There were also records and inventory indicating the perpetual log maintained in the pharmacy was not accurate in some instances. In addition, respondent was initially unable to produce complete and accurate records for the period of January to March 2003 for [eight drugs]. . . . Subsequently, respondent was able to produce some of the requested records, but not all of them. The PVH pharmacy was unable to provide complete records of drugs from the Pixis [sic] machine. . . . [The inspector] requested Pixis [sic] records for review, but respondent was unable to provide complete and accurate Pixis [sic] records. The inspection generally revealed that respondent failed to keep accurate and complete records of the acquisition and disposition of some of the controlled substances at PVH pharmacy.

The board found that Respondent Oduyale did not have a written quality assurance program that he was required to maintain for the pharmacy. When the inspector asked to review the Drug Enforcement Agency (“DEA”) Inventory, which is required to be maintained by the pharmacy for two years, respondent produced what he believed to be a DEA Inventory, but it was not a DEA Inventory.

Respondent Oduyale also improperly permitted non-pharmacists to receive and sign for drugs delivered to the hospital. Respondent Oduyale “admitted he was unaware of the requirement that only the pharmacist is permitted to accept drug deliveries” The board found that Respondent Oduyale “seemed to be ill-informed about the requirements of his job as the pharmacist;” however, it did not find that he falsified information provided to the inspector or that he attempted to subvert the board’s investigation.

The board found that Respondent Oduyale was a caring individual who tried to help those in need. It found that he was active in volunteer activities in his community and had a reputation in the medical community as a very good pharmacist who was smart, kind-hearted, and helpful to everyone. However, the board also found it “apparent that [Respondent Oduyale] has played fast and loose with some of the rules when it comes to helping his poor or elderly customers. He has admitted some mistakes, but he needs to be re-trained so that he understands he cannot bend the rules just because he wants to help someone.”

2006 TERMS OF PROBATION & COMPLETION

6. The board placed Respondent Oduyale's pharmacist license on probation for three years and imposed 18 conditions of probation. Among the terms of probation, Respondent Oduyale was required to complete at least 40 hours of "remedial education related to the grounds for discipline, as required by the board."

Respondent Oduyale completed probation in Case No. 2733 on December 20, 2009.

2010 APPLICATION FOR PHARMACY PERMIT AND 2011 STIPULATED SETTLEMENT

7. In late June 2010, the board received an application for a pharmacy permit from Respondent Cal-Mex. Three individuals signed the application, including Respondent Oduyale as President of Respondent Cal-Mex and one of its board members. The application proposed that Respondent Oduyale was to be the pharmacist-in-charge of Respondent Cal-Mex.

8. The board denied Respondent Cal-Mex's application on November 22, 2010.

9. On May 10, 2011, complainant filed a Statement of Issues, Case No. 4009, against Respondent Cal-Mex. The Statement of issues alleged seven causes for denying Respondent Cal-Mex a pharmacy permit; each cause for denial was based upon the acts and omissions of Respondent Oduyale as described in the board's 2006 Decision.

10. On May 29, 2011, Respondent Oduyale, on behalf of Respondent Cal-Mex, signed a Stipulated Settlement and Disciplinary Order (Stipulation) which was adopted by the board on July 20, 2011, and became effective on August 19, 2011. The Stipulation provided that the board would issue a license to Respondent Cal-Mex; the license would immediately be revoked; the revocation stayed; and Respondent Cal-Mex would be placed on probation for 35 months on 14 specified terms and conditions. The terms and conditions of probation included that Respondent Cal-Mex obey all rules and regulations governing pharmacies; submit quarterly reports to the board; provide notice to all employees of the terms and conditions of Respondent Cal-Mex's probation; post a probation notice on its premises that was visible to the public; "maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances," and certify by a signed statement that its officers and owners are familiar with state and federal laws and regulations governing pharmacies. The board agreed to accept Respondent Oduyale as the pharmacist-in-charge of Respondent Cal-Mex.

Respondent Cal-Mex's probation was to terminate on July 18, 2014; however, the Stipulation provided: "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."

2013 Accusation and Petition to Revoke Probation-Amended 2014

11. On July 3, 2013, complainant signed an Accusation and Petition to Revoke Probation, Case Number 4724. On July 11, 2014, complainant signed a First Amended Accusation and Petition to Revoke Probation (Accusation and Petition), the operative pleading at issue here. The Accusation and Petition sought to revoke or suspend Respondent Oduyale's pharmacist license, revoke or suspend Respondent Cal-Mex's pharmacy permit, and revoke Respondent Cal-Mex's probation. The Accusation and Petition alleged twenty causes for discipline, two causes to revoke probation, and referenced the 2005 Accusation as other matter that may be considered in determining the degree of discipline, if any, to be imposed in this proceeding. The Accusation and Petition also sought the recovery of reasonable costs pursuant to Business and Professions Code section 125.3

12. Prior to the presentation of evidence, complainant moved to dismiss the Second Cause for Discipline. The motion was granted over respondents' objection.

13. On the fourth day of the hearing, complainant moved to amend the Fifth Cause for Discipline to conform to proof by replacing the word "four" on page 19, line 13 with the word "five," and by inserting after "in paragraph 39," the phrase "and as evidenced by the dispensing of the Testim prescription." The motion was granted over respondents' objection.

Inspections Conducted at Cal-Mex

14. On February 6, 2011, Cardinal Health, a pharmaceutical wholesaler, notified the board that Respondent Cal-Mex had "been identified ... as an entity for which Controlled and Monitored Substance sales create an unreasonable risk for potential diversion," and it had been denied an account with Cardinal Health. When it received the notice of account denial, the board opened a case file to investigate whether there were problems at the pharmacy that caused Cardinal Health to deny Respondent Cal-Mex an account.

CHRISTINE ACOSTA

15. Christine Acosta, an inspector with the board, was assigned Respondent Cal-Mex's case in mid-2012. She has been a licensed pharmacist since 2006. She worked for three years in a retail pharmacy; she worked for two of those years as a pharmacist-in-charge. She also worked for three years in a hospital pharmacy where she performed inspections of medical units where drugs were kept to ensure compliance with state and federal regulations. In her clinical work, Ms. Acosta worked in labor and delivery and medical/surgical units. She has experience with compounding drugs, including sterile compounding. She received over 50 hours of on-line training in compounding when she became a board inspector and she attended a three-day training within the last year.

The board hired Ms. Acosta as an inspector in 2011. She was promoted to Supervising Inspector in July 2014. As an inspector, Ms. Acosta was assigned to the diversion team, whose responsibilities included investigating pharmacies in which inventories contain discrepancies. Since July 2014, Ms. Acosta has been supervising the sterile compounding team. This team

performs inspections of all companies involved with sterile compounds, including those outside of California that sent sterile compounds into California.

OLUBENGA SOLOMON ODUYALE

16. Respondent Oduyale received his pharmacy degree in North Dakota in 1979. He was licensed in Arizona in 1986 and California in 1989. He has worked in hospital and retail pharmacies. For thirteen years, from 1989 to 2002, Respondent Oduyale was the manager of a Calexico Thrifty/Rite Aid pharmacy where he was responsible for all the operations of the store. From 1989 to 1994, Respondent Oduyale also worked as a pharmacist at Calexico Hospital. He worked at Palo Verde Hospital as a pharmacy director where, in addition to his responsibilities as pharmacist, he provided drug information to the medical staff and supervised six employees.

In 2003, Respondent Oduyale began working for Pioneer Memorial Hospital (Pioneer). For three years during the time he worked for Pioneer, he also worked for the State Prison in Centinella as a contractual staff pharmacist. Respondent Oduyale was terminated from his employment at Pioneer in early 2014 for conduct alleged in the Fifteenth through Twentieth Causes for Discipline of the Accusation and Petition.

Respondent Cal-Mex is the first pharmacy Respondent Oduyale owned.

JANUARY 2013 INSPECTION

17. On January 28, 2013, Ms. Acosta and another board inspector, Brandon Mutrux, conducted an unannounced routine inspection of Respondent Cal-Mex. Ms. Acosta was not aware that Respondent Cal-Mex's license was on probation until she saw the probation notice in the pharmacy.

Respondent Oduyale, two pharmacy technicians, and a driver were present during the inspection. Ms. Acosta and Mr. Mutrux reviewed 200 controlled prescriptions, 100 Schedule II prescriptions, invoices from wholesalers, the pharmacy's quality assurance binder, the DEA inventory, and other similar records maintained by Respondent Cal-Mex. The inspectors also inspected the customer pick-up area and the drug dispensing shelves.

After the inspection, Ms. Acosta issued an Inspection Report. The Inspection Report noted that refill requests were presented on pre-printed forms, faxed prescriptions were accepted without a handwritten signature, and controlled medications were dispensed from pre-printed prescription blanks. These practices are not permitted, and Respondent Oduyale was instructed to correct them. The Inspection Report noted that Ms. Acosta questioned Respondent Oduyale about why a patient, whose doctor's office (Dr. Street) was in Victorville, drove to Calexico to fill prescriptions. Ms. Acosta and Respondent Oduyale also discussed the verification of Dr. Street's prescriptions. The report also confirmed that Respondent Oduyale told Ms. Acosta that River City Pharma, an out-of-state pharmaceutical supplier, did business as Masters, which had a California wholesale license. The report requested, among other things, that Respondent Oduyale perform an audit of hydrocodone/acetaminophen 10 mg/325 mg, commonly referred to as Norco 10, and provide a statement regarding how he processed prescriptions, including those on pre-

printed check-off prescription blanks from Dr. Atef Rafla.³ Respondent Oduyale signed the Inspection Report acknowledging that he “reviewed, discussed, [understood] and received a copy of this form.”

Ms. Acosta also issued Respondent Cal-Mex an Official Receipt indicating that she had taken approximately 127 pages of documents, including patient profiles, doctor prescribing profiles, and original prescriptions. Ms. Acosta issued a written notice concerning the preprinted check-off prescriptions; the written notice was signed by Respondent Oduyale.

On February 1, 2013, Respondent Oduyale emailed a group of documents purporting to be back-up materials (verifications) for some of the prescriptions Ms. Acosta questioned. The documents did not explain the processing of the prescriptions Ms. Acosta had questioned and caused some additional confusion regarding Respondent Cal-Mex’s practices.

MARCH 2013 INSPECTION

18. Ms. Acosta and Mr. Mutrux returned to Respondent Cal-Mex on March 28, 2013, to conduct a second inspection. During this second inspection, Respondent Oduyale and two pharmacy technicians were present. Ms. Acosta told Respondent Oduyale she was there to understand the documents she was reviewing. During the March inspection, Ms. Acosta took some of Cal-Mex’s original documents and provided Respondent Oduyale a receipt. The day after the inspection, Ms. Acosta asked Respondent Oduyale to provide additional information, which he provided.

DEA INSPECTION

19. On April 22, 2014, Diversion Investigators from the Drug Enforcement Administration (DEA) conducted an inspection of Respondent Cal-Mex; Respondent Cal-Mex’s DEA registration was up for renewal in August 2014. The DEA investigators requested that Ms. Acosta accompany them to the pharmacy. Following the inspection, the DEA’s Special Agent in Charge wrote to Respondent Oduyale and advised him that the inspection had revealed two violations relating to the pharmacy’s failure to properly record its receipt of drug shipments. Respondent Oduyale responded to the letter and explained what corrective actions Respondent Cal-Mex had taken to address the violations asserted.

The DEA issued Respondent Cal-Mex an unrestricted registration in August 2014.

Allegation that Respondents Failed to Maintain an Accurate Inventory of Hydrocodone

20. A pharmacy is required to maintain readily retrievable records of the sale, acquisition, or disposition of dangerous drugs for three years and to maintain a current inventory. (Bus. & Prof. Code § 4081, subd. (a); Cal. Code Regs., tit.16 § 1718.)

³ Dr. Rafla visited Crosby Square Chiropractic Clinic approximately once a month to provide pain management consultations to workers compensation claimants.

21. During the January 2013 inspection, Ms. Acosta asked Respondent Oduyale to prepare an audit of Norco 10 and Oxycodone 30 mg from May 1, 2012, to January 28, 2013; the audits were received on February 1, 2013. Ms. Acosta also performed audits for these two drugs.

22. The results of Respondent Oduyale's audit and Ms. Acosta's audit of Oxycodone 30 mg were consistent and showed no discrepancies.

23. Respondent Oduyale's audit of Norco 10 showed an overage of 33 pills in stock,⁴ meaning that he dispensed 33 more pills than his records showed he had. Ms. Acosta's audit of Norco 10 showed that Respondent Cal-Mex had an overage of 623 pills. The 590 pill discrepancy between these audits resulted from Ms. Acosta's determination that Respondent Cal-Mex had dispensed 6,330 Norco 10 tablets, and Respondent Oduyale's calculation that Respondent Cal-Mex had dispensed 5,740. An overage of pills can be evidence of a clerical error or a failure to accurately record the acquisition of medications. It can also be evidence of fraudulent billing practices by billing an insurance company for medications that were not dispensed. When a pharmacy has more pills than it can account for having received, the public and the board cannot be assured that the medications came from a reliable source.

Ms. Acosta considered that, because Norco 10 came in bottles of 500, Respondent Cal-Mex may have received a delivery of Norco 10 that it failed to account for in its inventory, and for which it had no record. Ms. Acosta reviewed Respondent Cal-Mex's records to see if she could find where a delivery had been missed or entered in the wrong place, but she did not find the missing pills. Ms. Acosta also considered that occasionally Norco 10 deliveries are mistakenly entered in the inventory column for Norco 5. If a bottle of Norco 10 was mistakenly entered in the Norco 5 column, an overage of 500 would show in a Norco 5 audit. Ms. Acosta and Respondent Oduyale searched Respondent Cal-Mex's records, but neither found a delivery of Norco 10 that had been entered in the Norco 5 column.

24. In her review, Ms. Acosta noted that Respondent Oduyale removed 630 Norco 10 pills (500 and 130) from the inventory in August 2012 in an apparent attempt to balance the inventory at that time. Respondent Oduyale told Ms. Acosta that he made those corrections because 500 pills had been wrongfully entered into the inventory and the 630 correction included those 500 pills. However, Ms. Acosta found in Respondent Cal-Mex's acquisition records that Respondent Cal-Mex received 500 tablets on July 6, 2012, and the tablets were properly added to the inventory at that time.

25. In discovery provided to the board during the preparation for this hearing, Respondent Oduyale provided another inventory of Norco 10. In this inventory, Respondent Oduyale determined that there was a 473 tablet overage - a number closer to that determined by Ms. Acosta's inventory. Regarding each inventory the question is: if the pharmacy dispensed more pills than it shows it received, where did the pills come from?

26. Clear and convincing evidence supports a finding that Respondent Oduyale and Respondent Cal-Mex failed to maintain accurate inventories of Norco 10.

⁴ According to his audit, the number of pills taken from the last biannual inventory was 540; 7,500 were received; 5,740 were dispensed; 2,300 were to be accounted for; actual on hand was 2,333; resulting in a 33 pill overage.

Allegation that Respondents Failed to File CURES Reports on a Weekly Basis

27. A pharmacy is required to report specific information about every prescription it fills for a Schedule II, III or IV⁵ controlled substance to the Department of Justice weekly. (Health & Saf. Code § 11165, subd. (d).) The dispensing data submitted by California pharmacies is stored in the Controlled Substance Utilization Review and Evaluation System (CURES) database.⁶ CURES data is used by regulatory bodies, prescribers and dispensers. CURES is a valuable tool for prescribers and dispensers. CURES data contains a drug history so that a physician can see what medications have been prescribed to a patient in the past and if any medications are currently prescribed. Similarly, a pharmacist can see the customer's drug history and seek additional information if it appears a patient is being over-prescribed, is engaging in drug shopping by obtaining prescriptions from multiple physicians, or is prescribed medications that may conflict with one another. According to Ms. Acosta, a pharmacy is required to file a weekly CURES report whether or not it has dispensed Schedule II, II or IV drugs in the weekly period; however, the Health and Safety Code does not so provide and the Accusation and Petition does not allege that respondents were required to file CURES reports in weeks in which no controlled substances were dispensed.

28. Respondent Cal-Mex, like other pharmacies, was required to send the data required by CURES to Atlantic Associates. Atlantic Associates receives the electronic data from pharmacies in the format specified by the Department of Justice. It processes the information and forwards all compliant entries to the Department of Justice. It rejects entries that do not comply with the Department of Justice's requirements or are missing information. Atlantic Associates sends an email to the reporting pharmacy when it has rejected an entry, and it provides the pharmacy an explanation of why the entry was rejected. The pharmacy is required to correct the problem and resubmit the information. Almost all pharmacies receive rejection notices, and it is not a violation to receive one. However, failing to correct rejected entries, and therefore, failing to have weekly reports filed with CURES, is a violation.

THE BOARD'S INSPECTORS' FINDINGS

29. Ms. Acosta obtained a certified Pharmacy Compliance Report from CURES for Respondent Cal-Mex dated March 20, 2014. The report showed that in the 37 weeks following April 19, 2012, Respondent Cal-Mex filed 16 CURES reports.⁷ No CURES reports are shown submitted in June, only one in October, two in November and one in December 2012. No months show four reports filed.

⁵ Drugs are classified into five schedules depending upon the drug's acceptable medical use and the drug's potential for abuse. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and Schedule V drugs represents the least potential for abuse.

⁶ CURES is one feature of California's prescription drug monitoring program (also known as a PDMP).

⁷ April 19, 2012, is the first date after Respondent Cal-Mex obtained its permit that a CURES report was filed.

Of the 52 weeks from January 1, 2013, to December 31, 2013, Respondent Cal-Mex filed CURES reports on 35 days. No reports are shown filed between February 8 and March 20, 2013. One report was filed in June and one in November.

The report also shows controlled substances that were not reported to CURES for months after they were dispensed. For example, controlled substances dispensed in December 2013, were not reported until February 2014; prescriptions filled in January, February, March, April, May, June, July, August, September and October 2013 were not reported until December 2013.

RESPONDENTS' RESPONSE

30. Respondent Cal-Mex received its pharmacy license on August 19, 2011. It obtained its business license on March 15, 2012, and opened for business on April 20, 2012. No prescriptions were dispensed before April 20, 2012, which accounts for Respondent Cal-Mex's failure to file any CURES reports up to that date.

Respondent Oduyale testified that, once Respondent Cal-Mex began dispensing controlled substances, CURES reports were submitted to Atlantic Associates at the end of each week. His testimony was confirmed by Pharmacy Technician Lydia Garcia who testified that CURES reports were regularly filed on Friday. Respondent Oduyale described the process of submitting reports as being as easy as pushing a button on the computer. He did not understand where the information went after it was submitted.

Respondent Cal-Mex received notice from Atlantic Associates if there was an error in the data submitted. A prescription for a controlled substance cannot be filled without a DEA number for each prescriber. Most of the errors reported to them were the result of entering an incorrect DEA number in the data submitted to Atlantic Associates. When that happened, Respondent Cal-Mex staff telephoned the prescriber's office, obtained the correct DEA number, and resubmitted the information to Atlantic Associates. Ms. Garcia confirmed that she would sometimes call a doctor's office to obtain the correct information for the CURES report. She stated that Cal-Mex resent the corrected reports with the end of the week submissions. Respondent Oduyale stated that he had not been notified by Atlantic Associates or any state or federal agency that Respondent Cal-Mex was not timely filing CURES reports.

When Respondent Oduyale received the accusation in this case, he instructed his staff to resubmit every prescription submitted to Atlantic Associates for several months. He did not know the status of the CURES reports. He did not know what prescriptions had, or had not been submitted, and he did not have a way to prove what was submitted, so on December 3, 2013, he re-submitted 1,844 prescriptions to ensure that all controlled substances dispensed were reported.

EVALUATION

31. Pursuant to the Imperial Court's decision, the weight of the evidence does not support a finding that respondents had knowledge that the CURES reports were not being filed weekly.

Allegation that Respondents Failed to Properly Dispense Oxycodone When Making a Substitution

32. Pursuant to the Imperial Court's decision, when a prescription order for a drug product is prescribed by its trade or brand name, a pharmacist is permitted to substitute the prescribed drug product with another drug product as long as the substituted product has the same active chemical ingredients in the same strength, quantity and dosage form as the prescribed product. (Bus. & Prof. Code § 4073, subd. (a).) If a pharmacist makes a change to a prescription that materially changes the prescription, including the instructions for taking the medication, strength of the medication, or number of days of medication provided, it is considered a deviation, which must be authorized by the prescribing physician. (Bus. & Prof. Code § 4301, subdivision (o); Cal. Code Regs., tit. 16, § 1716.)

33. On August 8, 2012, Dr. Wendell Street prescribed 120 pills of oxycodone 30 mg for patient AS. He instructed her to take one tablet four times a day. The 120 pills prescribed were, if taken correctly, a 30-day supply. On August 9, 2012, AS went to Respondent Cal-Mex to fill her prescription, but Respondent Cal-Mex did not have sufficient oxycodone 30 mg in stock to fill the prescription. Respondent Oduyale told AS that he had only 200 tablets of oxycodone 15 mg in stock which was 40 tablets fewer than the substitution required and was a 25-day supply. AS agreed to accept the 200 oxycodone 15 mg. Respondent Oduyale instructed AS to take two tablets four times a day to account for the substitution.

THE BOARD'S INSPECTORS' FINDINGS

34. Ms. Acosta reviewed AS's prescription for oxycodone during her inspection of Respondent Cal-Mex. She saw a note on the back of the prescription that said "Gave 200 of oxycodone 15 mg as complete RX. Pt consented. Sol."⁸ Neither the prescription nor the note indicated that Dr. Street was consulted and approved the changes to the prescription. Ms. Acosta testified that substituting two 15 mg tablets for one 30 mg tablet was within the authority of a pharmacist to do and did not require consulting the prescriber. However, because Respondent Cal-Mex was unable to fill the entire prescription, the pharmacist was required to obtain approval from Dr. Street before a 25 day supply of oxycodone was substituted for a 30 day supply. Ms. Acosta stated that the unilateral alteration of the prescription could deny the patient the therapeutic benefit of the medication and could cause the prescriber to question the patient if the patient returned for a refill of medication after 25 days. She agreed that it was appropriate that Respondent Oduyale obtained AS's consent to change the prescription; however, AS's consent did not satisfy Respondent Oduyale's obligation to obtain the prescribing physician's permission.

When Ms. Acosta questioned Respondent Oduyale about the changes to the prescription, he relied on the fact that he obtained AS's consent to the change; he did not tell Ms. Acosta that he had verified the change with Dr. Street. In discovery in this case, Respondent Oduyale produced a letter from Dr. Street dated December 14, 2013, one year and four months after the prescription was filled, in which Dr. Street wrote that he had authorized the change to the prescription.

⁸ "Sol" is Respondent Oduyale.

RESPONDENT ODUYALE'S RESPONSE

35. Respondent Oduyale asserted that, when Respondent Cal-Mex received the prescription for AS, he contacted Dr. Street and told him that he did not have sufficient stock to dispense the amount of oxycodone prescribed. Dr. Street agreed that Respondent Cal-Mex should dispense 200 tablets of 15 mg to AS. Ms. Garcia testified that she heard Respondent Oduyale call Dr. Street to confirm the substitution. Respondent Oduyale told Ms. Garcia that it was acceptable to partially fill the prescription.

At the hearing, respondents submitted a typed note on blank paper that says, "Rx Notes 2013. 8/9/12 called Dr. Street got auth to give 15 mg oxycodone # 200 instead of oxy 30 mg due to non-availability of the 30 mg." Respondent Oduyale testified that the note was typed in the pharmacy's computer to document his contact with Dr. Street. Respondent Oduyale stated that notes in the computer, such as these, are private and confidential. He did not explain why he did not provide this note to the board's inspectors until discovery was exchanged in this proceeding.

EVALUATION

36. The evidence does not support a finding that Respondent Oduyale and Respondent Cal-Mex obtained Dr. Street's authorization to partially fill AS's prescription for oxycodone. Even if respondents had obtained Dr. Street's consent as they contend, the inefficient methods of record keeping employed at Cal-Mex do not allow an inspector to readily determine how a prescription was dispensed and on what authority. Entering private and confidential notes in a computer explaining a change in a prescription is not a reasonable practice. The documentation for changes to a prescription should be readily available at inspection and in the event a question is raised about the dispensing of a medication.

The confidential notes submitted at the hearing were not provided to the board's inspectors in a timely manner, which supports a finding that the computer notes were recent fabrications. At best, they are unreliable to readily track how a prescription was dispensed. Respondent Oduyale documented that the patient consented to the change in the prescription in a way that it was readily available, but he did not similarly document that he obtained consent from the doctor. Long after the fact, Respondent Oduyale obtained a letter dated December 14, 2013, from Dr. Street that verified the August 2012 transaction and confirmed that Dr. Street authorized the change in prescription. Ms. Garcia's testimony was not persuasive on this issue. Clear and convincing evidence supports a finding that Respondent Oduyale did not obtain Dr. Street's authorization when he made a substitution in AS's prescription. As Respondent Oduyale was the pharmacist-in-charge and acting on behalf of Respondent Cal-Mex, Respondent Cal-Mex is responsible for Respondent Oduyale's conduct.

Pursuant to the Imperial Court's decision, the evidence does not support a finding that Business and Professions Code section 4073, subdivision (a), was violated because the substitution in this case did not involve a substitution of a generic drug for a brand name drug.

Allegation that Respondents Deviated from the Instructions for Usage on Prescriptions

37. A pharmacist is not permitted to change the requirements of a prescription unless he or she obtains prior consent from the prescriber. (Cal. Code Regs., tit. 16, § 1716.) In four instances in addition to the findings related to patient AS above, Respondent Oduyale and, through him, Respondent Cal-Mex, altered the instructions for drug usage given by the prescribers without contacting the prescriber or documenting that the change was authorized.

38. On October 17, 2012, Dr. David Johnson wrote a prescription for Lorazepam 0.5 mg for patient MF. Dr. Johnson instructed MF to take the medication every 8 to 12 hours; however, the instructions written on the medication given to MF by Respondent Cal-Mex advised MF to take the medication every 8 to 12 hours as needed. Lorazepam is used to control anxiety. There can be a desired therapeutic benefit with the course of treatment as prescribed by Dr. Johnson, and he may have intended that the medication be taken regularly to control anxiety rather than wait until the anxiety occurred. Respondent Oduyale was not authorized to change the instructions provided by Dr. Johnson. This change had the potential to deny the patient the therapeutic benefit Dr. Johnson intended and harm the patient. Respondent Oduyale admitted that changing the directions on this prescription was a mistake.

39. On October 17, 2012, Dr. Johnson prescribed hydrocodone/APAP for patient EL. Dr. Johnson instructed EL to take the medication every 8 hours as needed. The instructions given to EL were to "Take 1 tablet orally every 8 hours." Respondent Oduyale admitted that changing the directions on this prescription was a mistake.

40. On December 5, 2012, Dr. Johnson prescribed Ambien (generic is zolpidem) 5 mg for patient EH and instructed that she take one a night for seven weeks. The instructions given to EH were to take a tablet at bedtime "as needed for sleep." Respondent Oduyale admitted that changing the directions on this prescription was a mistake.

41. In a prescription dated December 5, 2012, Dr. Johnson prescribed Testim gel 1.0% for patient DF. Dr. Johnson instructed that DF apply a half of a tube to his shoulder daily. The instructions given to DF were "Apply daily as directed." Respondent Oduyale did not dispute the inaccuracy of the instructions.

42. Respondent Oduyale attributed the variances in the directions on medicine labels to oversights caused by the volume of work at the pharmacy. He pointed out that from March 2012 through January 28, 2013, Respondent Cal-Mex pharmacy had filled over 7,500 prescriptions and that number of mistakes constituted a small percentage of the total prescriptions filled.

43. Respondent Oduyale admitted the errors made when the instructions for usage provided to customers were not the instructions provided by the prescriber. A high volume of filling prescriptions does not excuse or mitigate the violation; accurate directions are essential to consumer protection and patient safety. Clear and convincing evidence supports a finding that Respondent Oduyale and Respondent Cal-Mex improperly deviated from the prescribed instructions for usage of medications.

Allegation that Respondents Improperly Dispensed Drugs from Noncompliant Prescriptions

PROCESS FOR DISPENSING PRESCRIPTIONS

44. Pharmacies may dispense medications pursuant to written or oral prescriptions. When a pharmacist dispenses from a written prescription, he or she must first verify that the prescription complies with state and federal requirements.

If a prescription is submitted to the pharmacy that does not comply with state and federal regulations, the pharmacist must contact the prescriber or the prescriber's authorized agent and either obtain a prescription that is compliant or verify the prescription, re-write it on pharmacy prescription blanks, and fill it. The pharmacy prescription must note who from the pharmacy verified the prescription and who from the prescriber's office authorized it.

If the pharmacist has questions about a written prescription or wants to modify the prescription in any way, he or she must similarly contact the prescriber or the prescriber's agent to get clarification and/or authorization.

A pharmacy may also fill an oral prescription. In this situation, a prescriber telephones the pharmacy and authorizes a prescription for a patient. The pharmacist writes an oral prescription on the pharmacy's prescription blanks and must note who from the prescribing office called and who from the pharmacy received the oral prescription. Any changes to a rewritten prescription or an oral prescription must be documented in the same way as changes to a written prescription are documented.

Any changes to a prescription and/or communication with the prescriber's office should be noted on the face of a prescription, or, at the very least, on the "backer."⁹ At Respondent Cal-Mex, the pharmacist or a pharmacy technician enters information about a prescription into the pharmacy's computer system. The computer program prompts the technician to provide information for specific fields, for example, date, name of prescriber, medication and usage instructions. If the technician enters that the prescription is oral or "phoned in," the software prompts the technician to enter the name of the person who authorized the prescription. The technician must answer that question before a prescription label can be generated. The computer program assigns a prescription number and creates a backer and a medicine bottle label. The prescription, with the backer affixed to the back of the prescription, is filed in the pharmacy's records.

Respondent Oduyale reviews the prescription and the printed label. According to Respondent Oduyale and Respondent Cal-Mex employees, once Respondent Oduyale approves the prescription, no changes can be made to the backer. The inability to change the backer includes not being able to add the name of the person contacted.

⁹ The backer contains all of the information about the prescription including the newly assigned prescription number, prescriber's name, patient's name, date of the prescription, how the prescription was received by the pharmacy, and direction for use.

THE BOARD'S INSPECTORS' FINDINGS

45. Prescriptions for controlled substances that are classified as schedule II, III, IV or V must be made on California controlled substance forms. A pharmacist is prohibited from dispensing a controlled substance from a "pre-printed multiple check-off prescription blank." (Health & Saf. Code, § 11164, subd. (a); Cal. Code Regs., tit. 16, § 1717.3.) According to Ms. Acosta, for schedule III, IV or V drugs, the pharmacist can verify prescriptions written on noncompliant forms by speaking to the prescriber or his or her agent and documenting the conversation. The pharmacist can put a note on the original prescription documenting the verifying conversation, or he or she can re-write the prescription as an oral prescription. Schedule II drugs are handled differently.

46. Ms. Acosta discovered many prescriptions filled by Respondent Cal-Mex that were issued by Drs. Johnson and Atef Rafla on non-compliant forms. Respondent Oduyale initially told Ms. Acosta that he did not know that Drs. Johnson's and Rafla's prescription forms were non-compliant and that he could not dispense drugs from the non-compliant forms. After Ms. Acosta told Respondent Oduyale that he could dispense drugs from the non-compliant prescriptions if they were properly verified, he represented that he had verifications, but had to find them. Respondent Oduyale did not provide Ms. Acosta verifications during the January 2013 inspection.

47. Respondent Oduyale sent documents to Ms. Acosta after her January inspection, some of which were verifications for the non-compliant prescriptions. Ms. Acosta reconciled as many prescriptions as possible with the verifications sent to her and found that respondent dispensed controlled substances from 24 prescriptions that were written by Dr. Rafla on non-authorized check-off forms for which no verifications were provided. Of the 24 non-verified prescriptions, 3 were filled on September 10, 2012; 9 were filled on September 11, 2012; and 12 were filled on November 16, 2012.

48. In response to a questionnaire that Ms. Acosta sent to Dr. Rafla, he stated that he spoke "sporadically" with Respondent Cal-Mex employees when "they have questions about some of my prescriptions." In response to a question asking how prescriptions on September 7, 2012, and November 16, 2012, were verified, Dr. Rafla wrote, "Can't remember exactly. I write the Rx and give to patients."

RESPONDENT'S RESPONSE

49. Respondent Oduyale claimed that he and his pharmacy technician, Ms. Garcia, met Dr. Rafla in the fall of 2012 at Crosby Chiropractic Clinic after Respondent Cal-Mex began to receive prescriptions he wrote. Respondent Oduyale introduced himself to Dr. Rafla and told him that Respondent Cal-Mex could not accept prescriptions on the pre-printed, check-off forms Dr. Rafla was using. Dr. Rafla told Respondent Oduyale that he left his prescription blanks at his other office. Respondent Oduyale agreed to accommodate Dr. Rafla and his patients "this time," but said he could not accept them again. Respondent Oduyale accepted Dr. Rafla's acknowledgement of the prescriptions as verbal authorization, and he re-wrote them on Respondent Cal-Mex's prescription pad. Respondent Oduyale and Dr. Rafla did not discuss who was authorized to verify prescriptions for Dr. Rafla.

Dr. Rafla told Respondent Oduyale that his patients were all workers compensation claimants. Respondent Oduyale was not familiar with what workers compensation insurance would cover for medications. Dr. Rafla introduced Respondent Oduyale to a person Respondent Oduyale understood to be named “Maria”¹⁰ who worked for him. “Maria” went to Respondent Cal-Mex that day and said she would explain how to process workers compensation liens for payment. Myra told Respondent Oduyale and Ms. Garcia that many pharmacies did not accept prescriptions for workers compensation patients because there is a risk of not being paid or being paid less than what is charged. If a pharmacy did not accept workers compensation insurance, the patient must pay the pharmacy fees out of pocket. Respondent Cal-Mex was the only local pharmacy that accepted workers compensation insurance. Workers compensation claims were processed in a different room by Respondent Cal-Mex staff dedicated to processing those prescriptions.

50. Respondents submitted documents at the hearing that were represented to be printed computer images of prescriptions questioned by Ms. Acosta from September 7 through November 16, 2012, as they exist in Respondent Cal-Mex’s records. Respondents asserted that the documents showed that the remaining questioned prescriptions were properly verified. The backers to the prescriptions noted they were phoned in by Dr. Rafla, Maria or “Alex,” even though they were presented on non-compliant prescription forms.

51. Respondent Oduyale asserted that when he received a non-compliant prescription from Dr. Rafla, Respondent Cal-Mex personnel called Dr. Rafla’s office to verify the prescription. When the prescription was verified, Respondent Oduyale re-wrote it on a Cal-Mex prescription pad. The rewritten prescription became the dispensing document. Respondent Oduyale stated that this was the practice followed by other pharmacies he worked in.

52. Respondent Oduyale testified that, at some point, Dr. Rafla told him to call his assistant for verifications. Respondent Oduyale spoke to “Maria” or “Felix,” whose name he now understands to be Alex; Alex told Respondent Oduyale that he could verify prescriptions.¹¹ Mr. Oduyale stated that he had no reason to believe that “Maria” could not verify prescriptions. Respondent Oduyale rarely dealt with Katherine Ramirez from Dr. Rafla’s office.

53. On February 1, 2013, Dr. Rafla signed a letter addressed to Ms. Acosta, which stated that all prescriptions he wrote that were filled by Respondent Cal-Mex pharmacy “were either verified by phone or in person by the pharmacist, Sol, of Respondent Cal-Mex Pharmacy.”

EVALUATION

54. Respondent Oduyale was not aware that the prescriptions written by Drs. Johnson and Rafla did not comply with state requirements. Therefore, it is not credible that the noncompliant prescriptions were verified. Properly authorized verifications were not located for several of Drs. Johnson’s and Rafla’s non-compliant prescription blanks. Respondent Oduyale’s

¹⁰ Dr. Rafla’s assistant is named Myra; she always accompanied him when he saw patients at Crosby Square Chiropractic Clinic.

¹¹ “Alex” contradicted Respondent Oduyale and testified that he was not authorized to, and never did, verify prescriptions. See discussion *infra*.

credibility is affected by the purported verifications that were produced prior to hearing, but not in the minimum of three prior opportunities he had to provide them timely to Inspector Acosta.

Dr. Rafla's responses to Ms. Acosta and respondents' counsel are inconsistent. On the one hand, he confirmed that every prescription he wrote that Respondent Cal-Mex filled was properly verified, and on the other, he was unable to recall how some prescriptions were verified. Dr. Rafla's blanket statement that all prescriptions were verified is not persuasive.

Clear and convincing evidence supports a finding that Respondent Oduyale and Respondent Cal-Mex improperly dispensed drugs from non-compliant prescriptions.

Allegation that Respondents Failed to Document the Name of the Verifying Agent

55. A pharmacist is permitted to dispense controlled substances classified in Schedule III, IV or V from a prescription that is orally or electronically transmitted by an authorized agent of a prescriber as long as the pharmacy records specify the name of the agent who transmitted the prescription. (Health & Saf. Code § 11164, sub. (b)(3).) A pharmacist is required to make a "reasonable effort" to determine if the person transmitting a prescription is an authorized agent. (Bus. & Prof Code § 4071.)

THE BOARD'S INSPECTORS' FINDINGS

56. Ms. Acosta stated that the name of the authorizing agent must be written on the face of the prescription that becomes the dispensing document. Respondents were not authorized to dispense controlled substances from non-compliant prescriptions written by Drs. Johnson and Rafla. However, respondents could verify the prescriptions by speaking to the doctors or their authorized agents and noting, on the front of the original prescription or on a re-written prescription, the name of the agent who verified the prescription. In 39 prescriptions reviewed by Ms. Acosta, 36 from Dr. Rafla and 3 from Dr. Johnson, respondents rewrote the prescriptions, but the name of the authorized agent was not on the front of the original prescription or Respondent Cal-Mex's re-written prescription.

In documents received shortly before the hearing in this case, Ms. Acosta found documents she had never before seen. She found even more inconsistencies in these documents as the verifications were different from those she had previously viewed. Ms. Acosta testified that, with all the variations of documents respondents produced, she could not determine which document was the final dispensing document, although she believed the actual dispensing documents are the ones she took with her after the January inspection.

57. On November 16, 2012, Dr. Rafla wrote a prescription on his pre-printed check-off pad for hydrocodone/APAP for patient NM; the backer for this prescription, number 40332, indicates the origin as "written." Ms. Acosta obtained this prescription and backer on January 28, 2013. On February 1, 2013, Respondent Cal-Mex provided Ms. Acosta with documents represented to be verifications of prescriptions that could not be located during the January inspection. One of the documents provided on February 2, 2013, was Respondent Cal-Mex's re-written prescription for Rx number 40332. The re-written prescription does not contain the name of the person who verified the prescription. The backer to Rx number 40332 provided in

February is not for NM's original prescription but for a refill of the prescription dispensed on December 14, 2012. This backer states it was "Phoned in by: Rafla." At the hearing, respondents submitted only the backer for the refill prescription. Respondents did not produce a verification for the original prescription.

On November 16, 2012, Dr. Rafla prescribed Norco 10 for patient JP on a pre-printed, check-off prescription. In January, Ms. Acosta received a backer indicating that the origin of the prescription, Rx number 40342, was "Written." The documents provided in February included a re-written prescription on a Respondent Cal-Mex prescription pad. The re-written prescription for Rx number 40342 does not contain the name of the person who verified the prescription. The backer is not for the original prescription, but it is for a refill of the prescription that was dispensed on January 14, 2013. This backer indicates the prescription was phoned in by Rafla. The document respondents submitted at the hearing is for the refill prescription. A verification for the original prescription was never submitted.

On November 16, 2012, Dr. Rafla prescribed hydrocodone/APAP for patient OP on a pre-printed form. The backer for this prescription, prescription number 40355, noted the origin of the prescription as "Written." Ms. Acosta received this prescription and backer in January. In February, respondents provided Ms. Acosta with a re-written prescription on a Respondent Cal-Mex prescription blank. The prescription does not include the name of an agent verifying the prescription. The backer provided in February indicated the origin of the prescription was "written." At the hearing, respondents submitted a different backer for prescription number 40355, which states the prescription was phoned in by Dr. Rafla.

Ms. Acosta testified that there were 15 to 20 instances of similar discrepancies.

RESPONDENT'S RESPONSE

58. Respondent Oduyale testified that, when a pre-printed prescription form was faxed to Respondent Cal-Mex, the original prescription noted it was received by fax or was written. The prescription was required to be verified by contacting the prescriber's office. Once verification was obtained, the prescription was re-written on a Respondent Cal-Mex prescription pad, and the backer was changed to indicate the prescription was "phoned in." Respondent Oduyale stated that changing the origin of the prescription from written to telephone was one of the "corrections" he made when reviewing a prescription.

EVALUATION

59. Complainant asserts that the standard of practice in the industry is that the name of the authorizing agent is written on the front of the dispensing prescription and not on the backer. While this may be the general practice, it is not required by the Health and Safety Code. It is important that the name of the agent can be determined by a relatively quick review of pharmacy records. Since backers derive their name from the fact that they are attached to the back of prescriptions, determining the identity of the authorizing agent should be relatively simple if the name is on the front or back of the prescription. However, the practice for each prescription must be consistent to facilitate understanding of the medication records for inspection, but also for patient safety.

By his explanation of how prescriptions were verified, Respondent Oduyale suggested that two backers could exist for one prescription. This suggestion does not comport with other explanations given about the processing of prescriptions. If Respondent Cal-Mex receives a prescription, they should not enter it into the computer system until it has been verified. At the least, no backer should be printed until the prescription has been verified. Once verified, the prescription is re-written and constitutes an oral prescription. The fact that it is oral should be noted on the face of the prescription or at least on the backer. There is no reason to have a backer for an invalid prescription. The confusion caused by Respondent Cal-Mex generating a backer for a prescription that had not been verified was evident throughout the hearing.

60. Furthermore, Respondent Oduyale stated that the verifications for the form prescriptions from Dr. Rafla were not available to Ms. Acosta because they were in the billing room for processing. However, the “missing” verifications were for prescriptions that had been filled some two months before the inspection. Additionally, Ms. Acosta obtained some of Dr. Rafla’s prescriptions with backers on them in January 2013. Many of those prescriptions were sent to her in February with different backers. Respondent Oduyale’s explanations were not credible and suggest that the verifications provided to Ms. Acosta after the January inspection did not exist when the prescriptions were dispensed but were created at a later time. Clear and convincing evidence supports a finding that Respondents Oduyale and Cal-Mex failed to obtain the name of the authorizing agent when verifying prescriptions.

Allegation that the Individuals Claimed to have Verified Prescriptions Were Not Authorized Agents

AUTHORIZED AGENTS AND VERIFICATION PROCEDURES AT CROSBY SQUARE

61. Alexander Martinez, Guadalupe Sanchez, and Elizabeth Gonzalez, each of whom was employed at Crosby Square, testified at the hearing regarding the policies and practices in Drs. Rafla’s and Johnson’s offices. Maria Villagomez’s declaration was received as direct evidence. Credible testimony established the following:

Mr. Martinez has been the Office Manager of Crosby Square Chiropractor for six years. No one named “Felix” worked for Crosby Square. Mr. Martinez learned the day of his testimony that Respondent Oduyale erroneously called him “Felix.”

Guadalupe “Lupita” Sanchez was an interpreter at Crosby Square.

Elizabeth Gonzalez has been the front office manager for Crosby Square for three years. She performed clerical functions, including making employee schedules, answering the telephone and sending medical reports.

Maria Villagomez was employed by Dr. Johnson. She traveled to Crosby Square with Dr. Johnson on Mondays. Part of her responsibilities included verifying prescriptions on behalf of Dr. Johnson. She was not authorized to, and did not, verify prescriptions on behalf of Dr. Rafla. Ms. Villagomez was the only employee named “Maria” who worked in the Crosby Square Clinic.

Dr. Rafla visited Crosby Square approximately once a month to provide pain management consultations. Dr. Rafla's assistant, Myra, always accompanied him when he saw patients at Crosby Square. Myra gave Dr. Rafla the patient folders and directed patients to the exam room. Dr. Rafla returned the patient folders and any prescriptions he wrote to Myra after the consultation. Myra gave the folders to Ms. Gonzalez to enter the demographic information. Ms. Gonzalez gave the patient the prescriptions from the folder for the patient to take to the pharmacy.

Elizabeth Gonzalez or Lupita Sanchez answered the telephones at Crosby Square. Ms. Gonzalez did not recall getting telephone calls from Respondent Cal-Mex. She does not know anything about medications, and she was not authorized to, and did not, verify prescriptions. She directed anyone who asked questions about prescriptions to call Dr. Rafla.

Mr. Martinez did not work for Dr. Rafla. He was not authorized to prepare or verify Dr. Rafla's prescriptions. Dr. Rafla instructed everyone at Crosby Square to direct any questions that involved him to his office. Mr. Martinez did not answer telephones for Crosby Square, but he overheard calls that came in from Respondent Cal-Mex and was aware that Respondent Cal-Mex staff called the office several times on the days Dr. Rafla was there.

Respondent Oduyale was seen in the Crosby Square offices a "couple of times" talking to Myra or Dr. Rafla. Lydia Garcia was seen speaking to Dr. Rafla three to four times.

62. In a declaration dated March 27, 2014, Dr. Rafla declared:

In the past three years, Katherine Ramirez is the only individual at my office who has been authorized to verify a prescription on my behalf. In the past three years, I have never given anyone authority, other than Katherine Ramirez, to authorize prescriptions or verify prescriptions on my behalf. In the event that a pharmacy contacts the [Crosby] Clinic for authorization or verification of a prescription written by me, the Clinic is instructed to contact my office directly. I do not have [an] agent by the name of "Maria" working for me. In the past three years, I have never given anyone by the name of "Maria" authority to verify prescriptions or authorize prescriptions on my behalf.

In response to a questionnaire provided to Dr. Rafla by respondents' attorney, Dr. Rafla wrote that he had conversations with Respondent Cal-Mex employees "1 or 2 times," and he met Respondent Oduyale on one occasion for five minutes. Dr. Rafla identified Katherine as the only employee who could authorize refills "after checking with me" and Myra as his employee whose responsibilities were limited to "paperwork only." He also verified his February 1, 2013, letter in which he wrote that all prescriptions written by him that were filled by Respondent Cal-Mex "were either verified by phone or in person by the pharmacist, Sol, of Respondent Cal-Mex Pharmacy." Dr. Rafla's statements are contradictory.

VERIFICATION PRACTICES AND PROCEDURES AT RESPONDENT CAL-MEX

63. Lydia Garcia, Esteban Martinez and Valerie Banda, each of whom was employed at Respondent Cal-Mex, testified at the hearing regarding the policies and practices of Respondent Cal-Mex and how copies of prescriptions were copied and produced for Ms. Acosta. Their testimony included the following:

Lydia Garcia has been licensed as a pharmacy technician since March 2002. She has been employed as a pharmacy technician for Respondent Cal-Mex since April 2012; Respondent Cal-Mex opened one week before she began working there. Her duties include typing prescriptions, conducting inventories, reconciling checks, engaging in customer service, calling for re-fills, and requesting authorization for insurance coverage.

Esteban Martinez (Esteban) worked for Respondent Oduyale at Respondent Cal-Mex from February 2012 to April 2013. He did general marketing work for the pharmacy and delivered medications to customers. He also drove patients to doctor's appointments; Respondent Cal-Mex did this as a free service for patients, mostly senior citizens who had prescriptions filled at Respondent Cal-Mex.

Valerie Banda has been a pharmacy clerk for Respondent Cal-Mex for almost three years.

64. Dr. Rafla authorized "Katherine" in his office in Santa Ana to verify his prescriptions. Respondent Oduyale and Respondent Cal-Mex employees knew that Myra was Dr. Rafla's assistant and that she traveled to Calexico with him when he saw patients at the Crosby Square Clinic. They believed that Myra was also authorized to verify Dr. Rafla's prescriptions. Ms. Garcia identified an undated page from a notebook that contained telephone numbers for "Mayra" [sic] and "Katherine." Ms. Garcia stated she was told these were the individuals she could call if there were questions about Dr. Rafla's patients. Ms. Garcia and Respondent Oduyale also believed that the clinic manager, Alex Martinez, could verify prescriptions.

Ms. Garcia stated that Respondent Cal-Mex did not dispense medications based on Dr. Rafla's pre-printed form without first obtaining verifications from Dr. Rafla or one of the persons believed to be his agent.

EVALUATION

65. The evidence does not support a finding that Mr. Martinez, erroneously referred to as Felix, was authorized to verify prescriptions or that Respondent Oduyale and Respondent Cal-Mex reasonably believed he had such authority. The evidence does not support a finding that Myra was authorized to verify prescriptions; however, the evidence supports a finding that Respondent Cal-Mex reasonably believed she was authorized to do so.

Allegation that Respondents Dispensed a Refill Without Authorization from the Prescriber

66. A pharmacist may not dispense a refill of a dangerous drug unless it is authorized by the prescriber orally or the refill is included on the original prescription. (Bus. & Prof. Code § 4063.)

THE BOARD'S INSPECTORS' FINDINGS

67. On November 16, 2012, Dr. Rafla prescribed Motrin 600 mg for patient JP. The original prescription was on a pre-printed, check-off prescription blank and did not authorize refills. On December 12, 2012, respondents dispensed a refill of the Motrin 600 mg to JP (prescription number 603306). When Ms. Acosta questioned Respondent Oduyale about the refill, he was unable to identify from whom he obtained authorization or explain why the refill was dispensed.

68. In a declaration signed by Dr. Rafla on March 27, 2014, he stated that it was his practice to document each instance in which he authorized a refill of a prescription. Dr. Rafla reviewed JP's files and declared that there were no records in JP's file that indicated a refill for Motrin 600 mg was prescribed or that his office was contacted to request authorization for a refill. He confirmed that the last prescription he wrote for JP for Motrin 600 mg was in November 2012.

RESPONDENT'S RESPONSE

69. Respondent Oduyale agreed that the original prescription for Motrin 600 mg issued by Dr. Rafla for patient JP did not contain authorization for a refill. Respondent Oduyale stated that, when JP learned that the prescription did not indicate a refill was authorized, he became belligerent and alleged that the pharmacy had made an error. JP returned to the Crosby Clinic to complain. Thereafter, Dr. Rafla telephoned Respondent Cal-Mex and authorized one refill.

Respondent Oduyale submitted an undated, typed note on blank paper that he represented was a confidential note in the computer records of Respondent Cal-Mex. The note confirmed that JP "exploded" when he learned there was no refill on his prescription; that he returned to the clinic and that "aria"¹² called the pharmacy to authorize adding one refill to JP's prescription. Respondent Oduyale asserted that these confidential notes are the way he records matters that occur concerning prescriptions. By email dated March 3, 2014, over a year after the incident, Katherine Ramirez, who was authorized to verify prescriptions for Dr. Rafla, verified that JP's prescription for Motrin 600 mg was authorized for one refill.

EVALUATION

70. This is another example of the difficulty involved in determining the validity of a prescription when notes are contained in a confidential file on the pharmacy's computer. The fact that these notes were provided in discovery and were not provided to the board's inspectors during or following their inspections evidences their ineffectiveness. The creation of a paper trail

¹² The first letter of each line of the copied note is missing. It is assumed that the note intended to read, "Maria."

over one year later is not an efficient way to verify prescriptions and calls into question the credibility of the information. In this instance, Dr. Rafla and Katherine contradict one another in trying to recreate what occurred long after the prescription was written. Although respondents assert that Dr. Rafla confirmed he authorized a refill, the document he signed indicates only that the November prescription for Motrin was authorized, not the refill dispensed in December.

It is noted that the backer to JP's prescription indicates the origin as "written." This is also an example of a failure to provide a verification for a pre-printed prescription. There is no notation on the face of the prescription that Dr. Rafla or his agent was contacted to verify the prescription. The backer confirms that a refill was authorized, but indicates the origin of the prescription as "written." Given Respondent Oduyale's explanation, and the fact that the prescription was required to have been verified, the origin would more accurately have been that the prescription was phoned in.

However, no authority was provided to support a finding that Motrin 600 mg is classified as a dangerous drug. For this reason, the allegation as pled cannot support disciplinary action.

Allegation that Respondents Dispensed Testim Before the Prescription was Written

THE BOARD'S INSPECTORS' FINDINGS

71. a. Ms. Acosta found a December 5, 2012, prescription for Testim for patient DF that had a backer suggesting the Testim was dispensed on November 28, 2012. When asked about this prescription, Respondent Oduyale could not explain it. Ms. Acosta stated that she later learned this situation was related to billing problems.

RESPONDENT'S RESPONSE

71. b. On November 28, 2012, Respondent Cal-Mex memorialized a prescription for Testim 1% for patient DF. David Johnson was written into the space after "Dr." and "Maria" was handwritten on the prescription under Dr. Johnson's name. The prescription was signed by "Sol." A backer for the prescription submitted by respondents was dated November 28, 2012. Respondent Oduyale testified that Respondent Cal-Mex did not have Testim in stock when Dr. Johnson requested it for DF. Respondent Oduyale said he spoke to DF who told Respondent Oduyale that he would wait until the pharmacy could get the Testim. Respondent Oduyale ordered the Testim and billed DF's insurance that day. He created the backer for billing purposes, but Testim was not dispensed on that day.

Pharmacy technician Ms. Garcia placed an order for Testim after receiving the prescription from Dr. Johnson and learning that DF would wait until the pharmacy could get the Testim in stock. An invoice to Respondent Cal-Mex from Valley Wholesale Drug shows that Respondent Cal-Mex placed an order for Testim on November 28, 2012. On December 5, 2012, a second prescription for the Testim, but with different directions for use, was written on a Respondent Cal-Mex prescription pad. A backer for the December prescription was not produced. Respondent Cal-Mex pick-up logs indicate that DF picked up the Testim on December 5, 2012.

EVALUATION

72. Respondents' record keeping is consistently poor. This contributes to confusing and contradictory documents. Regardless of the explanation, there should not be two documents that could constitute the dispensing document. At the very least, if prescriptions must be created for billing purposes, all copies of prescriptions and backers should be kept together with a clear explanation attached to them of why there are two presumptively dispensing documents with different dates. It should not require hours of investigation to determine how the Testim was dispensed. However, the evidence supports a finding that Testim was not dispensed before a prescription was written. For this reason, the evidence does not support disciplinary action.

Allegation that Respondents Dispensed a 90 Day Supply of Oxycodone in 30 Days

73. The prescriber of controlled substances is responsible to write only prescriptions that are for a legitimate medical purpose. A pharmacist, however, has a corresponding responsibility to be aware of, and question, any prescription that appears out of the ordinary. (Health & Saf. Code § 1153, subd. (a).) Even after verifying a prescription, a pharmacist may not "dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose." (Cal. Code Regs., tit. 16, § 1761, subd. (b).)

THE BOARD'S INSPECTORS' FINDINGS

74. On December 6, 2012, respondents dispensed 150 tablets of oxycodone 30 mg, a 30 day supply, to patient BS. On December 20, 2012, fourteen days later, respondents dispensed another 150 tablets of oxycodone 30 mg to BS. On January 4, 2013, fifteen days after that, respondents again dispensed 150 tablets of oxycodone 30 mg to BS¹³. The prescriber in this case was located in Victorville, a drive in excess of three hours from Calexico; the patient lived in Apple Valley, a drive of almost three and one-half hours from Calexico; and the patient paid cash for the prescriptions. Complainant asserts that these factors should have caused respondents to question the validity and medical necessity of the multiple prescriptions. Ms. Acosta noted that use of the CURES database is invaluable when issues such as these arise. Checking CURES allows a pharmacist to see if the patient had been prescribed oxycodone in the past, and if so, if a pattern of abuse was evident. Checking CURES could also alert the pharmacist as to whether the patient was new to the drug and could be uninformed about how to take it and possible side effects. Ms. Acosta stated that the prescription called for a large starting dose of oxycodone which also should have caused Respondent Oduyale to take notice. She stated that, even if the prescriber authorized the prescription, Respondent Oduyale should have questioned it, particularly if he did not know the physician or the patient.

During the January inspection, when initially questioned about the apparent excessive dispensing of medication, Respondent Oduyale told the inspectors that he did not realize the dates were so close, and he did not contact the prescribing physician to confirm the legitimate medical purpose for the multiple prescriptions.

¹³ Oxycodone can be misused and is sometimes sold illegally as a recreational drug.

RESPONDENT'S RESPONSE

75. Respondent Oduyale noted that BS was almost 73 years old when she presented the prescriptions to Respondent Cal-Mex. He testified that BS told him she required more prescriptions of oxycodone because she was on an extended vacation. Respondent Oduyale stated that oxycodone is prescribed for pain. If a patient's supply ran out before obtaining a new prescription, the pain could return and the patient could suffer withdrawal, either of which could result in discomfort, anxiety, depression and temporary disability.

Respondent Oduyale stated that he contacted Dr. Street, and Dr. Street authorized him to dispense the three prescriptions. Respondents submitted a typed note on blank paper stating "[BS] getting vacation supply won't be back for some time. Talked to Dr. Street to confirm the rx as issued and legitimate."

76. By letter dated January 9, 2014, Dr. Street confirmed the three prescriptions issued to BS and wrote, "As per phone conversation with Pharmacist, Sol Oduyale[,] I requested these prescriptions to be issued as such to cover the patient's medication needs while she was on vacation. No prescriptions were issued during February and her next prescription was issued March 27, 2013."

EVALUATION

77. Ms. Acosta asserted that Respondent Oduyale told her he did not realize that Respondent Cal-Mex dispensed a 90-day supply of oxycodone to BS in 30 days and that he did not contact Dr. Street. However, Respondent Oduyale later asserted that he was aware of the situation and that he had contacted Dr. Street to receive authorization to dispense the oxycodone as prescribed. In addition to the issue of credibility, this example again emphasizes Respondent Cal-Mex and Respondent Oduyale's poor and utterly inadequate record-keeping. There is no indication on any of the three prescriptions or their backers that Dr. Street was contacted and questioned about prescribing a 90-day supply of oxycodone in 30 days. Instead, respondents rely on a note allegedly entered in Respondent Cal-Mex's computer at the time the second prescription was presented by BS¹⁴ but was not provided to Ms. Acosta during the inspection or before the Accusation was filed. Respondents also rely on a note from a doctor written over one year after the prescriptions were written. Respondents' evidence to support a claim that they contacted Dr. Street is not credible. It is not reasonable that pharmacy records are not clear on their face. It should not require lengthy inquisition to determine how and why a prescription was dispensed.

78. Despite raising concerns about respondents credibility and recordkeeping, pursuant to the Imperial Court's decision, under these specific circumstances with patient BS, however, it was not established that Respondents failed to implement their corresponding responsibility.

¹⁴ The note references the prescription number for the December 19, 2012, prescription that was filled on December 20, 2012.

Allegation that Respondents Provided Altered Documents that Falsely Represent Facts

79. Complainant alleged that respondents provided false documents to the board's inspectors during the course of their investigation. A pharmacist is prohibited from making or signing any document that falsely represents facts. (Bus & Prof. Code § 4301, subd. (g).)

THE BOARD'S INSPECTORS' FINDINGS

80. During their January inspection, the board's inspectors reviewed original prescriptions on non-compliant prescription forms. The backers of at least 20 of these prescriptions showed the origin of the prescription to be "fax" or "written." Respondent Oduyale signed or initialed the backers of 16 of the 20 prescriptions. Ms. Acosta took the prescriptions and backers, along with other prescriptions, with her after her January inspection.

Respondent Oduyale told the inspectors that he verified the prescriptions by calling the prescribing physician's office or walking across the street to his office and then re-wrote the prescriptions. There were no notes on the face of the prescriptions or on the backers to indicate the prescriptions were verified. Respondents did not have the verifications for these prescriptions available to show the inspectors during their January inspection. Although the prescriptions were filled between September and December 2012, Respondent Cal-Mex told Ms. Acosta that the prescription verifications had been unavailable because the re-written prescriptions were in a separate room being processed.

A few days after the board's inspection, respondents provided re-written prescriptions on Respondent Cal-Mex prescription pads and new backers for the 20 prescriptions. Where the original prescriptions had backers that indicated the prescriptions were sent by facsimile or were written, the new backers indicated that the prescriptions were called in by "Maria" or "Rafla."

RESPONDENT'S RESPONSE

81. Respondent Oduyale and Respondent Cal-Mex employees adamantly denied altering documents after the board's inspection.

82. Esteban was present during Ms. Acosta's January inspection. He helped look for the prescription records Ms. Acosta wanted to review. He described it as an "overwhelming day" because it was a day that Dr. Rafla was in Calexico, and there were many customers in the pharmacy. He heard Ms. Acosta tell Respondent Oduyale to get the missing prescription records to her as soon as possible.

83. After Ms. Acosta's January inspection, Respondent Oduyale asked Ms. Garcia where the original prescriptions were, and Ms. Garcia told him. Respondent Oduyale asked Esteban to make copies of the newly located records. He asked Ms. Banda to print the prescriptions and labels questioned by the board's inspectors from Respondent Cal-Mex's computer. Ms. Banda printed the prescriptions and labels as requested.

The next day, Esteban copied the requested prescriptions on an industrial copier at Respondent Oduyale's copy center. Esteban put a couple of prescriptions on some pages in order

to minimize the stack of documents to be sent to Ms. Acosta. He made exact copies of the documents that were found. He returned the copied documents to Respondent Oduyale. Ms. Garcia put the documents in large envelopes and sent them to Ms. Acosta. Several Respondent Cal-Mex employees were present while copies of the prescriptions were made. None of the employees saw anyone make any changes to the prescriptions while they were being copied. No notes were created in the records or on the computer after Ms. Acosta left.

EVALUATION

84. Respondent Oduyale testified that a technician who input information from an invalid prescription and then printed a dispensing backer made a mistake. If Respondent Oduyale was correct, this mistake was repeated multiple times. Additionally, Respondent Oduyale's testimony does not explain why he signed the backers to the invalid prescriptions. The only logical explanation for the state of the records is that these 20 prescriptions were changed and new documents were created after the January inspection.

When the inspectors pointed out the non-conforming prescriptions to Respondent Oduyale, he did not understand why they were non-compliant or how to verify them. Ms. Acosta spoke to Dr. Rafla in January, and she testified that he did not know his forms were non-compliant. Board inspector Simin Samari confirmed that Dr. Rafla told her he learned his forms were non-compliant from Ms. Acosta. These facts further support a finding that respondents created documents after Ms. Acosta completed her inspection.

Clear and convincing evidence supports a finding that Respondent Oduyale and Respondent Cal-Mex gave documents to Ms. Acosta that were altered and contained false facts.

Expert Testimony on Behalf of Respondents Regarding Pharmacy Practices

85. Phillip K. Evans received his pharmacist license in 1973. He received his juris doctorate degree in 2000. He is studying for a master's degree in pharmacy. He has worked extensively in the pharmaceutical industry and has experience in hospital, retail and government-run pharmacies. He has worked in many pharmacies. He has extensive experience preparing sterile injectable medications. He also has had a career as an attorney. He is currently the pharmacist-in-charge in a retail pharmacy in San Diego.

86. In 1993, Mr. Evans' pharmacist license was suspended for 60 days, and he was placed on probation for three years for improperly increasing the quantity of drugs authorized by a prescribing physician, dispensing refills when refills were not authorized and for increasing the dosage of a prescribed drug without authorization from the prescriber. Mr. Evans recently received a citation from the board relating to his pharmacy license; however, he is disputing the citation.

87. In 2013, Mr. Evans' license to practice law was suspended for two years; however, the suspension was stayed and his license was placed on probation for three years with an actual suspension of six months. Mr. Evans was required to pay restitution to five clients in the total amount of approximately \$3,800 and to pay disciplinary costs. In a stipulation to resolve the disciplinary action, Mr. Evans admitted that his misconduct significantly harmed clients and

evidenced multiple acts of wrongdoing. The incidents that led to the discipline involved accepting money in advance for services that were not performed. Mr. Evans testified that he was undergoing medical treatment and sold his practice to another attorney who had agreed to provide the services Mr. Evans had contracted to provide. Mr. Evans, nonetheless, accepted responsibility for the misconduct.

88. Mr. Evans has been professionally associated with Respondent Oduyale for approximately 18 years, and they are very close friends. Mr. Evans worked at Respondent Cal-Mex for five days in December 2014 and was covering for Respondent Oduyale while this hearing was held.

89. Mr. Evans puts his initials on each prescription he reviews. He would not put his initials on a prescription if there was a problem with the prescription. He observed that the practices at Respondent Cal-Mex were standard compared with what he has observed at other pharmacies.

90. Mr. Evans considers a prescription “dispensed” when the medication is handed to the patient, not when the prescription is ready for the patient to pick it up. Until the patient receives the medication, the pharmacist retains possession and control of the medication.

REVIEW OF RECORDS RELATING TO BS

91. Mr. Evans reviewed the prescriptions for oxycodone dispensed to BS. He identified the typed note produced in discovery as being similar to what he has seen in other pharmacies, either in the computer or written on the prescription. He did not see such notes at Respondent Cal-Mex during his time there. Mr. Evans said this type of note is readily retrievable.

Mr. Evans testified that it was mandatory to contact the prescribing doctor when the quantity of medication prescribed exceeded expected usage. He agreed that if a patient with a chronic pain condition, who was likely dependent upon medications, was going on vacation, it was reasonable that an increased quantity of medication would be prescribed. If such a patient were to run out of medication, he or she could go through withdrawal, which could be life threatening. Mr. Evans found the prescribing doctor’s letter written one year after the prescriptions were dispensed to be persuasive evidence that Respondent Cal-Mex verified the prescriptions.

REVIEW OF RECORDS RELATING TO AS

92. Mr. Evans opined that respondents correctly dispensed 200 tablets of oxycodone 15 mg when the pharmacy did not have sufficient stock to fill the complete prescription because they obtained the prescribing doctor’s permission first. Although Mr. Evans stated that it was “most important” that respondents had obtained the prescriber’s permission to fill only part of the prescription, he later testified that respondents had acted properly if only the patient had been informed because providing the medication helped the patient.

ALTERED DIRECTIONS

93. As regards to bottle labels with different directions for use than indicated on the prescription, Mr. Evans, as did Respondent Oduyale, stated that these were in error, but Mr. Evans added that all pharmacies make mistakes. Mr. Evans also stated that pharmacists can alter a prescriber's directions when counseling the patient. For example, Mr. Evans stated that there are instances where the directions say to take a medication once a day and he will tell patients not to take the medication if they don't need it. He called this "embellishing" and stated that it was appropriate pharmacy practice. He also testified that it was not necessary to obtain a doctor's authorization to change instructions on a prescription from a standing order (example, one a day) to an "as needed" order. On cross-examination, Mr. Evans said he may not change the instructions on the medicine bottle but, depending on the circumstances, would tell the patient orally that they should take the medication as needed. Mr. Evans's testimony that such changes are permissible was unpersuasive.

AUDIT OF NORCO-10

94. As part of his duties as a pharmacist, Mr. Evans maintains controlled substance records and performs audits. He stated that his goal in conducting an audit is to zero out, but it does not always happen. A broken tablet or a miscount can result in an audit that does not zero out. Mr. Evans felt that having a 473 count overage indicated a problem in invoicing since Norco-10 comes in bottles of 500; he stated that it was better to be over than under by that amount.

VERIFYING PRESCRIPTIONS

95. Mr. Evans opined that pharmacists generally know a prescriber's staff. He described the process of verifying a prescription as: telephoning the doctor's office; advising the person answering the phone what the call is about; and receiving an "ok" from the person who answered the telephone. He believes that a doctor's staff can review a patient's chart and give authorization to fill a prescription. He testified that in 40 years of being licensed as a pharmacist he never contacted a doctor to determine who was authorized to verify a prescription, and he never heard of anyone doing that.

When Mr. Evans verifies a prescription he writes on the face of the prescription the date, time and who he spoke to, and he initials the prescription. If he re-wrote the prescription, he would include this information in a note on the prescription or on a piece of paper attached to the prescription.

When shown a pre-printed prescription from Dr. Rafla, Mr. Evans stated he would verify the prescription the first few times he received it from the doctor relating to a particular patient until he was comfortable with the prescription. When shown a prescription re-written by Respondent Cal-Mex, he agreed that he would have made more complete notes that what was on the prescription, but disagreed that the prescription did not meet the requirements of a prescription because all of the information needed was on the backer. He believes that as long as the pharmacist is the one who verified a prescription, the pharmacist can document the verification in any way he or she wants.

Mr. Evans did not see pharmacy technicians verify prescriptions while he was filling in at Respondent Cal-Mex.

96. Mr. Evans has worked with 4,000 to 5,000 pharmacists. He believes Respondent Oduyale is a competent and versatile pharmacist and that he has a reputation for honesty and integrity. He described Respondent Oduyale as a better pharmacist than himself.

97. In many ways, Mr. Evans and Respondent Oduyale disagreed as to what was standard and acceptable practice by pharmacists and pharmacies. Overall, Mr. Evans appeared rather cavalier in his manner of testifying and several times contradicted himself. His testimony was not found to be helpful in determining the issues in this matter, and was not given any weight.

Allegation that Respondent Oduyale Improperly Extended an Expiration Date for Oxytocin.

EXTENSION OF BEYOND USE DATE AND HOSPITAL INVESTIGATION

98. A pharmacist may not distribute drugs that they knew, or had reason to know, were adulterated or misbranded. (Bus. & Prof. Code § 4169, subd. (a); Health & Saf. Code § 111440.) When compounding drugs (combining two or more substances to make one drug product) a pharmacist must assign an expiration date to the compound beyond which the pharmacist, using his professional judgment, determines the product should not be used. This “beyond use date” (BUD) may not exceed the “shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.” (Cal. Code Regs., tit. 16, § 1735.2(h).)

99. On February 26, 2014, Respondent Oduyale was working as a pharmacist at Pioneer Memorial Hospital. Jaime Gudino, a pharmacy technician who was licensed for ten years and employed by Pioneer for over three and one-half years, was working with Respondent Oduyale. Mr. Gudino did not know Respondent Oduyale before they worked together at Pioneer, but they became friends and they frequently socialize.

Mr. Gudino worked in six to ten pharmacies before working at Pioneer. He was aware that Respondent Oduyale had a good reputation in the hospital and stated that he was the “go-to guy” for the other pharmacists on staff. Mr. Gudino observed that the nurses on staff asked Mr. Oduyale questions about medications more than they did any other staff pharmacist.

100. Mr. Gudino observed Respondent Oduyale preparing labels for sterile compounded bags of oxytocin¹⁵ which Pioneer purchased from Cantrell Drug Company. Mr. Gudino told Respondent Oduyale that the labels indicated that the oxytocin bags were expired. Respondent Oduyale disregarded Mr. Gudino’s concern and told him that it was all

¹⁵ Oxytocin is a medication used in the Obstetrics Department to induce and augment labor and to control post-partum bleeding. Oxytocin is compounded by adding a concentrated form of oxytocin to a sterile solution which is then administered to the patient intravenously. The oxytocin manufactured by Cantrell added concentrated oxytocin to lactated Ringer’s bags.

right, he was going to re-label the bags. Respondent Oduyale told Mr. Gudino that there was an urgent need for oxytocin. Mr. Gudino testified that he saw Respondent Oduyale look at the sterile compound bags but he did not know what Respondent Oduyale was looking for. He did not see Respondent Oduyale researching whether the expiration date could be extended. Mr. Gudino did not question Respondent Oduyale further because Respondent Oduyale was his boss.

HOSPITAL'S INVESTIGATION OF RESPONDENT ODUYALE'S EXTENSION OF BEYOND USE DATE

101. John Paul Teague is the Director of Pharmacy (Pharmacist-in-Charge) at Pioneer Hospital. He has worked at Pioneer in a variety of positions since 2005 and has been the Director for almost two years. He has been a licensed pharmacist for approximately seven years. As the Director of Pharmacy, Mr. Teague is responsible for the management and oversight of the hospital's pharmacy operations. Respondent Oduyale reported to Mr. Teague. Mr. Teague occasionally worked with Respondent Oduyale at the hospital and considered him a "pretty good" employee.

102. Mr. Teague overheard pharmacy technicians discussing Respondent Oduyale's relabeling of expired Cantrell bags, and he interviewed Mr. Gudino. Mr. Gudino told Mr. Teague that he saw Respondent Oduyale re-label the expired bags.

Mr. Teague searched the pharmacy computer logs for February 26, 2014, and could find no documentation that Respondent Oduyale had changed the expiration date of the compounded oxytocin. He expected to find a note in the system that the expiration dates had been changed, why they were changed, and upon what authority they had been extended. Mr. Teague found expired Cantrell bags in an area of the pharmacy designated for products that were to be discarded; there were no expired bags on the pharmacy shelves. He also found unexpired multiuse vials of concentrated oxytocin in the overstock area that were available for pharmacy staff to use to compound oxytocin. Further, Mr. Teague found that oxytocin was compounded by pharmacy staff the next morning, February 27, 2014, without extending an expiration date, thus supporting his belief that sufficient non-expired stock was available in the pharmacy on February 26, 2014.

Mr. Teague examined the Pyxis¹⁶ records in the Obstetrics Department and learned that compounded oxytocin bags were placed in Pyxis on regular intervals on February 26, 2014. Except for the bags relabeled by Respondent Oduyale, the compounded bags complied with hospital policy and were correctly compounded. Mr. Teague determined that two oxytocin bags were in the Pyxis machine when Respondent Oduyale put five expired bags in. Six bags of oxytocin were used between when Respondent Oduyale stocked the machine and it was refilled the next day. The first bag of oxytocin was taken 20 minutes after Respondent Oduyale loaded them into the machine. Mr. Teague was not aware of any literature that supported Respondent Oduyale's extension of Cantrell's assigned beyond use date.

¹⁶ Pyxis is the trade name for an automatic, computer-controlled medication dispensing system. Pyxis machines are located in several departments in the hospital. The Pyxis machine records a variety of information, including name of any individual who accesses the machine and the date and time medication is placed in, or withdrawn from, the machine.

Mr. Teague found small unexpired vials of concentrated oxytocin in the Obstetrics Department's Pyxis machine that were available to use to compound oxytocin. The Obstetrics Department also maintained an emergency supply of oxytocin. Mr. Teague spoke with the physician on call on February 26 and learned that the physician had not been contacted by Mr. Oduyale to advise him that expired sterile compound bags were placed in the Pyxis machine. Mr. Teague was not aware of any literature that supported Respondent Oduyale's extension of Cantrell's assigned beyond use date.

Mr. Teague interviewed Respondent Oduyale a few days after he learned that Respondent Oduyale had re-labeled the compounded oxytocin. Respondent Oduyale admitted that he had changed the expiration date on the Cantrell bags from February 24, 2014, to February 28, 2014, because there was no stock available. Mr. Teague asked Respondent Oduyale if he documented what he did, including referencing literature that supported his extension of the manufacturer's beyond use date. Mr. Oduyale insisted that he was within his rights to use his professional judgment to extend the date.

Mr. Teague testified that all pharmacy staff personnel received training about the hospital's drug compounding policy and were required to sign a document attesting that they understood the policy. The hospital maintained multiple logs to document the compounding of drugs and impressed upon the pharmacy staff that it was very important to accurately complete the logs. Mr. Teague had discussed with the pharmacy staff the significance of the beyond use date. The hospital maintained extensive policies about expired medications and provided bins in multiple locations for discarded pharmacy waste. He stated that unless the pharmacist was the person who compounded the drug, the expiration date of a compounded product could not be extended because the pharmacist could not know how the expiration date assigned by a manufacturer had been determined.

If, in an emergency situation, the only stock remaining was expired, the pharmacist was to contact the physician on call or the treating physician to give the physician the opportunity to decide if he or she wanted to use the expired product. An expired product may be less sterile, less stable and less potent. It may not provide the therapeutic response relied upon by the physician when treating his or her patient. In some cases, ineffective product could lead to a patient not progressing as expected and result in an otherwise unnecessary cesarean section. Further, if a patient was not progressing on inefficient medication, the physician might order a higher dosage, which could be excessive when full-strength medication was subsequently administered. Although in this case, no harm was reported, a potential for harm was created by extending the expiration dates of the compounding bags.

103. Respondent Oduyale did not have any negative job performance issues at Pioneer prior to February 26, 2014. Mr. Teague, however, considered Respondent Oduyale's actions very serious. Mr. Teague found that Respondent Oduyale used poor judgment in extending the expiration dates on the oxytocin without performing research to determine if the extension was supported by empirical data; he failed to document that he had extended the beyond use date; and he failed to advise the physician on call that he had stocked the Pyxis machine with expired compound bags. As a result of this misconduct, Mr. Teague determined to terminate Respondent Oduyale from his employment at Pioneer.

104. On cross-examination, a draft of a letter written by Mr. Teague, dated January 27, 2014, supporting Respondent Oduyale was introduced in evidence. The letter was addressed to the California State Board of Pharmacy and appeared to be originally intended to support Respondent Oduyale's application for a license for Respondent Cal-Mex. In the letter, Mr. Teague wrote that Respondent Oduyale had a reputation for "honesty, integrity and good moral character," and that "[a]s owner of his own pharmacy I believe Sol will continual [sic] to uphold his reputation as an honest, competent and ethical pharmacist." It is noted that the letter was never finalized or signed and was dated approximately one month before the incident that lead to Respondent Oduyale's termination from Pioneer Hospital. Mr. Teague testified that Respondent Oduyale's re-labeling of the expired oxytocin bag changed his opinion that Respondent Oduyale exercised good judgment as a pharmacist.

BOARD'S INVESTIGATION OF RESPONDENT ODUYALE'S EXTENSION OF BEYOND USE DATE

105. On April 30, 2014, Ms. Acosta performed a sterile compounding annual renewal inspection at Pioneer Hospital's pharmacy and investigated Respondent Oduyale's conduct in extending the beyond use date of the oxytocin bags. Ms. Acosta testified that ensuring the safety of sterile products, such as the sterile injectable oxytocin, is one of the board's priorities.

106. Ms. Acosta reviewed scientific literature relating to the expiration date of compounded oxytocin. Lawrence Trissel is the leading expert in the field of sterile injectables, such as oxytocin, and the assignment of beyond use dates. His writings are considered to be the best authority on the subject of sterile injectables. Published research conducted by Trissel, with others, confirmed that "oxytocin in lactated Ringer's injection should be restricted to a use period no greater than 28 days at room temperature to prevent microprecipitate formation¹⁷ and drug loss." In an article by Lisa A. Boothby and others, it is suggested that compounded oxytocin "could have beyond use dates of 31 days" if the bags are refrigerated and if sterility tests are conducted on them. Here, there was no testimony that the bags were refrigerated, and it was established that Respondent Oduyale did not perform sterility tests on the oxytocin bags before he re-labeled them.

107. Ms. Acosta subpoenaed documents from Pioneer and obtained a copy of a packing slip from Cantrell Drug Company dated January 29, 2014. The packing slip indicated that 60 oxytocin bags were delivered to Pioneer Hospital and provided, "**BUD: 2/24/2014**" (Bold in the original.).

Ms. Acosta contacted Cantrell for further information. Cantrell personnel advised Ms. Acosta that Respondent Oduyale had not contacted Cantrell before he extended the expiration date of the compounded oxytocin from February 24 to February 28, 2014; it had never provided data or authorized the extension of the beyond use date past 28 days; and it did not have sterility or stability data that would allow the extension of the beyond use date beyond the assigned 28 days. Cantrell provided a copy of the shipping label and a label attached to the prescription indicating a discard date of February 24, 2014.

¹⁷ Microprecipitates are not visible by the naked eye.

RESPONDENT ODUYALE'S POSITION RELATING TO EXTENSION OF BEYOND USE DATE

108. Respondent Oduyale worked at Pioneer Hospital from 2003 until his termination in early 2014. In a 2012 performance evaluation, Respondent Oduyale received an overall rating of 2.06 out of 3.0 from his supervisor, Santos S. Milosevich. Mr. Milosevich noted that "Sol is a reliable and dependable pharmacist. Sol makes good judgment [sic] and is an integral part of Pharmacy Healthcare team."

In November 2013, Respondent Oduyale received a performance evaluation prepared by Mr. Teague. In that review, Respondent Oduyale received an overall rating of 2.32 out of 3.0. In the performance evaluation, Mr. Teague wrote, "Sol consistently makes himself available to all staff and routinely rounds patient care areas before leaving and closing the pharmacy for the evening. This is not a requirement of our pharmacists but shows his commitment and care for our patients and Pioneer Memorial Hospital staff that we serve." Additional comments included, "Sol can handle matters without requiring assistance, he offers advice and communicates not only with pharmacy staff but our nursing staff as well. Sol offers a wealth of knowledge and experience and is the first to offer his assistance to anybody in need."

109. Respondent Oduyale testified that he received a lot of training regarding sterile injectables. His training covered compounding, mixing concentration vials, pharma-kinetics and the preparation of intravenous bags.

110. Respondent Oduyale testified that, on February 26, 2014, a call came into Pioneer Hospital's pharmacy at approximately 11:15 p.m. from a nurse in the labor and delivery unit requesting oxytocin immediately. Although the pharmacy was scheduled to be closed at 11:00 p.m., Respondent Oduyale responded to the call. He looked for compounded oxytocin bags on the pharmacy's shelves and found more than a dozen there. The beyond use date on all of the bags had expired by one or two days. Respondent Oduyale said he checked the Pyxis machines for other departments to see if oxytocin could be located there. He looked for vials of oxytocin from which he could compound oxytocin bags, but he could not find any. He considered whether he could get oxytocin from another hospital or retail pharmacy but they were closed. He determined that the call for oxytocin was an emergency because the failure to administer oxytocin when needed could injure a baby or cause suffering in the mother. Respondent Oduyale determined that the Cantrell oxytocin bags were compounded on January 29, 2014, and made the decision to extend the beyond use date.¹⁸

111. Respondent Oduyale stated that manufacturers were required to put the prepared date on compounded sterile injectables. He therefore assumed that the January 29, 2014, date on the Cantrell bags reflected the compounded date. No other witness confirmed this assertion.

112. Respondent Oduyale stated that he shook the compound bags and inspected them against the light to see if he could observe any particulates in the fluid; he did not see any. He also squeezed the bags to determine if there was any leakage. The bags looked stable to him; he had three women in labor; and he decided to extend the beyond use date. Respondent Oduyale also stated that he consulted a website, the name of which he could not recall, on his telephone and a book on intravenous admixture by Trissel. He claimed the website he consulted on his

¹⁸ Twenty-eight days from January 29, 2014 is February 26, 2014.

telephone supported a beyond use date of 28 to 31 days. The page of Trissel cited by Respondent Oduyale provides that oxytocin is physically compatible with a lacerated ringer's bag "with little or no loss of oxytocin in 28 days at 23° C protected by light. Microprecipitate forms and loss of oxytocin occurs after that date." This citation does not support Respondent Oduyale's extension of the beyond use date.

113. Respondents rely on hospital policy that states, "A pharmacist may adjust expiration dates based on current literature and professional judgment." It also says that expiration dates for compounded sterile products "shall not extend beyond the stability period established by the manufacturer or listed in a current, authoritative reference. . . . A pharmacist shall determine if the products are usable after this date." Respondent Oduyale believed this policy gave him discretion to extend the beyond use date of the oxytocin in an emergency situation. He stated he changed the dates on four or five bags.¹⁷

TESTIMONY OF PHARMACY TECHNICIAN RICARDO ARRIQUIVE

114. Ricardo Arriquive has been a licensed pharmacy technician for ten years. He worked at Pioneer Hospital for seven years until his employment there was involuntarily terminated in October 2013. He has worked at Respondent Cal-Mex for three months. Mr. Arriquive opined that he would adjust expiration dates on products that he compounded after he researched how long the product remained stable and sterile. If a medication was needed but not in stock, Mr. Arriquive would research the issue and make a decision whether to extend the expiration date. He would not adjust the expiration date on a manufactured compound. He was not authorized to adjust the beyond use date for any product; he was required to get authorization from a pharmacist. He stated that the hospital did not use expired medications, although expired medications were found in the Pyxis machine from time to time. Staff was instructed to pull any medication they saw that was expired. He testified that Labor and Delivery nurses had totes and concentrated oxytocin on the unit. Although Respondent Oduyale's counsel called Mr. Arriquive to testify, Mr. Arriquive's testimony tends to support a finding that Respondent Oduyale should not have extended the beyond use date of the oxytocin.

Mr. Arriquive testified that, having access to medications could be challenging at Pioneer Hospital because Elvira Martinez Gonzalez, a pharmacy technician, put some medications in locked storage so that departments that did not need medications would not be overstocked. It became difficult to get medications at night because Ms. Martinez Gonzalez was not on duty at night and there was not an extra key to the locked medications. Mr. Arriquive stated that Respondent Oduyale was well-respected at the hospital and even the Directors of Pharmacy came to him for advice. He felt that Respondent Oduyale was the most knowledgeable pharmacist he had ever worked with. Mr. Arriquive is a social friend of Respondent Oduyale.

TESTIMONY OF ELVIRA MARTINEZ GONZALEZ

115. Elvira Martinez Gonzalez has been a licensed pharmacy technician for sixteen years; she has worked at Pioneer Hospital for thirteen years. Her responsibilities include medical billing, preparing medications, answering the pharmacy telephone, bringing medications to hospital floors, compounding drug products, and acting as buyer for the pharmacy department at

the direction of the pharmacist. Ms. Gonzalez worked for Rite Aid several years ago. She testified in response to Mr. Arriquite's testimony.

116. Ms. Gonzalez denied that there was a locked drug cabinet that was accessible only by her and denied that staff was hiding drugs. A cabinet that is located close to her desk was locked a few years ago because narcotics boxes for the operating room were stored there. Since Pyxis machines were installed in the hospital, there was no need to lock the cabinet, and Mrs. Gonzalez testified there is no key for the cabinet now. If something is ordered that the hospital does not need or an incorrect item is delivered, Ms. Gonzalez puts those items in the cabinet until they can be returned.

The hospital pharmacy has shelving units on the walls of the pharmacy; each wall contains medications and devices for various purposes. For example, one wall is for intravenous applications, one is for ear related medications, one is inhalation gasses, and one is for emergency room medications. A few feet from the intravenous wall is the overstock wall for compounding. Every Thursday during staff meetings, Ms. Gonzalez asks what items are overstocked and what items need to be ordered. Hospital pharmacists have access to all drugs in the hospital regardless of where they are located. Pharmacy staff is required to make corrections in Pyxis when they see that the count is not correct. The accuracy in the count is determined by whether each user enters the correct amount of medication being removed and removing the amount entered.

It is not common for someone in the pharmacy department to re-label a compounded drug product to extend the expiration date. The hospital policy is that expired drugs should not be used.

The pharmacy has concentrated vials of oxytocin for compounding in the event there is an unexpected volume in the Labor and Delivery Department or if the bags they have are expired. It takes no more than five minutes to compound a bag of oxytocin. Ms. Gonzalez reviewed pharmacy records and determined that, on February 26, 2014, there were multiple unexpired vials of oxytocin in Pyxis machines and in emergency "totes" (tackle boxes) in the obstetrics department that were available to be compounded. Additionally, a pharmacy technician compounded 5 bags of oxytocin in the morning on February 26. On February 27, 2014, oxytocin was compounded in the pharmacy using vials that were available on February 26, 2014. There was no need, emergency or otherwise, to extend the beyond use date of the Cantrell oxytocin bags.¹⁹

Before this incident, Ms. Gonzalez felt Respondent Oduyale was a hard-working pharmacist with integrity. After this incident, she is not sure how she feels about his abilities as a pharmacist.

Respondent's Expert Testimony Relating to Extension of Beyond Use Date

117. Anna K. Brodsky received a Doctor of Pharmacy degree from the University of Southern California in 2010. She participated in one to two month externships/clerkships in 2006, 2008, 2009 and 2010. From August 2006 to January 2010, Dr. Brodsky worked as an

¹⁹ Pyxis records show that Respondent Oduyale placed five bags of oxytocin in the machine.

intern pharmacist for CVS Pharmacy. She was a pharmacist for Target Corporation from May 2010 to June 2013, where she received experience compounding medications. From February 2013 through March 2014, Dr. Brodsky was a clinical pharmacist for Absolute Wellcare Pharmacy, LLC, a company that operated long-term care facilities. She served as a panel expert appointed by the Los Angeles County Superior Court to assist attorneys in criminal trials in matters relating to pharmacology. Dr. Brodsky has worked for Medico Rx Specialty and Home Infusion as Pharmacy Director since March 2014, where she has administrative duties as well as responsibilities that include dispensing medications. She teaches at the University of Southern California and is a preceptor to pharmacy students. Dr. Brodsky could not recall if she ever compounded oxytocin, but if she had, it would have been limited to when she was a student intern in a hospital setting.

118. Dr. Brodsky was asked to evaluate and render an opinion regarding Respondent Oduyale's extension of the beyond use date of the oxytocin. She was provided a copy of the Cantrell prescription label which indicated "Discard after 2/24/2014" below which was the date "1/29/2014." Dr. Brodsky testified that, in her experience, the January 29, 2014, date on the label represents the date the medication was compounded - or the "make" date and that it was reasonable for a pharmacist to assume January 29, 2014, was the "make" date. She also testified that other literature in the scientific community supports the proposition that oxytocin may remain potent to ninety percent up to 31 days or more, although she qualified her response by saying that more studies were needed. She opined nonetheless, that extending oxytocin by two days past the "beyond use date" is not harmful even if the concentration of drugs was lower. She stated that a nurse might need to adjust the amount given, but that there was nothing to suggest the drug would not work. Dr. Brodsky felt that allowing hospitals to use medications for a longer period helps patients by lowering health care costs. She stated that a pharmacist may use his or her professional judgment whether to extend a beyond use date by considering when the drug was compounded and reviewing scientific literature.

119. Dr. Brodsky made the following assumptions when she opined that Respondent Oduyale properly exercised his professional judgment to extend the oxytocin by two days past the beyond use date assigned by Cantrell: Respondent Oduyale inspected the oxytocin bags; research supported the extension of the dates; the oxytocin bags were compounded on January 29, 2014; and February 26 was the 28th day after the product was compounded. In response to a hypothetical question, Dr. Brodsky opined that if a patient needed oxytocin and the only oxytocin in a hospital pharmacy was expired, the pharmacist should pull the current scientific literature concerning beyond use dates and check the oxytocin bag to confirm there are no precipitates in the bag. If the literature supported a date extension, there were no precipitates visible, the bag was stored under good conditions and the hospital policy allowed the pharmacist to change the date, then the pharmacist could properly exercise his or her professional judgment to extend the date. In this case, Dr. Brodsky testified that, assuming the "make" date was January 29, 2014, the literature supports a beyond use date of February 26, 2014, and the medication would not have changed significantly in the two days the date was extended by Respondent Oduyale. Dr. Brodsky stated that in the balance of risk versus patient need, the patient's need prevails.

120. Under cross-examination, Dr. Brodsky stated that she could not recall if she ever extended the beyond use date of a manufactured sterile injectable. She acknowledged that she

was not aware of any literature that supported a determination that compounded oxytocin bags remained sterile after 28 days. Contrary to her original opinion, Dr. Brodsky testified that, were she to extend the beyond use date of a manufactured sterile injectable, she would do research and send the product to a laboratory to determine if the drugs remained sterile and stable; however, it would take three to seven days to get the results from the laboratory. She agreed that to safely extend the beyond use date of a manufactured drug product it was necessary to know the expiration dates of the components used to compound the drug. She admitted she really did not know what Cantrell's January 29, 2014, date meant or how they assigned expiration dates. She also acknowledged that a pharmacist could not see microprecipitates by looking at a compounded drug product.

121. Dr. Brodsky subsequently opined that if the "made" date of the compounded oxytocin was other than January 29, 2014, she would follow the beyond use date of February 24, 2014, assigned by Cantrell, and she would not extend that date because it would be more than 28 days after the compound was made. Dr. Brodsky was unaware that Respondent Oduyale had extended the oxytocin beyond use date to February 28, 2014. She stated that it was "probably not" acceptable to extend the beyond use date to February 28 and that no studies supported such an extension. She testified that, if she had compounded a drug product and assigned a beyond use date, she would have assigned the correct date and no one should extend the date she assigned. Dr. Brodsky testified that if the oxytocin was given an expiration date past the beyond use date assigned by the manufacturer, the drug is not misbranded but the label would contain false or misleading information. Finally, Dr. Brodsky confirmed that she would not extend the beyond use date by four days and that it was not the exercise of good professional judgment to do so without contacting the manufacturer, calling the physician on call, and looking for the medication in other places in the hospital.

EVALUATION

122. Clear and convincing evidence supports a finding that Respondent Oduyale improperly extended the expiration date of five bags of oxytocin. Respondent Oduyale's claim that the invoice date of the compounded oxytocin was the "made" date was unsupported by any evidence and was wrong. The Cantrell oxytocin bags were clearly labeled with an expiration date of February 24, 2014. Respondent Oduyale had no way to know the expiration date of the materials used to make them or when the compound was made. The fact that Respondent Oduyale, a pharmacist with many years of experience, believed he could hold a compounded product up to the light to see if there were any microprecipitates in it is alarming.

Respondent Oduyale's assertion that there was no concentrated oxytocin he could use to compound is unfounded and was unanimously disproved by witnesses and hospital records. Pharmacy technicians had compounded oxytocin earlier in the day on February 26 and in the morning of February 27 without using expired products. Although Respondent Oduyale claimed the need for oxytocin was an emergency, no oxytocin was taken from the Pyxis machine for twenty minutes after he stocked it with expired oxytocin. None of the scientific articles submitted at the hearing supported Respondent Oduyale's assertion that oxytocin remains stable, sterile and potent after 28 days, and none provided a justification for him to extend the beyond use date of the Cantrell bags. Significantly, even Respondent Oduyale's expert reconsidered her opinion when she became aware of the actual facts in this case and withdrew her previously held

opinion that Respondent Oduyale had properly exercised his professional judgment to extend the expiration date of the oxytocin.

Clear and convincing evidence supports a finding that Respondent Oduyale improperly extended the expiration date of the Cantrell compounded oxytocin.

Professional Reputation and Character Evidence

CAM TRAN

123. Several witnesses testified at the hearing regarding Respondent Oduyale's professional knowledge and reputation in the community.

124. Cam Tran has been a licensed pharmacist since 2001. She has been the Pharmacy Director at Alvarado Hospital, an acute care hospital in San Diego, for five years. Ms. Tran supervises eight pharmacists. Ms. Tran was a Pharmacy Director for Scripps Hospital from 2006 to 2009 and was the Pharmacy Director at Pioneer Hospital from 2002 to 2006. When she was a new pharmacist, Ms. Tran worked at Rite Aid in Calexico; Respondent Oduyale was her manager. When she worked at Pioneer Hospital, Respondent Oduyale was one of her pharmacists. She has not worked with Respondent Oduyale since 2006.

Ms. Tran stated that Respondent Oduyale is as competent as any other pharmacist she has working for her. She described him as a dedicated pharmacist. Ms. Tran hired Respondent Oduyale to work as a pharmacist at Alvarado Hospital; however, after a few days of training, Respondent Oduyale decided the commute was too long to pursue the job any further. Ms. Tran hired him because she trusted and valued him as a pharmacist. She never heard any complaints about Respondent Oduyale. Ms. Tran testified that she did not know exactly what the hearing was about although she understood the hearing was related to the board of pharmacy.

Ms. Tran stated that when she was at Pioneer Hospital, there were small tackle boxes in the labor and delivery department that had oxytocin in them for emergency use. She testified that she extended the date on a medication on one occasion when a surgeon asked for a medication and there was only one expired product in stock. She called the surgeon and told him the situation. He gave the authorization to use the expired product. She sent a sample to a laboratory the next day and learned the product was fine. She stated that hospital pharmacy practices did not allow a pharmacist to extend the beyond use date; the standard practice is that pharmacists follow what is on the label. She stated that intravenous bag labels always have the expiration date on them and confirmed that the labels may not include information about when the product was made.

VINCENT NGUYEN

125. Vincent Nguyen has been a licensed pharmacist since 2001; he and Ms. Tran are married. He is a floating pharmacist and works on a per diem basis. Mr. Nguyen interned for Respondent Oduyale in 2001; Respondent Oduyale was his preceptor at Rite Aid Pharmacy in Calexico. When Mr. Nguyen became licensed, he worked for Rite Aid with Respondent Oduyale. Mr. Nguyen has worked as a per diem pharmacist at Respondent Cal-Mex. He usually

fills in for a few days; however, he worked at Respondent Cal-Mex for two weeks in late 2014 when Respondent Oduyale returned to Nigeria to attend his mother's funeral.

Mr. Nguyen has worked in many pharmacies. He did not see any differences in the way Respondent Cal-Mex was run and how other pharmacies he has worked in are run. Mr. Nguyen believes Respondent Oduyale is a good pharmacist and that he has a reputation as a good man. Respondent Oduyale speaks Spanish for his Spanish-speaking customers. Mr. Nguyen never heard a complaint about Respondent Oduyale or Respondent Cal-Mex.

Mr. Nguyen was the pharmacist on duty one of the times that the board's probation monitor, Simin Samari, came to inspect the pharmacy. Ms. Samari was in the pharmacy for approximately one to two hours. She reviewed computer records, hard copies of prescriptions, backers and invoices. Ms. Samari told Mr. Nguyen that there were errors in the manufacturer National Drug Code (NDC) numbers on some prescriptions in the customer pick up area. Several manufacturers may make a generic brand of a medication. The NDC number identifying the manufacturer of the generic dispensed is required to be on each prescription. Ms. Samari educated him about the issue and told him he had to be careful. Mr. Nguyen stated that human errors occurred at Respondent Cal-Mex as they do in all pharmacies. Listing the wrong NDC number does not cause harm as long as the correct medication and strength is dispensed. Ms. Samari left a letter explaining a number of record keeping items that needed to be corrected. Mr. Nguyen advised Respondent Oduyale of the letter, and Respondent Oduyale responded to Ms. Samari.

MARCIA NESINIGUEZ

126. Marcia Nesiniguez has been a registered nurse for fourteen years. She is currently a Charge Nurse/Clinical Manager at Pioneer Hospital. She works in the Medical/Surgery Unit and is responsible for the movement of patients and nurse performance. She also helps in professional development of nurses on the floor. She has worked at Pioneer for six years.

Ms. Nesiniguez met Respondent Oduyale when he was a pharmacist at Pioneer. She stated that a patient care team includes the doctor, the nurse and the pharmacist. Respondent Oduyale was often the night pharmacist for the first five years Ms. Nesiniguez worked for Pioneer. Ms. Nesiniguez said that Respondent Oduyale was always available to help and educate students and nurses. She felt that Respondent Oduyale was knowledgeable and caring. She had seen him work and had trust in his decisions and recommendations concerning the care and medications needed for patients. He was careful and would look things up if he had questions. She believes he had a good reputation in the hospital. Ms. Nesiniguez is also familiar with Respondent Cal-Mex and has personal prescriptions filled there. She has never heard a complaint about the pharmacy.

Ms. Nesiniguez did not read the accusation in this matter and did not know what the hearing was about. She did not know Respondent Oduyale's license was previously on probation and did not know that he had once been arrested with drugs on him. She was not aware of why Respondent Oduyale was terminated from Pioneer Hospital. She relies on the pharmacy to check expiration dates of injectable products and trusts the information they give her.

CECILE MARIE ARELLANO ALCARAZ

127. Cecile Marie Arellano Alcaraz has been a licensed pharmacist in California since 2007. She has worked in retail pharmacies as a manager and on a per diem basis. Ms. Alcaraz met Respondent Oduyale in March 2013 at a professional meeting. She felt Respondent Oduyale was well rounded as a pharmacist.

In June 2013, Respondent Oduyale requested Ms. Alcaraz to observe Respondent Cal-Mex as a paid consultant to see if she had any recommendations about the operation of the pharmacy. Ms. Alcaraz observed how prescriptions were checked and filed. She saw Respondent Oduyale talking to patients and getting information from them. Ms. Alcaraz did not stay long at Respondent Cal-Mex, but she sent Respondent Oduyale a note regarding follow through. She also advised him of seminars offered by the board that might be helpful to him.

Ms. Alcaraz understood that it takes time to explain medications and instructions for use, especially to senior citizen patients. She felt Respondent Oduyale's care with this population and his ability to communicate with them in Spanish was a virtue of a good pharmacist. She saw Respondent Oduyale check the computer screen against the prescription label and look at the actual medication. Ms. Alcaraz suggested ways to improve the staff's work load. She discussed that the filing should be more organized. She also suggested updating the temperature log on the refrigerator and providing separate trash bins for empty bottles to better protect patient confidential information.

Ms. Alcaraz felt Respondent Cal-Mex was typical of other pharmacies she has worked in and supervised. She did not see anything she felt was being done incorrectly.

OLAYEMI FALOWO

128. Olayemi Falowo has been a pharmacist for 27 years; however, she has only an intern pharmacist license in California. She has had many positions in pharmacies in Minnesota, California and Arizona. She worked with Respondent Oduyale for three years, from 2006 through 2009, at the CVS Pharmacy in Yuma, Arizona, where he was the manager and she was a staff pharmacist. Ms. Falowo opined that Respondent Oduyale was a very good pharmacist, dependable; he went the extra mile and was hard working. He was exceptional amongst all the pharmacists she has worked with.

Ms. Falowo has observed Respondent Cal-Mex once a week for approximately four hours for the last two years because she aspires to have her own pharmacy. Respondent Oduyale has been her mentor. She observed all aspects of the pharmacy. From her observations, she opined that Respondent Cal-Mex was a good pharmacy. It helps seniors by providing transportation for them and delivers medications at no cost. She observed that Respondent Cal-Mex did a good job and she did not observe any violations of pharmacy laws or regulations.

Character and Reputation Evidence - Customers and Community Leaders

129. Respondents submitted approximately 13 character and reputation letters from customers and community leaders. These letters described Respondent Oduyale as "a very caring

man,” “charismatic,” “a pleasure to work with,” “reliable,” “hard working,” “community minded,” “professional,” “generous,” “ethical,” “dedicated,” “diligent,” “compassionate,” and “knowledgeable.” Additionally, respondents submitted approximately nine letters from Respondent Cal-Mex customers who wrote glowingly about exceptional services they have received from Respondent Oduyale and Respondent Cal-Mex. Respondents also submitted over 20 customer surveys that were returned to Respondent Cal-Mex. In each survey, Respondent Cal-Mex was rated “5” on a scale of one to five. Comments from customers included that the staff was friendly and helpful and that Mr. Oduyale provided excellent service.

HILDY CARRILLO

130. Hildy Carrillo has been the Executive Director of the Calexico Chamber of Commerce for 15 years. Through this position she has become familiar with the reputations of businesses in Calexico. She sometimes receives complaints about other pharmacies, but she has not received any about Respondent Cal-Mex. She has known Respondent Oduyale for 20 years and believes him to be a well-respected and honest member of the business community. She is aware that he has generously sponsored events for senior citizens. She is aware that Respondent Cal-Mex’s license was on probation, but she did not know what the hearing she was attending was about.

JOHN RENISON

131. John Renison has served for almost 20 years in many community and public service positions in Imperial County and the City of Calexico including Mayor, City Councilman and County Supervisor. He also held a management position with San Diego State University for 16 years. He is familiar with Calexico’s local businesses and their reputations in the community. He has known Respondent Oduyale since the mid - 1990s and believes him to be a good hearted, community minded businessman who is always willing to help the economically disadvantaged in the community. Mr. Renison noted that more than 40 percent of the citizens in the area receive government assistance, and the unemployment rate is at 26 percent. He commented that it is important to the community when local businesses reach out to help. Mr. Renison described Respondent Oduyale and Respondent Cal-Mex Pharmacy as above reproach, honest, and having integrity; he has not heard any complaints about Respondent Cal-Mex. Mr. Renison did not know what the hearing for which he was providing testimony was about; he had not read the accusation. He knew that Respondent Cal-Mex was on probation, but he did not know why. He did not know that Respondent Oduyale’s license had been on probation, why his license was on probation, or that Respondent Oduyale was terminated from Pioneer Hospital.

Other Matters Impacting the Level of Discipline

132. Simin Samari has been a licensed pharmacist in California since 1989. She has been an inspector with the board since 2005. For the past several years, Ms. Samari has been on the probation team. Her case load is 65 - 70 probationers each quarter. Her duties include inspecting pharmacies and answering probationers’ questions. Her goal is to help pharmacists do well in their probation.

When Ms. Samari is first assigned a probationer, she conducts inspections three to four times a year. She then reduces the number of inspections to approximately two a year. As a member of the probation team, she does not investigate complaints against pharmacies or pharmacists. As a probation monitor, Ms. Samari inspects to make sure the probationer is compliant with rules and regulations governing pharmacists and pharmacies and with the terms and conditions of probation.

133. In an inspection conducted in April 2012, one month after Respondent Cal-Mex opened, Ms. Samari observed that the pharmacy appeared to be in disarray and unorganized. The inspection report noted three areas that the pharmacy was required to improve. Ms. Samari discussed the deficiencies with Respondent Oduyale and how to correct them.

134. In an inspection report concerning an inspection conducted on July 5, 2012, Ms. Samari noted compliance with the previous inspection requirements. Ms. Samari found the pharmacy was still unorganized.

135. Ms. Samari inspected Respondent Cal-Mex on February 12, 2013, shortly after the board's inspection by Ms. Acosta and Mr. Mutrux. She reviewed the controlled and non-controlled substance books and controlled substance records. In the report for this inspection, Ms. Samari discussed Dr. Rafla's pre-printed prescriptions. Ms. Samari educated Respondent Oduyale about these and told him that all prescriptions must be written on board approved prescription pads. Ms. Samari also spoke to Dr. Rafla and advised him that the pre-printed prescriptions he was using did not comply with California requirements. Dr. Rafla acknowledged that he had spoken with Ms. Acosta and had stopped using pre-printed prescription blanks. Although Ms. Samari testified that she still found the pharmacy cluttered, she did not note that on the report.

136. On June 27, 2013, Ms. Samari inspected Respondent Cal-Mex. She reviewed the controlled and non-controlled substance books and controlled substance records. She issued a reminder to "Keep the pharmacy clean and organized."

137. On January 30, 2014, Ms. Samari inspected Respondent Cal-Mex. Mr. Nguyen was the pharmacist on duty. She reviewed the controlled and non-controlled substance books and controlled substance records. On this inspection, Ms. Samari found two medications in the will call area for which the description of the dispensed medication on the label did not match the medication in the bottle. Mismatched medication can be an indicator of billing fraud. A brand name drug is generally much more expensive than a generic brand of the same drug. A pharmacy engaged in billing fraud could bill for the more expensive drug but dispense the less expensive generic brand. Respondent Oduyale was instructed to provide a statement to Ms. Samari explaining how he planned to prevent this error from happening again.

Respondent Oduyale responded that the medications prescribed and dispensed were correct once the error was realized. He stated that the error occurred because NDC numbers on the label did not match the NDC from the original container. He stated that a special training meeting was held for all the pharmacy staff to educate them about the issue.

138. Ms. Samari inspected Respondent Cal-Mex on July 1, 2014. She found five prescriptions ready to be dispensed where the medication in the bottle did not match the description on the label. This was the same error noted in her previous inspection. In this inspection Respondent Oduyale told Ms. Samari that he was no longer accepting prescriptions for controlled substances if the doctor is outside the area and the patient is not known to him.

139. On March 5, 2015, Ms. Samari inspected Respondent Cal-Mex. The previous issue regarding label descriptions not matching the medication appeared to be corrected. However, in this inspection, Ms. Samari found “numerous” medications with labels indicating drug expiration dates in December 2016; however, the prescriptions were filled with medications whose expiration dates were earlier than that shown on the label. For example, one prescription with a label that indicated an expiration date of December 2016, was filled from stock that had an expiration date of June 2015. Potency and sterility decrease after the manufacturer’s expiration date. Ms. Samari issued a non-compliance notice to Respondent Cal-Mex based on her findings.

140. Ms. Samari testified that respondents failed to file two recent quarterly reports as required by the terms and conditions of probation. Respondent Oduyale, however, stated that he was not aware that he was required to continue to file quarterly reports because, absent the current administrative proceedings, Respondent Cal-Mex’s probation would have terminated.

Ms. Samari opined that Respondent Cal-Mex was not a good probationer. Respondent Cal-Mex and Respondent Oduyale, its pharmacist-in-charge, were given ample opportunities to comply with the rules and regulations governing pharmacies and pharmacists, but they have not demonstrated an ability to comply. She stated that there may have been additional deficiencies in the pharmacy that she spoke to Respondent Oduyale about, but did not include in her report in order to give respondents a chance to improve.

Allegations of Poor Quality of the Board’s Investigation

141. Respondents claim that the board’s inspections were of such a poor quality that the inspectors’ findings are suspect and should be disregarded. Respondents refer to claims alleged in the originally filed Accusation and Petition to Revoke Probation but dropped in the First Amended Accusation and Petition and a cause for discipline dismissed at the hearing as evidence of the poor quality of the investigations. Respondents argue that the board’s inspectors should have taken affirmative actions to determine that the dropped claims were not meritorious.

Costs

142. The board filed a Certification of Costs of investigation by Agency Executive Officer; a Certification of investigative Costs with Declaration of Christine Acosta; an Amended Certification of investigative Costs with Declaration of Brandon Mutrux; and a Certification of Prosecution Costs with Declaration of Nicole R. Trama seeking to recover costs of investigation and prosecution pursuant to Business and Professions Code section 125.3.

The certification of prosecution costs filed by the Attorney General sought recovery of costs in the amount of \$26,920.00 and was supported by a billing summary detailing the

professionals who worked on the matter, the date the professional worked on the matter, the tasks performed, the amount of time billed for the activity and the hourly rate of the professional who performed the work. The total amount sought included \$1,700.00 which was an estimate of additional hours that would be incurred by the prosecution in preparation of the case up to the commencement of the hearing. The costs sought by the Attorney General are reasonable.

The certifications of investigative costs with declarations from Ms. Acosta and Mr. Mutrux sought the recovery of \$25,066.50. The certifications listed the total of investigative hours spent working on the case, the hourly rate charged and a breakdown of activities by categories; the total number of hours worked on the matter was divided into investigation, travel, report preparation and hearing preparation. These certifications did not detail the date the activities were performed or the time spent performing those activities on each date. Due to the lack of specificity, it cannot be determined whether the costs claimed for investigative hours are reasonable.

Ms. Acosta testified that this matter was a difficult case with many documents that she was required to review. She did not know if the costs claimed included time she accompanied the DEA to Respondent Cal-Mex in April 2014. She did not pro-rate the amount of costs claimed by the amount of time devoted to claims that were later dismissed.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Complainant bears the burden of proof of establishing that the charges in the accusation and petition to revoke probation are true.

2. a. With respect to the accusation portion of the pleadings against a professional license, including a pharmacist's license, the standard of proof required is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) This is because a professional license represents the licensee's fulfillment of extensive education, training, and testing requirements; the licensee has an extremely strong interest in retaining the license that she has expended so much effort in obtaining. The obligation to establish charges by clear and convincing evidence is a heavy burden. It requires a finding of high probability; it is evidence so clear as to leave no substantial doubt, or sufficiently strong evidence to command the unhesitating assent of every reasonable mind. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

b. To establish cause for discipline for an occupational non-professional license, including a pharmacy license, cause for discipline need only be established by the preponderance of the evidence standard. (*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; *Mann v. Dep't of Motor Vehicles* (1999) 76 Cal. App. 4th 312, 319, 90 Cal. Rptr. 2d 277, 282.) A preponderance of the evidence means that the evidence on one side outweighs the evidence on the other side, not necessarily in number of witnesses or quantity, but in its effect on those to whom it is addressed. In other words, it refers to evidence that has more

convincing force than that opposed to it. (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

c. With respect to the charges in the petition to revoke probation, the standard of proof is also preponderance of the evidence. (*Sandarg v. Dental Bd. of California* (2010) 184 Cal.App.4th 1434, 1441.)

3. Although the standards of proof are different for the two license types and for the charges in the petition to revoke, each violation found was established by clear and convincing evidence to a reasonable certainty.

4. The board's highest priority in exercising its licensing, regulatory, and disciplinary functions is protection of the public. Whenever the protection of the public is inconsistent with other interests sought to be promoted, protection of the public shall be paramount. (Bus. & Prof. Code § 4001.1)

5. Business and Professions Code section 4063 regulates how a prescription can be refilled. It provides:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

6. Business and Professions Code section 4022 defines "dangerous drug" as "any drug ... unsafe for self-use in humans or animals." Subdivision (a) provides that a dangerous drug is "Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,'" or words of similar import. Subdivision (c) provides that a dangerous drug includes, "Any other drug ... that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

7. Business and Professions Code section 4071 provides:

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

8. Business and Professions Code section 4073, subdivision (a), regulates how a pharmacist can make substitutions in filling a prescription. It provides:

A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN)

and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

9. Business and Professions Code section 4081, subdivision (a), requires a pharmacy to maintain records of the “manufacture and sale, acquisition, receipt, shipment, or disposition of dangerous drugs” for three years. The records must be “at all times during business hours open to inspection by authorized officers of the law” The subdivision also requires that every pharmacy maintain a current inventory of dangerous drugs.

10. Business and Professions Code section 4169, subdivision (a), provides, in part:

(a) A person or entity shall not do any of the following:

[¶] ... [¶]

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs ... after the beyond use date on the label.

11. Business and Professions Code section 4301 provides, in 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:

[¶] ... [¶]

(c) Gross negligence.

[¶] ... [¶]

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

[¶] ... [¶]

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

[¶] ... [¶]

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

12. Business and Professions Code section 4306.5 provides in part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

13. Health and Safety Code section 11153, subdivision (a), provides:

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

14. Health and Safety Code section 11164 provides, in part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

[¶] ... [¶]

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

15. Health and Safety Code section 11165 provides, in part:

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) 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.

[¶] ... [¶]

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, 'clinic, or other dispenser shall 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 specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate 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.

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

16. Health and Safety Code section 11172 provides, "No person shall antedate or postdate a prescription."

17. Health and Safety Code section 111440 provides, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

18. Health and Safety Code section 111335 provides, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

19. Health and Safety Code section 110290 provides:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

20. Health and Safety Code section 111455 provides that, “It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded.”

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

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

22. California Code of Regulations, title 16, section 1717.3 regulates the use of preprinted forms and provides, in part:

(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

[¶]

(c) “Preprinted multiple check-off prescription blank,” as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a “check-off,” indicates a prescription order for that drug.

23. California Code of Regulations, title 16, section 1718 requires a pharmacy to maintain a current inventory which “shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.” Controlled substances inventories “shall be available for inspection upon request for at least 3 years after the date of the inventory.”

24. California Code of Regulations, title 16, section 1735.2 regulates when and how medications can be compounded. Subdivision (h) provides:

Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the

pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

25. California Code of Regulations, title 16, section 1761, subdivision (a) provides:

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

Disciplinary Guidelines

26. The board’s Disciplinary Guidelines (rev. 10/2007) provide that the board “serves the public by: protecting the health, safety, and welfare of the people of California with integrity and honesty...” (Cal. Code Regs., tit. 16, § 1760.)

27. The Disciplinary Guidelines provide that the following factors should be considered when determining the level of discipline to be imposed in a disciplinary case:

1. Actual or potential harm to the public.
2. Actual or potential harm to any consumer.
3. Prior disciplinary record, including level of compliance with disciplinary order(s).
4. Prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s).
5. Number and/or variety of current violations.
6. Nature and severity of the act(s), offense(s) or crime(s) under consideration.
7. Aggravating evidence.
8. Mitigating evidence.
9. Rehabilitation evidence.
10. Compliance with terms of any criminal sentence, parole, or probation.

11. Overall criminal record.
12. If applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code.
13. Time passed since the act(s) or offense(s).
14. Whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct.
15. Financial benefit to the respondent from the misconduct.

Evaluation

28. Pharmacists occupy positions that require trustworthiness, honesty, clear headedness, and the exercise of impeccable judgment; they have access to confidential personal and financial information as well as highly regulated medications and devices. Pharmacies are a highly regulated industry because they possess and control dangerous drugs and devices. Lax practices and the failure to comply with the rules and regulations regarding pharmacies and pharmacists allow for a high potential for abuse and significant harm to individuals and the public. Pharmacies with a reputation for skirting the legalities of dispensing medications have a high potential to create great harm to individuals and their communities.

CAUSES FOR DISCIPLINE ALLEGED AGAINST RESPONDENT CAL-MEX AND RESPONDENT ODUYALE

29. Cause exists under Business and Professions Code sections 4301, subdivision (o) and 4081, subdivision (a), and California Code of Regulations, title 16, section 1718 to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they failed to maintain adequate records of the acquisition and disposition of the controlled substance of Norco 10 and failed to keep a current accurate inventory between May 1, 2012, through January 28, 2013, as described in the Factual Findings above. (First Cause for Discipline.²⁰)

30. Cause does not exist under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11165, subdivision (d), to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license as described in Factual Finding 31 above. (Third Cause for Discipline.)

31. Cause does not exist under Business and Professions Code sections 4301, subdivision (o), and 4073, subdivision (a), to impose discipline on Respondent Cal-Mex's

²⁰ As noted in Factual Finding 12, the Second Cause for Discipline was dismissed by complainant at hearing.

pharmacy permit and Respondent Oduyale's pharmacist's license pursuant to Factual Findings 32-36. (Fourth Cause for Discipline.)

32. Cause exists under Business and Professions Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1716, to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they improperly deviated from the requirements of five prescriptions to five different patients without documentation of the prior consent of the prescriber on the prescription or a rewrite of the prescription. (Fifth Cause for Discipline, as amended at hearing; Factual Findings 13, 32 through 43.)

33. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11164, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions for controlled substances which were not written on a controlled substance form as required by law as discussed in the Factual Findings above. (Sixth Cause for Discipline, Factual Findings 44 through 54.)

34. Cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1717.3, subdivision (a), to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions for controlled substances which were written on preprinted, multiple check-off prescription blanks as discussed in the Factual Findings above. (Seventh Cause for Discipline, Factual Findings 44 through 54.)

35. Cause does not exist under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code sections 11164, subdivision (a)(1), and 11172, to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence failed to establish that respondents dispensed a controlled substance where the prescription was written after the medication was dispensed as discussed in the Factual Findings above. (Eighth Cause for Discipline, see Factual Findings 71 and 72.)

36. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11164, subdivision (b)(3), to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they failed to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions on multiple occasions as discussed in the Factual Findings above. (Ninth Cause for Discipline, see Factual Findings 44 through 65.)

37. Cause does not exist under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1761, subdivision (a), to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's

pharmacist's license. Pursuant to the Imperial Court's decision, there is insufficient evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions containing significant errors, omissions, irregularities, uncertainties, ambiguities or alterations as discussed in the Factual Findings above. (Tenth Cause for Discipline.)

38. Cause does not exist under Business and Professions Code sections 4301, subdivision (o), and 4063, to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence failed to establish that Motrin 600 mg is a dangerous drug as discussed in the Factual Findings above. (Eleventh Cause for Discipline, see Factual Findings 67 through 70.)

39. Cause does not exist under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11153, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. The evidence did not establish that respondents failed to implement corresponding responsibility when dispensing a 90 day supply of a controlled substance in 30 days as discussed in the Factual Findings above. (Twelfth Cause for Discipline, see Factual Findings 73 through 78.)

40. Cause exists under Business and Professions Code section 4301, subdivision (g), to impose discipline on Respondent Cal-Mex's pharmacy permit and Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they provided altered documents to the board's inspector that falsely represented the existence of facts as discussed in the Factual Findings above. (Thirteenth Cause for Discipline, see Factual Findings 17, 35, 56 through 60, 70, 79 through 84.)

CAUSES FOR DISCIPLINE ALLEGED AGAINST RESPONDENT ODUYALE

41. Cause exists under Business and Professions Code sections 4301 and 4306.5, subdivision (b), to impose discipline on Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that Respondent Oduyale engaged in unprofessional conduct when he failed to exercise or implement his best professional judgment as it relates to the dispensing or furnishing of drugs or services and as found in the Fifth through Seventh, and Ninth Causes for Discipline in the Accusation and as discussed in the Factual Findings and Legal Conclusions above. (Fourteenth Cause for Discipline, see Factual Findings 13, 32 through 65.)

42. Cause does not exist under Business and Professions Code sections 4301, subdivision (o), and 4169, subdivision (a), and Health and Safety Code section 111440, to impose discipline on Respondent Oduyale's pharmacist's license. Pursuant to the Imperial Court's decision, Respondent Oduyale's extension of the expiration date of compounded oxytocin beyond the manufacturer's beyond use date did not constitute a misbranding of the compounded oxytocin in this matter. Further, pursuant to the Imperial Court's decision, Business and Professions Code section 4169, subdivision (a), does not apply. (Fifteenth Cause for Discipline, see Factual Findings 98-122.)

43. Cause does not exist under Business and Professions Code section 4301, subdivision (j), and California Code of Regulations, title 16, section 1735.2, subdivision (h), to impose discipline on Respondent Oduyale's pharmacist's license. Pursuant to the Imperial

Court's decision, the sections alleged do not apply because Respondent Oduyale was not the compounder of the oxytocin. (Sixteenth Cause for Discipline, see Factual Findings 98-122.)

44. Cause exists under Business and Professions Code section 4301, subdivision (c), to impose discipline on Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that Respondent Oduyale engaged in gross negligence when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Factual Findings above. (Seventeenth Cause for Discipline, see Factual Findings 98 through 122.)

45. Cause exists under Business and Professions Code section 4301, subdivision (g), to impose discipline on Respondent Oduyale's pharmacist's license. Clear and convincing evidence established that Respondent Oduyale engaged in misconduct when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date by relabeling the product as discussed in the Factual Findings above. The relabeling of the compounded oxytocin constituted the making of a document that falsely represents the existence of a state of facts. (Eighteenth Cause for Discipline, see Factual Findings 98 through 122.)

46. Cause does not exist under Business and Professions Code sections 4301 and 4306.5, subdivision (a) to impose discipline on Respondent Oduyale's pharmacist's license. Pursuant to the Imperial Court's decision, as it was applied to Respondent Oduyale in this matter, the terms were insufficiently specific to find that he misused his education, experience and training when he extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Factual Findings above. (Nineteenth Cause for Discipline, see Factual Findings 98 through 122.)

47. Cause does not exist under Business and Professions Code sections 4301 and 4306.5, subdivision (b), to impose discipline on Respondent Oduyale's pharmacist's license. In this matter, pursuant to the Imperial Court's ruling, the weight of the evidence and law prevent a finding that Respondent Oduyale failed to exercise his best professional judgment when he extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Factual Findings above. (Twentieth Cause for Discipline, see Factual Findings 98 through 122.)

PETITION TO REVOKE RESPONDENT CAL-MEX'S PROBATION

48. In 2011, Respondent Cal-Mex's application for a pharmacy permit was granted, the permit was immediately revoked, the revocation stayed, and Respondent Cal-Mex was placed on 35 months of probation under certain terms and conditions. Under Condition 11 of the terms and conditions of probation, the board retained jurisdiction to revoke Respondent Cal-Mex's probation if Cal-Mex failed to comply with all of the terms and conditions of probation.

49. Cause exists under Condition 1 to revoke Respondent Cal-Mex's probation. Condition 1 of Respondent Cal-Mex's probation requires that Respondent Cal-Mex "and its officers shall obey all state and federal laws and regulations." Overwhelming evidence established that Respondent Oduyale, and thereby Respondent Cal-Mex, did not obey all state

and federal laws and regulations, as established by the First, Fifth through Seventh, Ninth, and Thirteenth Causes for Discipline. (First Cause to Revoke Probation, see Legal Conclusions 29, 32 through 34, 36, and 40.)

50. Cause exists under Condition 13 to revoke Respondent Cal-Mex's probation. Condition 13 of Respondent Cal-Mex's probation required that Respondent Cal-Mex "maintain and make available for inspection a separate file of all records pertaining to the acquisition and disposition of all controlled substances." Clear and convincing evidence established that Respondent Cal-Mex did not comply with Condition 13 as established by the Findings of Fact and Legal Conclusions above. (Second Cause to Revoke Probation, see Legal Conclusion 29.)

Discipline Determination

51. The purpose of an administrative proceeding seeking the revocation or suspension of an occupational license or registration or revocation of probation is not to punish the individual; the purpose is to protect the public from dishonest, immoral, disreputable or incompetent practitioners. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

52. The determination of whether Respondent Cal-Mex's pharmacy permit or Respondent Oduyale's pharmacy license should be revoked or suspended includes an evaluation of the criteria set forth in the board's Disciplinary Guidelines and regulations. In this case, it is extremely fortuitous that there is no evidence of actual harm occurring to Respondent Cal-Mex's customers or to Pioneer Hospital patients. To establish a nexus between misconduct and fitness to practice a profession, however, patient harm is not required. The laws are designed to protect the public before a licensee harms any patient rather than after harm has occurred. (*Griffiths v. Superior Court* (2002) 96 Cal.App.4th 757, 771-772.) Even with the causes of action dismissed pursuant to the Imperial Court's decision, the multiple instances of failure to comply with laws and regulations applicable to pharmacies and pharmacists are serious and presented a significant potential of harm to the public.

Both Respondent Oduyale and Respondent Cal-Mex have a prior disciplinary record; however, Respondent Cal-Mex's disciplinary record is based entirely upon Respondent Oduyale's past misconduct. Although it is Respondent Cal-Mex that is on probation, it is Respondent Oduyale's continued misconduct as a pharmacist and pharmacist-in-charge and his failure to comply with pharmacy laws and regulations that threatens Respondent Cal-Mex's pharmacy permit. It is not possible to neatly separate Respondent Cal-Mex and Respondent Oduyale. Respondent Cal-Mex and Respondent Oduyale were given correction notices and warnings by Respondent Cal-Mex's probation inspector, Ms. Samari. The pattern that was established was that Respondent Cal-Mex would remedy one problem and on the next inspection there would be a new violation. However, on some occasions the prior violation would reappear.

Even after omitting the causes for discipline invalidated by the Imperial Court, there are numerous causes for discipline including those alleged in the Petition to Revoke Probation, although several causes overlap and/or relate to the same misconduct. The seriousness of the violations is underscored by the undeniable evidence that, for all his years of experience, Respondent Oduyale does not appear to understand the basic principles of operating a pharmacy

and is incapable of running an orderly and compliant pharmacy. The finding in 2006 that he “played fast and loose with some of the rules” is equally applicable, if not an understatement, in this proceeding. The re-labeling of oxytocin shows a fundamental lack of understanding of compounding, expiration dates, the requirement to document and notify others when medications are altered, and hospital policies. His cavalier attitude and lack of understanding of the serious nature of his misconduct in the context of the practice of pharmacy is alarming.

As relates to the record keeping and multiple versions of prescriptions, the only conclusions that can be drawn are that the pharmacy is out of control. There simply is no good explanation of how documents obtained in the January inspection were re-produced as different documents several days later, and then as something new again several months later. Record keeping deficiencies and the pervasive failure to attend to detail were present in 2005, in the inspections of Ms. Samari in 2012, in the inspections of Ms. Acosta in 2013, in the DEA inspection in 2014, and in inspections conducted in 2015. Respondent Oduyale does not seem fundamentally capable or willing of getting these issues under control.

The lack of understanding and inability to conform to the rules, regulations and policies applying to pharmacies and pharmacists allow no other determination but that Respondent Oduyale is not a competent pharmacist. These findings are not an indictment of Respondent Oduyale as a person. By all accounts, including reports by the board’s inspectors, Respondent Oduyale is a kind and generous man who cares about his customers and community. Unfortunately, those qualities need to be matched with an ability to understand and comply with complex rules and regulations governing pharmacies and pharmacists. Pharmacies and pharmacists are heavily regulated for good reason. They possess and control dangerous drugs and devices that can make them targets of drug abusing employees, customers and members of the public. A failure to maintain complete control and an inability to demonstrate complete control through clear and organized files, invites abuse and presents a significant potential of harm to the public.²¹ Patient safety requires that pharmacy law be followed, including the ability to demonstrate what dangerous drugs have been provided to a patient under what conditions. The Board’s priority in its disciplinary functions is to protect the public; only the outright revocation of Respondent Oduyale’s license will protect the public. Even after excluding the causes of action pursuant to the Imperial Court’s decision, the remaining causes and the prior history clearly reflect that public protection can only be accomplished if Respondent Oduyale can no longer practice as a pharmacist.

53. Although Respondent Cal-Mex is the respondent on probation, the allegations against it in the prior action and the present action are based upon the actions of Respondent Oduyale. In fact, the pharmacy was placed on probation before it ever opened because of the prior discipline of Respondent Oduyale. Calexico has an underserved population. Testimony in this hearing established that the loss of the pharmacy would be a detriment to the community and those it serves. An underserved population, however, does not permit a substandard pharmacy service. Under the management and control of a more competent pharmacist who can observe pharmacy law, the board hopes the pharmacy can continue to serve the community. The board seeks to fulfill its priority of protecting the public by revoking Respondent Cal-Mex’s permit, staying the revocation, and placing Respondent Cal-Mex on four more years of probation.

²¹ No evidence was presented to suggest that there currently is diversion or theft of drugs occurring at Respondent Cal-Mex.

Because Respondent Oduyale's license is revoked, he will no longer be able to serve as a pharmacist-in-charge, or as any other category of pharmacist, in Respondent Cal-Mex. Respondent Cal-Mex will be required to obtain and designate a new pharmacist-in-charge who will be responsible for ensuring that Respondent Cal-Mex complies with the terms and conditions of probation, including all state and federal regulations. This level of discipline comports with the board's recommended guidelines.

The Reasonable Costs of Investigation and Prosecution

54. Under Business and Professions Code section 125.3, complainant may request that an administrative law judge "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."

55. The Office of Administrative Hearings has enacted regulations for use when evaluating an agency's request for costs under Business and Professions Code section 125.3. (Cal. Code Regs., tit. 1, § 1042.) Under the regulations, a cost request must be accompanied by a declaration or certification of costs. The declaration "may be executed by the agency or its designee and shall describe the general tasks performed, the time spent on each task and the method of calculating the cost." Alternatively, the agency may provide a bill or invoice. (Cal. Code Regs., tit. 1, § 1042, subd. (b)(1).) For services provided by persons who are not agency employees, the declaration must be executed by the person providing the service and must describe the general tasks performed, the time spent on each task and the hourly rate. In lieu of the declaration, the agency may attach copies of the time and billing records submitted by the service provider. (Cal. Code Regs., tit. 1, § 1042, subd. (b)(2).)

56. Complainant seeks costs related to the investigation and prosecution of this matter in the amount of \$51,986.50, based on \$25,066.50 for investigative costs and \$26,920.00 for costs incurred by the Attorney General's Office. Under Business and Professions Code section 125.3, costs awarded may not exceed the reasonable costs of investigation and enforcement of the case with respect to the licensing act violations. In this case, complainant filed an accusation and petition to revoke probation. All of the charges alleged in the Accusation and Petition were allegations that respondents violated the rules, regulations and policies that govern pharmacies and pharmacists.

57. The Certification of Investigative Costs submitted by Ms. Acosta and Mr. Mutrux listed a total of hours spent on the case and the hourly rate charged for activities they performed in the investigation and prosecution of the case. The total hours was then broken down into four categories: investigation; travel; report preparation; and hearing preparation. For example, Ms. Acosta's certification seeks costs for 187.5 hours at the rate of \$102.00 per hour. Of the total hours, 79 hours were for investigation; 8.25 hours were attributed to travel; 80.75 hours were attributed to report preparation; and 8 hours were attributed to hearing preparation. No other information regarding investigative services or expenses was included. Mr. Mutrux's certification was on an identical form, but his total number of hours were fewer and the numbers were distributed differently.

58. Neither the inspectors' nor complainant's certification contained information regarding the specific tasks performed, the date they were performed, or how long each task took. Because the certification did not comply with the regulation, the ALJ denied complainant's request for investigation costs.

59. The Certification of Prosecution Costs was prepared by Deputy Attorney General Nicole R. Trama and requested costs of enforcement in the amount of \$26,920.00. The certification included an attached breakdown of tasks by the professional who performed them, their general nature, the amount of time spent, and the amount charged. The certification complied with the OAH regulation. Based on a review of the accusation and petition to revoke probation, it is found that the charges related to abandoned or dismissed claims constituted a negligible portion of the case. The time-consuming aspects of this matter involved sorting out multiple versions of prescription documents resulting from respondents' poor record-keeping. The reasonable costs of enforcement by the Attorney General's Office are \$26,920.00.

60. In determining costs, the board considers the factors discussed in *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal. 4th 32. In *Zuckerman*, the California Supreme Court decided, in part, that in order to determine whether the reasonable costs of investigation and prosecution should be awarded or reduced, the Administrative Law Judge must decide: (a) whether the licensee has been successful at hearing in getting charges dismissed or reduced; (b) the licensee's subjective good faith belief in the merits of his or her position; (c) whether the licensee has raised a colorable challenge to the proposed discipline; (d) the financial ability of the licensee to pay; and (e) whether the scope of the investigation was appropriate to the alleged misconduct.

After consideration of all of the relevant factors, the ALJ determined that it was reasonable to require Respondent Cal-Mex and Respondent Oduyale to pay \$20,000.00 in costs. Respondents were made jointly and severally liable for the costs. The costs are to be paid prior to Respondent Oduyale filing an application for reinstatement of his license.

ORDER

A. Pharmacist License Number 42719 issued to Olugbenga Solomon Oduyale is revoked. Respondent shall relinquish his wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Pursuant to section 4309 of the Business and Professions Code, Respondent Oduyale may not reapply or petition the board for reinstatement of his revoked license for three years from the effective date of this decision.

B. Olugbenga Solomon Oduyale and Respondent Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy are ordered to pay costs to the board in the amount of \$20,000.00. All costs shall be paid prior to Respondent Oduyale filing an application for reinstatement of his license.

C. Pharmacy Permit number PHY 50374, issued to Respondent Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy, is revoked; however, the revocation is

stayed and respondent is placed on probation for four years upon the following terms and conditions:

1. Obey All Laws. Respondent owner shall obey all state and federal laws and regulations.

2. Report Violations. 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; or
- Discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent Cal-Mex's pharmacy permit 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.

3. 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.

4. 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.

5. Cooperate with Board Staff. Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

6. 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 \$20,000.00. Respondent owner and the probation monitor may

agree on a payment plan. Once a payment plan has been agreed upon, there shall be no deviation from this plan absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

7. 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.

8. Status of License. Respondent owner shall, at all times while on probation, maintain Respondent Cal-Mex's 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 Respondent Cal-Mex's permit, and Respondent Cal-Mex shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent Cal-Mex's permit 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.

9. 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.

Upon surrender, 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.

10. 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.

11. Owners and Officers: Knowledge of the Law. Respondent Cal-Mex 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.

12. 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.

13. 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.

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

15. Separate File of Records. Respondent owner 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.

16. Report of Controlled Substances. Respondent owner shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

This Decision shall become effective at 5:00 p.m. on February 6, 2017.

It is so ORDERED on January 6, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amarylis "Amy" Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation and Petition to Revoke
Probation Against:

**CAL-MEX SPECIAL SERVICES, INC., dba
CAL-MEX PHARMACY**
Original Pharmacy Permit No. PHY 50374

and

OLUGBENGA SOLOMON ODUYALE
Original Pharmacist License No. RPH 42719

Respondents.

Case No. 4724

OAH No. 2013080330

**ORDER FIXING DATE FOR
SUBMISSION OF ARGUMENT
AS TO RESPONDENT
CAL-MEX PHARMACY
SERVICES, INC. ONLY**

TO ALL PARTIES AND THEIR ATTORNEY OF RECORD:

ORDER FIXING DATE FOR SUBMISSION OF 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 Reconsideration, In Part dated August 6, 2015. In addition to any arguments the parties may wish to submit, the board is interested in argument directed at the following issue: If cause for discipline exists, what penalty, if any, should be applied in this case.

Pursuant to said Order written argument shall be filed with the Board of Pharmacy, 1625 N. Market Blvd, Suite N-219, Sacramento, California, on or before October 14, 2015. **No new evidence may be submitted.**

IT IS SO ORDERED this 14th day of September 2015.



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 and Petition to
Revoke Probation Against:

CAL-MEX PHARMACY SERVICES, INC.
dba CAL-MEX PHARMACY
Original Pharmacy Permit No. PHY 50374

and

OLUGBENGA SOLOMON ODUYALE
Original Pharmacist License No. RPH 42719

Respondents.

Case No. 4724

OAH No. 2013080330

ORDER GRANTING PETITION FOR
RECONSIDERATION WITH RESPECT
TO RESPONDENT CAL-MEX
PHARMACY SERVICES, INC. ONLY

ORDER GRANTING RECONSIDERATION, IN PART

On July 2, 2015, Complainant timely requested reconsideration of the decision regarding Respondent Cal-Mex Pharmacy Services, Inc., dba Cal-Mex Pharmacy pursuant to section 11521 of the Government Code, and good cause appearing, IT IS HEREBY ORDERED:

- (1) That reconsideration be, and hereby is, granted, as to respondent Cal-Mex Pharmacy, Inc., dba Cal-Mex Pharmacy (PHY 50374), only, said reconsideration to be upon the pertinent parts of the record including the transcripts, exhibits and such additional written argument as the parties may wish to present;
- (2) That portion of the decision regarding respondent Cal-Mex Pharmacy, Inc., dba Cal-Mex Pharmacy (PHY 50374) issued on June 29, 2015 and stayed until August 10, 2015 for purposes of evaluating the petition for reconsideration, is hereby further stayed until the Board renders its decision on reconsideration; and,
- (3) That the parties will be notified of the date for submission of any written argument they may wish to submit when the complete record, including transcripts and exhibits, of the above-mentioned hearing becomes available. No new or additional evidence will be taken by the Board.

On July 20, 2015, Respondent timely requested reconsideration of the decision regarding Respondent Olugbenga Solomon Oduyale pursuant to section 11521 of the Government Code.

NOW THEREFORE IT IS ORDERED that the Respondent's petition is denied. The portion of the decision related to Respondent Olugbenga Solomon Oduyale initially effective July 29,

2015 and thereafter stayed until 5:00 p.m. August 10, 2015, shall become effective August 10, 2015, as previously ordered.

IT IS SO ORDERED this 6th day of August, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Amarylis Gutierrez", written in a cursive style.

By:

AMARYLIS (AMY) GUTIERREZ
Board President

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

In the Matter of the Accusation and Petition to
Revoke Probation Against:

**CAL-MEX SPECIAL SERVICES, INC. dba
CAL-MEX PHARMACY**

And

OLUGBENGA SOLOMON ODUYALE

Respondents.

Case No. 4724

OAH No. 2013080330

ORDER GRANTING STAY OF
EFFECTIVE DATE OF DECISION

ORDER GRANTING STAY OF EFFECTIVE DATE

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

IT IS HEREBY ORDERED that the effective date of the Decision and Order, in the above-entitled matter is further stayed until 5 p.m. on August 10, 2015.

IT IS SO ORDERED this 23rd day of July, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

VIRGINIA HEROLD
Executive Officer

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

In the Matter of the Accusation and Petition to Revoke
Probation Against:

CAL-MEX SPECIAL SERVICES, INC., dba
CAL-MEX PHARMACY

and

OLUGBENGA SOLOMON ODUYALE

Respondents.

Case No. 4724

OAH No. 2013080330

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical change is made to page 16, #35, second paragraph, first sentence:

“At the hearing, respondents submitted a typed note on blank paper that says,
“Rx Notes 2013.”

Also, the following technical change is made to page 17, #40, second sentence:

“The instructions given to EH were to take a tablet at bedtime “as needed for sleep.”

The technical changes made above do not affect the factual or legal basis of the Proposed Decision, which shall become effective on July 29, 2015.

IT IS SO ORDERED this 29th day of June, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

AMARYLIS GUTIERREZ
Board President

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

In the Matter of the Accusation and Petition
to Revoke Probation Against:

CAL-MEX SPECIAL SERVICES, INC., dba
CAL-MEX PHARMACY

and

OLUGBENGA SOLOMON ODUYALE

Respondents.

Case No. 4724

OAH No. 2013080330

PROPOSED DECISION

This matter was heard on December 1 through 5, 2014; March 9 through 11; and March 13, 2015, by Susan J. Boyle, Administrative Law Judge, Office of Administrative Hearings, in Calexico, El Centro and San Diego, California.

Nicole R. Trama, Deputy Attorney General, Department of Justice, represented Virginia Herold (complainant), the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, State of California.

Ronald S. Marks, Attorney at Law, represented respondents Cal-Mex Special Services, Inc., dba Cal-Mex Pharmacy (Cal-Mex) and Olugbenga Solomon Oduyale. Mr. Oduyale was present throughout the hearing.

Oral and documentary evidence was presented. The record remained open until April 17, 2015, to allow the parties to file written closing statements. Complainant's written closing statement was filed on March 23, 2015, and marked as Exhibit 108. Respondents' written closing statement was filed on April 10, 2015, and marked as Exhibit EEEE. Complainant's reply closing statement was filed on April 17, 2015, and marked as Exhibit 109. The written closing statements were received in evidence as legal argument.

On March 24, 2015, respondents moved to re-open the record to submit two character reference letters. The letters were marked for identification as Exhibit DDDD. Complainant

opposed the motion. Respondents' motion to re-open the record was denied on March 30, 2015.

On April 17, 2015, the record was closed, and the matter was submitted.

INTRODUCTION

Mr. Oduyale has been a pharmacist since 1989. He had disciplinary action taken against his license in 2006, and his license was placed on probation for three years. He successfully completed probation, and his license was fully restored.

In mid-2010, shortly after he completed probation, Mr. Oduyale and others applied for a pharmacy permit in the name of Cal-Mex. Mr. Oduyale planned to own the pharmacy and act as its pharmacist-in-charge.¹ The board denied Cal-Mex's application for a pharmacy permit based upon the prior discipline of Mr. Oduyale's license.

Mr. Oduyale and Cal-Mex challenged the denial of the pharmacy permit. The board filed a Statement of Issues. In mid-2011, Mr. Oduyale signed a Stipulated Settlement, which the board approved, through which the board agreed to issue Cal-Mex a probationary pharmacy permit for 35 months and to accept Mr. Oduyale as Cal-Mex's pharmacist-in-charge. The board agreed to issue Cal-Mex an unrestricted permit if it successfully completed probation. The board issued the probationary pharmacy permit to Cal-Mex on August 19, 2011. Cal-Mex opened for business in April 2012.

In January, 2013, board inspectors conducted a routine inspection at Cal-Mex. They found several discrepancies and requested additional information from Mr. Oduyale. Mr. Oduyale supplied some of the requested additional information; however, not all of the inspectors' questions were answered, and they were unable to reconcile the information provided with prior records received from Cal-Mex. The inspectors conducted a second inspection in March 2013. This inspection did not resolve the inspectors' questions and concerns.

In July 2014, complainant filed a First Amended Accusation and Petition to Revoke Probation (Accusation and Petition). The Accusation and Petition alleged that Mr. Oduyale and Cal-Mex engaged in conduct that violated the laws and regulations governing pharmacists and pharmacies. The Accusation and Petition asserted that this conduct warranted revocation of Cal-Mex's probation and revocation or suspension of Cal-Mex's pharmacy permit. The Accusation and Petition also called for the revocation or suspension

¹ A pharmacist-in-charge has administrative and management responsibilities in a pharmacy and is responsible for ensuring that the pharmacy complies with state and federal regulations and, in larger chain pharmacies, internal policies and procedures. (Bus. & Prof. Code § 4113.)

of Mr. Oduyale's pharmacist license. The Accusation and Petition sought reimbursement for reasonable costs of the investigation and enforcement of the case.

The Accusation and Petition alleged that Mr. Oduyale and Cal-Mex engaged in the following unlawful conduct:

- a. Failed to maintain proper records of acquisition and disposition of hydrocodone/acetaminophen 10 mg/325 mg from May 1, 2012, through January 28, 2013. (First Cause for Discipline)
- b. Failed to report dispensed controlled substances on a weekly basis from March 21, 2012, to November 2013. (Third Cause for Discipline)
- c. Failed to properly dispense oxycodone when making a substitution in August 2012. (Fourth Cause for Discipline)
- d. Improperly deviated from the directions and requirements of five prescriptions without obtaining authorization. (Fifth Cause for Discipline)
- e. Improperly dispensed 24 prescriptions for controlled substances that were not written on required controlled substance forms. Each prescription was written on a pre-printed, check-off, prescription blank that was not authorized for use in dispensing controlled substances. (Sixth, Seventh, and Tenth Causes for Discipline)
- f. Improperly dispensed Testim, a controlled substance, before the prescription was written and without documenting that the prescriber was contacted to correct or verify the prescription. (Eighth and Tenth Causes for Discipline)
- g. Failed to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions on 39 prescriptions. (Ninth and Tenth Cause for Discipline)
- h. Improperly dispensed Motrin 600mg to a customer without the authorization of the prescriber. (Eleventh Cause for Discipline)
- i. Improperly dispensed a ninety day supply of oxycodone 30mg in thirty days. (Twelfth Cause for Discipline)
- j. Provided altered documents to an inspector that falsely represented the existence of certain facts. (Thirteenth Cause for Discipline)

The Accusation and Petition alleged that Mr. Oduyale engaged in the following unlawful conduct:

- k. Failed to exercise his best professional judgment with regard to a through j above. (Fourteenth Cause for Discipline)

l. Improperly extended the expiration date of oxytocin and dispensed the medication for use by patients. (Fifteenth through Twentieth Cause for Discipline)

m. The Accusation and Petition sought to revoke Cal-Mex's probation and its pharmacy permit because it did not obey all state and federal laws and regulations (First Cause to Revoke Probation) and because it did not maintain a separate file of all records pertaining to the acquisition and disposition of all controlled substances (Second Cause to Revoke Probation).

PROTECTIVE ORDER

The names of the patients in this matter are subject to a protective order. No court reporter or transcription service shall transcribe the name of a patient but shall instead refer to the patient by his or her initials, which were identified during the administrative hearing, are listed in the Confidential Names List (Exhibit 109), and are used in this decision.

SEALING ORDER

Numerous exhibits were admitted into evidence that contain confidential medical information and patient names. It was not practical to delete this information from some of these exhibits. To protect privacy and confidential personal information from inappropriate disclosure, a written Protective Order Sealing Confidential Records was issued on December 3, 2014, and provided to the parties on the record. It has been marked and admitted as Exhibit 112. During and after the hearing, the parties identified exhibits that also require sealing. The administrative law judge has determined that additional exhibits (HHH, JJJ and XXX) contain confidential information and require sealing. An Amended Protective Order Sealing Confidential Records was issued on May 18, 2015. The Amended Protective Order lists all the exhibits that are ordered sealed. The order governs the release of documents to the public. A reviewing court, parties to this matter, their attorneys, and a government agency decision maker or designee under Government Code section 11517 may review the documents subject to this order, provided that such documents are protected from release to the public.

FACTUAL FINDINGS

1. On August 8, 1989, the board issued Original Pharmacist License Number RPH 42719 to respondent Oduyale. His pharmacist's license will expire on October 31, 2016, unless renewed.

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Prior Disciplinary History

2005 ACCUSATION AGAINST MR. ODUYALE

2. On April 29, 2005, the Executive Officer of the board filed an Accusation, Case No. 2733, against Mr. Oduyale. The Accusation alleged sixteen causes for discipline and sought the revocation or suspension of Mr. Oduyale's pharmacist license. The Accusation also sought the recovery of reasonable costs of the investigation and enforcement of the case pursuant to Business and Professions Code section 125.3. Nine of the causes for discipline related to an incident that occurred in December 2002; seven of the causes for discipline related to a 2004 pharmacy inspection.

2006 DECISION ON THE 2005 ACCUSATION

3. On February 6, 7, and 8, 2006, Administrative Law Judge Greer D. Knopf conducted a hearing on the Accusation. On April 2, 2006, Judge Knopf issued a proposed decision to revoke petitioner's license, stay the revocation and place petitioner on three years' probation with certain terms and conditions. The board adopted Judge Knopf's decision with the exception that it modified one of the 18 terms of probation. The decision became effective on December 21, 2006.

FINDINGS RELATING TO POSSESSION OF UNLABELED MEDICATIONS

4. In the decision, the board found the factual circumstances underlying the December 2002 incident to be as follows: Mr. Oduyale had been working as the pharmacist-in-charge of a Rite-Aid store in Calexico, California since March 1997. On December 31, 2002, just after midnight, a California Highway Patrol officer observed Mr. Oduyale driving erratically, drifting across the lanes. The officer pulled him over.

During the stop, the officer observed a wooden Billy club on the floor of the vehicle. When Mr. Oduyale opened his car door, the officer saw two brown prescription bottles in the driver's door pouch. The officer retrieved the weapon and the prescription bottles. The prescription bottles did not have any prescription labels on them but had tops with the Rite-Aid name printed on them. Mr. Oduyale told the officer that he was a pharmacist at the Calexico Rite-Aid, that one of the bottles contained Vicodin and the other contained Xanax and that he was delivering the drugs to a customer in Yuma. The officer opened the medication bottles and observed that one of the bottles had more than one type of pill in it. Mr. Oduyale then told the officer that the bottle contained Xanax as well as Viagra, an antibiotic, and Claritin. The officer asked Mr. Oduyale if he had a prescription for these medications and he said he did not but that his customer did. Mr. Oduyale told the officer that the customer contacted him because she was having trouble obtaining the medication she needed. Mr. Oduyale claimed he had called the customer's physician for authorization to fill the prescription. Mr. Oduyale said he was delivering the medication as a favor.

The officer arrested Mr. Oduyale for possession of controlled substances and possession of a dangerous weapon. The officer conducted a body search of Mr. Oduyale after his arrest and found more pills, identified as Viagra, Floxin, and Naproxen, loose in Mr. Oduyale's pocket. In addition, the officer found an unopened bottle of Viagra, a prescription bottle with no label on it containing more Viagra, two opened bottles of naproxen, and two foil wrapped cards with unidentified pills in the rear floor boards of respondent's car. In the trunk of the car, the officer found another prescription bottle of 51 Vicodin tablets labeled for a person in Coachella, California. Mr. Oduyale told the officer he was delivering Vicodin to a tenant at his trailer park who also worked for him. Mr. Oduyale told the officer that his tenant had serious arthritis and was unable to have his prescription filled in the Rite-Aid in Yuma and asked Mr. Oduyale for help. Mr. Oduyale found his tenant's prescription in the Rite-Aid computer and transferred it to the Calexico Rite-Aid where he was the pharmacist-in-charge. Mr. Oduyale said his employer did not know he had taken the medications for his customer and client. Respondent also stated that some of the medications in his possession were for his own personal use although he did not have prescriptions for them. Mr. Oduyale stated that he did not print a label for the Vicodin he was delivering to his tenant because the printer jammed; however, he could have cleared the printer or hand-written a label. The board found that Mr. Oduyale "cut corners" and "failed to follow proper pharmaceutical protocol for dangerous drugs;" however, the board also found "[t]here was insufficient evidence to establish that respondent illegally possessed, furnished, or transported the Vicodin or acted fraudulently to create a prescription for [his tenant]."

As related to his customer, the board found that Mr. Oduyale often helped by delivering medications to her. The board did not find evidence that Mr. Oduyale "illegally possessed, furnished, or transported the Xanax or acted fraudulently to obtain the Xanax," but the board found that Mr. Oduyale's practices relating to dangerous drugs, including possessing medications not properly labeled and in a bottle mixed with his own personal medications, "were at the very least sloppy."

FINDINGS RELATING TO THE 2004 INSPECTION

5. Mr. Oduyale was employed as the pharmacist-in-charge at Palo Verde Hospital (PVH) pharmacy from January 2003 to March 2005. In 2004, the board conducted an inspection of that pharmacy. The board made the following findings of fact relating to the inspection:

Respondent worked hard to cooperate and he made every effort to comply with [the inspector's] multiple requests for records. However, respondent was not able to provide all records requested and some of the records produced had errors. Some of the records for the period of January through March 2004 regarding acquisition and disposition of drugs were found to contain crossouts, corrections, and omissions There were also records and inventory indicating the perpetual log maintained in the pharmacy was not accurate in some instances. In addition,

respondent was initially unable to produce complete and accurate records for the period of January to March 2003 for [eight drugs] Subsequently, respondent was able to produce some of the requested records, but not all of them. The PVH pharmacy was unable to provide complete records of drugs from the Pixis [sic] machine. . . . [The inspector] requested Pixis [sic] records for review, but respondent was unable to provide complete and accurate Pixis [sic] records. The inspection generally revealed that respondent failed to keep accurate and complete records of the acquisition and disposition of some of the controlled substances at PVH pharmacy.

The board found that Mr. Oduyale did not have a written quality assurance program that he was required to maintain for the pharmacy. When the inspector asked to review the Drug Enforcement Agency ("DEA") Inventory, which is required to be maintained by the pharmacy for two years, respondent produced what he believed to be a DEA Inventory, but it was not a DEA Inventory.

Mr. Oduyale also improperly permitted non-pharmacists to receive and sign for drugs delivered to the hospital. Mr. Oduyale "admitted he was unaware of the requirement that only the pharmacist is permitted to accept drug deliveries" The board found that Mr. Oduyale "seemed to be ill-informed about the requirements of his job as the pharmacist;" however, it did not find that he falsified information provided to the inspector or that he attempted to subvert the board's investigation.

The board found that Mr. Oduyale was a caring individual who tried to help those in need. It found that he was active in volunteer activities in his community and had a reputation in the medical community as a very good pharmacist who was smart, kind-hearted, and helpful to everyone. However, the board also found it "apparent that [Mr. Oduyale] has played fast and loose with some of the rules when it comes to helping his poor or elderly customers. He has admitted some mistakes, but he needs to be re-trained so that he understands he cannot bend the rules just because he wants to help someone."

TERMS OF PROBATION

6. The board placed Mr. Oduyale's pharmacist license on probation for three years and imposed 18 conditions of probation. Among the terms of probation, Mr. Oduyale was required to complete at least 40 hours of "remedial education related to the grounds for discipline, as required by the board."

Mr. Oduyale's probation terminated on December 20, 2009.

2010 Application for Pharmacy Permit and 2011 Stipulated Settlement

7. In late June 2010, the board received an application for a pharmacy permit from Cal-Mex. Three individuals signed the application, including Mr. Oduyale as President of Cal-Mex. The application proposed that Mr. Oduyale was to be the pharmacist-in-charge of Cal-Mex.

8. The board denied Cal-Mex's application on November 22, 2010.

9. On May 10, 2011, complainant filed a Statement of Issues, Case No. 4009, against Cal-Mex. The Statement of Issues alleged seven causes for denying Cal-Mex a pharmacy permit; each cause for denial was based upon the acts and omissions of Mr. Oduyale as described in the board's 2006 decision.

10. On May 29, 2011, Mr. Oduyale, on behalf of Cal-Mex, signed a Stipulated Settlement and Disciplinary Order (Stipulation) which was adopted by the board on July 20, 2011, and became effective on August 19, 2011. The Stipulation provided that the board would issue a license to Cal-Mex; the license would immediately be revoked; the revocation stayed; and Cal-Mex would be placed on probation for 35 months on 14 specified terms and conditions. The terms and conditions of probation included that Cal-Mex obey all rules and regulations governing pharmacies; submit quarterly reports to the board; provide notice to all employees of the terms and conditions of Cal-Mex's probation; post a probation notice on its premises that was visible to the public; "maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances," and certify by a signed statement that its officers and owners are familiar with state and federal laws and regulations governing pharmacies. The board agreed to accept Mr. Oduyale as the pharmacist-in-charge of Cal-Mex.

Cal-Mex's probation was to terminate on July 18, 2014; however, the Stipulation provided: "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."

2013 Accusation and Petition to Revoke Probation – Amended 2014

11. On July 3, 2013, complainant signed an Accusation and Petition to Revoke Probation, Case number 4724. On July 11, 2014, complainant signed a First Amended Accusation and Petition to Revoke Probation (Accusation and Petition), the operative pleading at issue here. The Accusation and Petition sought to revoke or suspend Mr. Oduyale's pharmacist license, revoke or suspend Cal-Mex's pharmacy permit, and revoke Cal-Mex's probation. The Accusation and Petition alleged twenty causes for discipline, two causes to revoke probation, and referenced the 2005 Accusation as other matter that may be considered in determining the degree of discipline, if any, to be imposed in this proceeding.

The Accusation and Petition also sought the recovery of reasonable costs pursuant to Business and Professions Code section 125.3

12. Prior to the presentation of evidence, complainant moved to dismiss the Second Cause for Discipline. The motion was granted over respondents' objection.

13. On the fourth day of the hearing, complainant moved to amend the fifth cause for discipline to conform to proof by replacing the word "four" on page 19, line 13 with the word "five," and by inserting after "in paragraph 39," the phrase "and as evidenced by the dispensing of the Testim prescription." The motion was granted over respondents' objection.

Inspections Conducted at Cal-Mex

14. On February 6, 2011, Cardinal Health, a pharmaceutical wholesaler notified the board that Cal-Mex had been "been identified . . . as an entity for which Controlled and Monitored Substance sales create an unreasonable risk for potential diversion," and it had been denied an account with Cardinal Health. When it received the notice of account denial, the board opened a case file to investigate whether there were problems at the pharmacy that caused Cardinal Health to deny Cal-Mex an account.

CHRISTINE ACOSTA

15. Christine Acosta, an inspector with the board, was assigned Cal-Mex's case in mid-2012. She has been a licensed pharmacist since 2006. She worked for three years in a retail pharmacy; she worked for two of those years as a pharmacist-in-charge. She also worked for three years in a hospital pharmacy where she performed inspections of medical units where drugs were kept to ensure compliance with state and federal regulations. In her clinical work, Ms. Acosta worked in labor and delivery and medical/surgical units. She has experience with compounding drugs, including sterile compounding. She received over 50 hours of on-line training in compounding when she became a board inspector and she attended a three-day training within the last year.

The board hired Ms. Acosta as an inspector in 2011. She was promoted to Supervising Inspector in July 2014. As an inspector, Ms. Acosta was assigned to the diversion team, whose responsibilities included investigating pharmacies in which inventories contain discrepancies. Since July 2014, Ms. Acosta has been supervising the sterile compounding team. This team performs inspections of all companies involved with sterile compounds, including those outside of California that sent sterile compounds into California.

OLUGBENGA SOLOMON ODUYALE

16. Mr. Oduyale received his pharmacy degree in North Dakota in 1979. He was licensed in Arizona in 1986 and California in 1989. He has worked in hospital and retail pharmacies. For thirteen years, from 1989 to 2002, Mr. Oduyale was the manager of a Calxico Thrifty/Rite Aid pharmacy where he was responsible for all the operations of the

store. From 1989 to 1994, Mr. Oduyale also worked as a pharmacist at Calexico Hospital. He worked at Palo Verde Hospital as a pharmacy director where, in addition to his responsibilities as pharmacist, he provided drug information to the medical staff and supervised six employees.

In 2003, Mr. Oduyale began working for Pioneer Memorial Hospital. For three years during the time he worked for Pioneer, he also worked for the State Prison in Centinella as a contractual staff pharmacist. Mr. Oduyale was terminated from his employment at Pioneer in early 2014 for conduct alleged in the Fifteenth through Twentieth Causes for Discipline of the Accusation and Petition.

Cal-Mex is the first pharmacy Mr. Oduyale owned.

JANUARY 2013 INSPECTION

17. On January 28, 2013, Ms. Acosta and board inspector Brandon Mutrux conducted an unannounced routine inspection of Cal-Mex. Ms. Acosta was not aware that Cal-Mex's license was on probation until she saw the probation notice in the pharmacy.

Mr. Oduyale, two pharmacy technicians, and a driver were present during the inspection. Ms. Acosta and Mr. Mutrux reviewed 200 controlled prescriptions, 100 Schedule II prescriptions, invoices from wholesalers, the pharmacy's quality assurance binder, the DEA inventory, and other similar records maintained by Cal-Mex. The inspectors also inspected the customer pick-up area and the drug dispensing shelves.

After the inspection, Ms. Acosta issued an Inspection Report. The Inspection Report noted that refill requests were presented on pre-printed forms, faxed prescriptions were accepted without a handwritten signature, and controlled medications were dispersed from pre-printed prescription blanks. These practices are not permitted, and Mr. Oduyale was instructed to correct them. The Inspection Report noted that Ms. Acosta questioned Mr. Oduyale about why a patient, whose doctor's office (Dr. Street) was in Victorville, drove to Calexico to fill prescriptions. Ms. Acosta and Mr. Oduyale also discussed the verification of Dr. Street's prescriptions. The report also confirmed that Mr. Oduyale told Ms. Acosta that River City Pharma, an out of state pharmaceutical supplier, did business as Masters, which had a California wholesale license. The inspection report requested, among other things, that Mr. Oduyale perform an audit of hydrocodone/acetaminophen 10mg/325 mg, commonly referred to as Norco 10, and provide a statement regarding how he processed prescriptions, including those on pre-printed check-off prescription blanks from Dr. Atef Rafla.² Mr. Oduyale signed the Inspection Report acknowledging that he "reviewed, discussed, [understood] and received a copy of this form."

Ms. Acosta also issued Cal-Mex an Official Receipt indicating that she had taken approximately 127 pages of documents, including patient profiles, doctor prescribing

² Dr. Rafla visited Crosby Square Chiropractic Clinic approximately once a month to provide pain management consultations to workers compensation claimants.

profiles, and original prescriptions. Ms. Acosta issued a written notice concerning the pre-printed check-off prescriptions; the written notice was signed by Mr. Oduyale.

On February 1, 2013, Mr. Oduyale emailed a group of documents purporting to be back-up materials (verifications) for some of the prescriptions Ms. Acosta questioned. The documents did not explain the processing of the prescriptions Ms. Acosta had questioned and caused some additional confusion regarding Cal-Mex's practices.

MARCH 2013 INSPECTION

18. Ms. Acosta and Mr. Mutrux returned to Cal-Mex on March 28, 2013, to conduct a second inspection. During this second inspection, Mr. Oduyale and two pharmacy technicians were present. Ms. Acosta told Mr. Oduyale she was there to understand the documents she was reviewing. During the March inspection, Ms. Acosta took some of Cal-Mex's original documents and provided Mr. Oduyale a receipt. The day after the inspection, Ms. Acosta asked Mr. Oduyale to provide additional information, which he provided.

DEA INSPECTION

19. On April 22, 2014, Diversion Investigators from the Drug Enforcement Administration conducted an inspection of Cal-Mex; Cal-Mex's DEA registration was up for renewal in August 2014. The DEA investigators requested that Ms. Acosta accompany them to the pharmacy. Following the inspection, the DEA's Special Agent in Charge wrote to Mr. Oduyale and advised him that the inspection had revealed two violations relating to the pharmacy's failure to properly record its receipt of drug shipments. Mr. Oduyale responded to the letter and explained what corrective actions Cal-Mex had taken to address the violations asserted.

The DEA issued Cal-Mex an unrestricted registration in August 2014.

Allegation that Respondents Failed to Maintain an Accurate Inventory of Hydrocodone

20. A pharmacy is required to maintain readily retrievable records of the sale, acquisition, or disposition of dangerous drugs for three years and to maintain a current inventory. (Bus. & Prof. Code § 4081, subd. (a); Cal. Code Regs., tit. 16 § 1718.)

21. During the January 2013 inspection, Ms. Acosta asked Mr. Oduyale to prepare an audit of Norco 10 and Oxycodone 30mg from May 1, 2012, to January 28, 2013; the audits were received on February 1, 2013. Ms. Acosta also performed audits for these two drugs.

22. The results of Mr. Oduyale's audit and Ms. Acosta's audit of Oxycodone 30mg were consistent and showed no discrepancies.

23. Mr. Oduyale's audit of Norco 10 showed an overage of 33 pills in stock,³ meaning that he dispensed 33 more pills than his records showed he had. Ms. Acosta's audit of Norco 10 showed that Cal-Mex had an overage of 623 pills. The 590 pill discrepancy between these audits resulted from Ms. Acosta's determination that Cal-Mex had dispensed 6,330 Norco 10 tablets, and Mr. Oduyale's calculation that Cal-Mex had dispensed 5,740. An overage of pills can be evidence of a clerical error or a failure to accurately record the acquisition of medications. It can also be evidence of fraudulent billing practices by billing an insurance company for medications that were not dispensed. When a pharmacy has more pills than it can account for having received, the public and the board cannot be assured that the medications came from a reliable source.

Ms. Acosta's considered that, because Norco 10 came in bottles of 500, Cal-Mex may have received a delivery of Norco 10 that it failed to account for in its inventory, and for which it had no record. Ms. Acosta reviewed Cal-Mex records to see if she could find where a delivery had been missed or entered in the wrong place, but she did not find the missing pills. Ms. Acosta also considered that occasionally Norco 10 deliveries are mistakenly entered in the inventory column for Norco 5. If a bottle of Norco 10 was mistakenly entered in the Norco 5 column, an overage of 500 would show in a Norco 5 audit. Ms. Acosta and Mr. Oduyale searched Cal-Mex records but neither found a delivery of Norco 10 that had been entered in the Norco 5 column.

24. In her review, Ms. Acosta noted that Mr. Oduyale removed 630 Norco 10 pills (500 and 130) from the inventory in August 2012 in an apparent attempt to balance the inventory at that time. Mr. Oduyale told Ms. Acosta that he made those corrections because 500 pills had been wrongfully entered into the inventory and the 630 correction included those 500 pills. However, Ms. Acosta found in Cal-Mex's acquisition records that Cal-Mex received 500 tablets on July 6, 2012, and the tablets were properly added to the inventory at that time.

25. In discovery provided to the board during the preparation for this hearing, Mr. Oduyale provided another inventory of Norco 10. In this inventory, Mr. Oduyale determined that there was a 473 tablet overage – a number closer to that determined by Ms. Acosta's inventory. Regarding each inventory the question is: if the pharmacy dispersed more pills than it shows it received, where did the pills come from?

26. Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex failed to maintain accurate inventories of Norco 10.

³ According to his audit, the number of pills taken from the last biannual inventory was 540; 7500 were received; 5740 were dispensed; 2300 were to be accounted for; actual on hand was 2,333; resulting in a 33 pill overage.

Allegation that Respondents Failed to File CURES Reports on a Weekly Basis

27. A pharmacy is required to report specific information about every prescription it fills for a Schedule II, III or IV⁴ controlled substance to the Department of Justice weekly. (Health & Saf. Code § 11165, subd. (d).) The Controlled Substance Utilization Review and Evaluation Services (CURES) collects all of the dispensing data for controlled substances in the state of California. CURES reports are used by regulatory bodies, prescribers and dispensers. The CURES report is intended to be a valuable tool for prescribers and dispensers. The report provides a drug history so that a physician can see what medications have been prescribed to a patient in the past and if any medications are currently prescribed. Similarly, a pharmacist can see the customer's drug history and seek additional information if it appears a patient is being over-prescribed, is engaging in drug shopping by obtaining prescriptions from multiple physicians, or is prescribed medications that may conflict with one another. According to Ms. Acosta, a pharmacy is required to file a weekly CURES report whether or not it has dispensed Schedule II, II or IV drugs in the weekly period; however the Health and Safety Code does not so provide and the Accusation and Petition does not allege that respondents were required to file CURES reports in weeks in which no controlled substances were dispensed.

28. Cal-Mex, like other pharmacies, was required to send the data required by CURES to Atlantic Associates. Atlantic Associates receives the electronic data from pharmacies in the format specified by the Department of Justice. It processes the information and forwards all compliant entries to the Department of Justice. It rejects entries that do not comply with the Department of Justice's requirements or are missing information. Atlantic Associates sends an email to the reporting pharmacy when it has rejected an entry, and it provides the pharmacy an explanation of why the entry was rejected. The pharmacy is required to correct the problem and resubmit the information. Almost all pharmacies receive rejection notices, and it is not a violation to receive one. However, failing to correct rejected entries, and therefore, failing to have weekly reports filed with CURES, is a violation.

THE BOARD'S INSPECTORS' FINDINGS

29. Ms. Acosta obtained a certified Pharmacy Compliance Report from CURES for Cal-Mex dated March 20, 2014. The report showed that in the 37 weeks following April 19, 2012⁵, Cal-Mex filed 16 CURES reports. No CURES reports are shown submitted in June, only one in October, two in November and one in December 2012. No months show four reports filed.

⁴ Drugs are classified into five schedules depending upon the drug's acceptable medical use and the drug's potential for abuse. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and Schedule V drugs represents the least potential for abuse.

⁵ This is the first date after Cal-Mex obtained its permit that a CURES report was filed.

Of the 52 weeks from January 1, 2013, to December 31, 2013, Cal-Mex filed CURES reports on 35 days. No reports are shown filed between February 8 and March 20, 2013. One report was filed in June and one in November.

The report also shows controlled substances that were not reported to CURES for months after they were dispensed. For example, controlled substances dispensed in December 2013, were not reported until February 2014; prescriptions filled in January, February, March, April, May, June, July, August, September and October 2013 were not reported until December 2013.

RESPONDENTS' RESPONSE

30. Cal-Mex Pharmacy received its pharmacy license on August 19, 2011. It obtained its business license on March 15, 2012, and opened for business on April 20, 2012. No prescriptions were dispensed before April 20, 2012, which accounts for Cal-Mex's failure to file any CURES reports up to that date.

31. Mr. Oduyale testified that, once Cal-Mex began dispensing controlled substances, CURES reports were submitted to Atlantic Associates at the end of each week. His testimony was confirmed by Pharmacy Technician, Lydia Garcia who testified that CURES reports were regularly filed on Friday. Mr. Oduyale described the process of submitting reports as being as easy as pushing a button on the computer. He did not understand where the information went after it was submitted.

Cal-Mex received notice from Atlantic Associates if there was an error in the data submitted. A prescription for a controlled substance cannot be filled without a DEA number for each prescriber. Most of the errors reported to them were the result of entering an incorrect DEA number in the data submitted to Atlantic Associates. When that happened, Cal-Mex staff telephoned the prescriber's office, obtained the correct DEA number, and resubmitted the information to Atlantic Associates. Ms. Garcia confirmed that she would sometimes call a doctor's office to obtain the correct information for the CURES report. She stated that Cal-Mex resent the corrected reports with the end of the week submissions. Mr. Oduyale stated that he had not been notified by Atlantic Associates or any state or federal agency that Cal-Mex was not timely filing CURES reports.

When Mr. Oduyale received the accusation in this case, he instructed his staff to resubmit every prescription submitted to Atlantic Associates for several months. He did not know the status of the CURES reports. He did not know what prescriptions had, or had not been submitted, and he did not have a way to prove what was submitted, so on December 3, 2013, he re-submitted 1844 prescriptions to ensure that all controlled substances dispensed were reported.

EVALUATION

Mr. Oduyale's testimony evidenced a lack of knowledge of the status of Cal-Mex's CURES reporting, how CURES reports were transmitted to the Department of Justice, and how the CURES reports were utilized. A pharmacist-in-charge, particularly one with his level of experience, is expected to be familiar with the CURES reporting system and to be aware of the status of a pharmacy's reporting. Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex failed to file weekly CURES reports and failed to timely correct errors in rejected submissions.

Allegation that Respondents Failed to Properly Dispense Oxycodone When Making a Substitution

32. A pharmacist is permitted to alter a prescription by substituting the prescribed drug product with another drug product as long as the substituted product has the same active chemical ingredients in the same strength, quantity and dosage form as the prescribed product. If a pharmacist makes a change to a prescription that materially changes the prescription, including the instructions for taking the medication, strength of the medication, or number of days of medication provided, it is considered a deviation, which must be authorized by the prescribing physician. (Bus. & Prof. Code § 4073, subd. (a).)

33. On August 8, 2012, Dr. Wendell Street prescribed 120 pills of oxycodone 30mg for patient AS. He instructed her to take one tablet four times a day. The 120 pills prescribed were, if taken correctly, a 30 day supply. On August 9, 2012, AS went to Cal-Mex to fill her prescription, but Cal-Mex did not have sufficient oxycodone 30mg in stock to fill the prescription. Mr. Oduyale told AS that he had only 200 tablets of oxycodone 15mg in stock which was 40 tablets fewer than the substitution required and was a 25 day supply. AS agreed to accept the 200 oxycodone 15mg. Mr. Oduyale instructed AS to take two tablets four times a day to account for the substitution.

THE BOARD'S INSPECTORS' FINDINGS

34. Ms. Acosta reviewed AS's prescription for oxycodone during her inspection of Cal-Mex. She saw a note on the back of the prescription that said "Gave 200 of oxycodone 15mg as complete RX. Pt consented. Sol."⁶ Neither the prescription nor the note indicated that Dr. Street was consulted and approved the changes to the prescription.

Ms. Acosta testified that substituting two 15mg tablets for one 30mg tablet was within the authority of a pharmacist to do and did not require consulting the prescriber. However, because Cal-Mex was unable to fill the entire prescription, the pharmacist was required to obtain approval from Dr. Street before a 25 day supply of oxycodone was substituted for a 30 day supply. Ms. Acosta stated that the unilateral alteration of the prescription could deny the patient the therapeutic benefit of the medication and could cause the prescriber to question the

⁶ "Sol" is Mr. Oduyale

patient if the patient returned for a refill of medication after 25 days. She agreed that it was appropriate that Mr. Oduyale obtained AS's consent to change the prescription; however, AS's consent did not satisfy Mr. Oduyale's obligation to obtain the prescribing physician's permission.

When Ms. Acosta questioned Mr. Oduyale about the changes to the prescription, he relied on the fact that he obtained AS's consent to the change; he did not tell Ms. Acosta that he had verified the change with Dr. Street. In discovery in this case, Mr. Oduyale produced a letter from Dr. Street dated December 14, 2013, one year and four months after the prescription was filled, in which Dr. Street wrote that he had authorized the change to the prescription.

RESPONDENT ODUYALE'S RESPONSE

35. Mr. Oduyale asserted that, when Cal-Mex received the prescription for AS, he contacted Dr. Street and told him that he did not have sufficient stock to dispense the amount of oxycodone prescribed. Dr. Street agreed that Cal-Mex should dispense 200 tablets of 15 mg to AS. Ms. Garcia testified that she heard Mr. Oduyale call Dr. Street to confirm the substitution. Mr. Oduyale told Ms. Garcia that it was acceptable to partially fill the prescription.

At the hearing, respondents submitted a typed note on blank paper that says, "Rx Notes 20013. 8/9/12 called Dr. Street got auth to give 15 mg oxycodone # 200 instead of oxy 30 mg due to non-availability of the 30 mg." Mr. Oduyale testified that the note was typed in the pharmacy's computer to document his contact with Dr. Street. Mr. Oduyale stated that notes in the computer, such as these, are private and confidential. He did not explain why he did not provide this note to the board's inspectors until discovery was exchanged in this proceeding.

EVALUATION

36. The evidence does not support a finding that Mr. Oduyale and Cal-Mex obtained Dr. Street's authorization to partially fill AS's prescription for oxycodone. Even if respondents had obtained Dr. Street's consent as they contend, the inefficient methods of record keeping employed at Cal-Mex do not allow an inspector to readily determine how a prescription was dispensed and on what authority. Entering private and confidential notes in a computer explaining a change in a prescription is not a reasonable practice. The documentation for changes to a prescription should be readily available at inspection and in the event a question is raised about the dispensing of medication.

The confidential notes submitted at the hearing were not provided to the board's inspectors in a timely manner, which supports a finding that computer notes were, at worst, recent fabrications and, at best, are unreliable to readily track how a prescription was dispensed. Mr. Oduyale documented that the patient consented to the change in the prescription in a way that it was readily available, but he did not similarly document that he obtained consent from the doctor. Long after the fact, Mr. Oduyale obtained a letter dated December 14, 2013, from Dr. Street that verified the August 2012 transaction and confirmed that Dr. Street authorized the change in prescription. Ms. Garcia's testimony was not persuasive on this issue. Clear and

convincing evidence supports a finding that Mr. Oduyale did not obtain Dr. Street's authorization when he made a substitution in AS's prescription.

Allegation that Respondents Deviated from the Instructions for Usage on Prescriptions

37. A pharmacist is not permitted to change the requirements of a prescription unless he or she obtains prior consent from the prescriber. (Cal. Code Regs., tit. 16, § 1716.) In four other instances, Mr. Oduyale altered the instructions for drug usage given by the prescribers without contacting the prescriber or documenting that the change was authorized.

38. On October 17, 2012, Dr. David Johnson wrote a prescription for Lorazepam 0.5mg for patient MF. Dr. Johnson instructed MF to take the medication every 8 to 12 hours; however, the instructions written on the medication given to MF by Cal-Mex advised MF to take the medication every 8 to 12 hours as needed. Lorazepam is used to control anxiety. There can be a desired therapeutic benefit with the course of treatment as prescribed by Dr. Johnson, and he may have intended that the medication be taken regularly to control anxiety rather than wait until the anxiety occurred. Mr. Oduyale was not authorized to change the instructions provided by Dr. Johnson. This change had the potential to deny the patient the therapeutic benefit Dr. Johnson intended and harm the patient. Mr. Oduyale admitted that changing the directions on this prescription was a mistake.

39. On October 17, 2012, Dr. Johnson prescribed hydrocodone/APAP for patient EL. Dr. Johnson instructed EL to take the medication every 8 hours as needed. The instructions given to EL were to "Take 1 tablet orally every 8 hours." Mr. Oduyale admitted that changing the directions on this prescription was a mistake.

40. On December 5, 2012, Dr. Johnson prescribed Ambien (generic is Zolpidem) 5mg for patient EH and instructed that she take one a night for seven weeks. The instructions given to EH were to take a table at bedtime "as needed for sleep." Mr. Oduyale admitted that changing the directions on this prescription was a mistake.

41. In a prescription dated December 5, 2012, Dr. Johnson prescribed Testim gel 1.0% for patient DF. Dr. Johnson instructed that DF apply a half of a tube to his shoulder daily. The instructions given to DF were "Apply daily as directed." Mr. Oduyale did not dispute the inaccuracy of the instructions.

42. Mr. Oduyale attributed the variances in the directions on medicine labels to oversights caused by the volume of work at the pharmacy. He pointed out that from March 2012 through January 28, 2013, Cal-Mex pharmacy had filled over 7,500 prescriptions and that number of mistakes constituted a small percentage of the total prescriptions filled.

43. Mr. Oduyale admitted the errors made when the instructions for usage provided to customers were not the instructions provided by the prescriber. Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex improperly deviated from the prescribed instructions for usage of medications.

Allegation that Respondents Improperly Dispensed Drugs from Noncompliant Prescriptions

PROCESS FOR DISPENSING PRESCRIPTIONS

44. Pharmacies may dispense medications pursuant to written or oral prescriptions. When a pharmacist dispenses from a written prescription, he or she must first verify that the prescription complies with state and federal requirements.

If a prescription is submitted to the pharmacy that does not comply with state and federal regulations, the pharmacist must contact the prescriber or the prescriber's authorized agent and either obtain a prescription that is compliant or verify the prescription, re-write it on pharmacy prescription blanks, and fill it. The pharmacy prescription must note who from the pharmacy verified the prescription and who from the prescriber's office authorized it.

If the pharmacist has questions about a written prescription or wants to modify the prescription in any way, he or she must similarly contact the prescriber or the prescriber's agent to get clarification and/or authorization.

A pharmacy may also fill an oral prescription. In this situation, a prescriber telephones the pharmacy and authorizes a prescription for a patient. The pharmacist writes an oral prescription on the pharmacy's prescription blanks and must note who from the prescribing office called and who from the pharmacy received the oral prescription. Any changes to a re-written prescription or an oral prescription must be documented in the same way as changes to a written prescription are documented.

Any changes to a prescription and/or communication with the prescriber's office should be noted on the face of a prescription, or, at the very least, on the "backer."⁷

At Cal-Mex, the pharmacist or a pharmacy technician enters information about a prescription into the pharmacy's computer system. The computer program prompts the technician to provide information for specific fields, for example, date, name of prescriber, medication and usage instructions. If the technician enters that the prescription is oral or "phoned in," the software prompts the technician to enter the name of the person who authorized the prescription. The technician must answer that question before a prescription label can be generated. The computer program assigns a prescription number and creates a backer and a medicine bottle label. The prescription, with the backer affixed to the back of the prescription, is filed in the pharmacy's records.

Mr. Oduyale reviews the prescription and the printed label. According to Mr. Oduyale and Cal-Mex employees, once Mr. Oduyale approves the prescription, no changes

⁷ The backer contains all of the information about the prescription including the newly assigned prescription number, prescriber's name, patient's name, date of the prescription, date the prescription was filled, medication prescribed, whether it is an original or refill prescription, how the prescription was received by the pharmacy, and direction for use.

can be made to the backer. The inability to change the backer includes not being able to add the name of the person contacted.

THE BOARD'S INSPECTORS' FINDINGS

45. Prescriptions for controlled substances that are classified as schedule II, III, IV or V must be made on a California controlled substance forms. A pharmacist is prohibited from dispensing a controlled substance from a "pre-printed multiple check-off prescription blank." (Health & Saf. Code, §11164, subd. (a); Cal. Code Regs., tit. 16, § 1717.3.) According to Ms. Acosta, for schedule III, IV or V drugs, the pharmacist can verify prescriptions written on non-compliant forms by speaking to the prescriber or his or her agent and documenting the conversation. The pharmacist can put a note on the original prescription documenting the verifying conversation, or he or she can re-write the prescription as an oral prescription. Schedule II drugs are handled differently.

46. Ms. Acosta discovered many prescriptions filled by Cal-Mex that were issued by Drs. Johnson and Atef Rafla on non-compliant forms. Mr. Oduyale initially told Ms. Acosta that he did not know that Drs. Johnson and Rafla's prescription forms were non-compliant and that he could not dispense drugs from the non-compliant forms. After Ms. Acosta told Mr. Oduyale that he could dispense drugs from the non-compliant prescriptions if they were properly verified, he represented that he had verifications but had to find them. Mr. Oduyale did not provide Ms. Acosta verifications during the January 2013 inspection.

47. Mr. Oduyale sent documents to Ms. Acosta after her January inspection, some of which were verifications for the non-compliant prescriptions. Ms. Acosta reconciled as many prescriptions as possible with the verifications sent to her and found that respondent dispensed controlled substances from 24 prescriptions that were written by Dr. Rafla on non-authorized check-off forms for which no verifications were provided. Of the 24 non-verified prescriptions, three were filled on September 10, 2012; nine were filled on September 11, 2012; and twelve were filled on November 16, 2012.

48. In response to a questionnaire that Ms. Acosta sent to Dr. Rafla, he stated that he spoke "sporadically" with Cal-Mex employees when "they have questions about some of my prescriptions." In response to a question asking how prescriptions on September 7, 2012, and November 16, 2012 were verified, Dr. Rafla wrote, "Can't remember exactly. I write the Rx and give to patients."

RESPONDENTS' RESPONSE

49. Mr. Oduyale claimed that he and his pharmacy technician, Ms. Garcia, met Dr. Rafla in the fall of 2012 at Crosby Chiropractic Clinic after Cal-Mex began to receive prescriptions he wrote. Mr. Oduyale introduced himself to Dr. Rafla and told him that Cal-Mex could not accept prescriptions on the pre-printed, check-off forms Dr. Rafla was using. Dr. Rafla told Mr. Oduyale that he left his prescription blanks at his other office. Mr. Oduyale agreed to accommodate Dr. Rafla and his patients "this time" but said he could not accept

them again. Mr. Oduyale accepted Dr. Rafla's acknowledgement of the prescriptions as verbal authorization, and he re-wrote them on Cal-Mex's prescription pad. Mr. Oduyale and Dr. Rafla did not discuss who was authorized to verify prescriptions for Dr. Rafla.

Dr. Rafla told Mr. Oduyale that his patients were all workers compensation claimants. Mr. Oduyale was not familiar with what workers compensation insurance would cover for medications. Dr. Rafla introduced Mr. Oduyale to a person Mr. Oduyale understood to be named "Maria"⁸ who worked for him. "Maria" went to Cal-Mex pharmacy that day and said she would explain how to process workers compensation liens for payment. Myra told Mr. Oduyale and Lydia that many pharmacies did not accept prescriptions for workers compensation patients because there is a risk of not being paid or being paid less than what is charged. If a pharmacy did not accept workers compensation insurance, the patient must pay the pharmacy fees out of pocket. Cal-Mex was the only local pharmacy that accepted workers compensation insurance. Workers compensation claims were processed in a different room by Cal-Mex staff dedicated to processing those prescriptions.

50. Respondents submitted documents at the hearing that were represented to be printed computer images of prescriptions questioned by Ms. Acosta from September 7 through November 16, 2012, as they exist in Cal-Mex's records. Respondents asserted that the documents showed that the remaining questioned prescriptions were properly verified. The backers to the prescriptions noted they were phoned in by Dr. Rafla, Maria or Alex, even though they were presented on non-compliant prescription forms.

51. Mr. Oduyale asserted that when he received a non-compliant prescription from Dr. Rafla, Cal-Mex personnel called Dr. Rafla's office to verify the prescription. When the prescription was verified, Mr. Oduyale re-wrote it on a Cal-Mex prescription pad. The re-written prescription became the dispensing document. Mr. Oduyale stated that this was the practice followed by other pharmacies he worked in.

52. Mr. Oduyale testified that, at some point, Dr. Rafla told him to call his assistant for verifications. Mr. Oduyale spoke to "Maria" or "Felix," whose name he now understands to be Alex; Alex told Mr. Oduyale that he could verify prescriptions.⁹ Mr. Oduyale stated that he had no reason to believe that "Maria" could not verify prescriptions. Mr. Oduyale rarely dealt with Katherine from Dr. Rafla's office.

53. On February 1, 2013, Dr. Rafla signed a letter addressed to Ms. Acosta, which stated that all prescriptions he wrote that were filled by Cal-Mex pharmacy "were either verified by phone or in person by the pharmacist, Sol, of Cal-Mex Pharmacy."

⁸ Dr. Rafla's assistant is named Myra; she always accompanied him when he saw patients at Crosby Square Chiropractic Clinic.

⁹ "Alex" contradicted Mr. Oduyale and testified that he was not authorized to, and never did, verify prescriptions. See discussion *infra*.

EVALUATION

54. Mr. Oduyale was not aware that the prescriptions written by Drs. Johnson and Rafla did not comply with state requirements. Therefore, it is not credible that the non-compliant prescriptions were verified. Properly authorized verifications were not located for several of Drs. Johnson's and Rafla's non-compliant prescription blanks.

Dr. Rafla's responses to Ms. Acosta and respondents' counsel are inconsistent. On the one hand, he confirmed that every prescription he wrote that Cal-Mex filled was properly verified, and on the other, he was unable to recall how some prescriptions were verified. Dr. Rafla's blanket statement that all prescriptions were verified is not persuasive.

Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex improperly dispensed drugs from non-compliant prescriptions.

Allegation that Respondents Failed to Document the Name of the Verifying Agent

55. A pharmacist is permitted to dispense controlled substances classified in Schedule III, IV or V from a prescription that is orally or electronically transmitted by an authorized agent of a prescriber as long as the pharmacy records specify the name of the agent who transmitted the prescription. (Health & Saf. Code § 11164, sub. (b)(3).) A pharmacist is required to make a "reasonable effort" to determine if the person transmitting a prescription is an authorized agent. (Bus. & Prof Code § 4071.)

THE BOARD'S INSPECTORS' FINDINGS

56. Ms. Acosta stated that the name of the authorizing agent must be written on the face of the prescription that becomes the dispensing document.

Respondents were not authorized to dispense controlled substances from non-compliant prescriptions written by Drs. Johnson and Rafla. However, respondents could verify the prescriptions by speaking to the doctors or their authorized agents and noting, on the front of the original prescription or on a re-written prescription, the name of the agent who verified the prescription. In 39 prescriptions reviewed by Ms. Acosta, 36 from Dr. Rafla and three from Dr. Johnson, respondents rewrote the prescriptions, but the name of the authorized agent was not on the front of the original prescription or the Cal-Mex re-written prescription.

In documents received shortly before the hearing in this case, Ms. Acosta found documents she had never before seen. She found even more inconsistencies in these documents as the verifications were different from those she had previously viewed. Ms. Acosta testified that, with all the variations of documents respondents produced, she could not determine which document was the final dispensing document, although she believed the actual dispensing documents are the ones she took with her after the January inspection.

57. On November 16, 2012, Dr. Rafla wrote a prescription on his pre-printed check-off pad for hydrocodone APAP for patient NM; the backer for this prescription, number 40332, indicates the origin as "written." Ms. Acosta obtained this prescription and backer on January 28, 2013. On February 1, 2013, Cal-Mex provided Ms. Acosta with documents represented to be verifications of prescriptions that could not be located during the January inspection. One of the documents provided on February 2, 2013, was Cal-Mex's re-written prescription for Rx number 40332. The re-written prescription does not contain the name of the person who verified the prescription. The backer to Rx number 40332 provided in February is not for NM's original prescription but for a refill of the prescription dispensed on December 14, 2012. This backer states it was "Phoned in by: Rafla." At the hearing, respondents submitted only the backer for the refill prescription. Respondents did not produce a verification for the original prescription.

On November 16, 2012, Dr. Rafla prescribed Norco10 for patient JP on a pre-printed, check-off prescription. In January, Ms. Acosta received a backer indicating that the origin of the prescription, Rx 40342, was "Written." The documents provided in February included a re-written prescription on a Cal-Mex prescription pad. The re-written prescription for Rx 40342 does not contain the name of the person who verified the prescription. The backer is not for the original prescription, but it is for a refill of the prescription that was dispensed on January 14, 2013. This backer indicates the prescription was phoned in by Rafla. The document respondents submitted at the hearing is for the refill prescription. A verification for the original prescription was never submitted.

On November 16, 2012, Dr. Rafla prescribed hydrocodone APAP for patient OP on a pre-printed form. The backer for this prescription, Rx number 40355, noted the origin of the prescription as "Written." Ms. Acosta received this prescription and backer in January. In February, respondents provided Ms. Acosta with a re-written prescription on a Cal-Mex prescription blank. The prescription does not include the name of an agent verifying the prescription. The backer provided in February indicated the origin of the prescription was "written." At the hearing, respondents submitted a different backer for Rx 40355, which states the prescription was phoned in by Dr. Rafla.

Ms. Acosta testified that there were 15 to 20 instances of similar discrepancies.

RESPONDENTS' RESPONSE

58. Mr. Oduyale testified that, when a pre-printed prescription form was faxed to Cal-Mex, the original prescription noted it was received by fax or was written. The prescription was required to be verified by contacting the prescriber's office. Once verification was obtained, the prescription was re-written on a Cal-Mex prescription pad, and the backer was changed to indicate the prescription was "phoned in." Mr. Oduyale stated that changing the origin of the prescription from written to telephone was one of the "corrections" he made when reviewing a prescription.

EVALUATION

59. Complainant asserts that the standard of practice in the industry is that the name of the authorizing agent is written on the front of the dispensing prescription and not on the backer. While this may be the general practice, it is not required by the Health and Safety Code. It is important that the name of the agent can be determined by a relatively quick review of pharmacy records. Since backers derive their name from the fact that they are attached to the back of prescriptions, determining the identity of the authorizing agent should be relatively simple if the name is on the front or back of the prescription. However, the name provided for each prescription must be consistent

By his explanation of how prescriptions were verified, Mr. Oduyale suggested that two backers could exist for one prescription. This suggestion does not comport with other explanations given about the processing of prescriptions. If Cal-Mex receives a prescription, they should not enter it into the computer system until it has been verified. At the least, no backer should be printed until the prescription has been verified. Once verified, the prescription is re-written and constitutes an oral prescription. The fact that it is oral should be noted on the face of the prescription or at least on the backer. There is no reason to have a backer for an invalid prescription. The confusion caused by Ca-Mex's generating a backer for a prescription that had not been verified was evident throughout the hearing.

60. Furthermore, Mr. Oduyale stated that the verifications for the form prescriptions from Dr. Rafla were not available to Ms. Acosta because they were in the billing room for processing. However, the "missing" verifications were for prescriptions that had been filled some two months before the inspection. Additionally, Ms. Acosta obtained some of Dr. Rafla's prescriptions with backers on them in January 2013. Many of those prescriptions were sent to her in February with different backers. Mr. Oduyale's explanations were not credible and suggest that the verifications provided to Ms. Acosta after the January inspection did not exist when the prescriptions were dispensed but were created at a later time. Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex failed to obtain the name of the authorizing agent when verifying prescriptions.

Allegation that the Individuals Claimed to have Verified Prescriptions Were Not Authorized Agents

AUTHORIZED AGENTS AND VERIFICATION PROCEDURES AT CROSBY SQUARE

61. Alexander Martinez, Guadalupe Sanchez, and Elizabeth Gonzalez, each of whom was employed at Crosby Square, testified at the hearing regarding the policies and practices in Drs. Rafla's and Johnson's offices. Maria Villagomez's declaration was received as direct evidence. Credible testimony established the following:

Mr. Martinez has been the Office Manager of Crosby Square Chiropractor for six years. No one named "Felix" worked for Crosby Square. Mr. Martinez learned the day of his testimony that Mr. Oduyale erroneously called him "Felix."

Guadalupe Sanchez was an interpreter at Crosby Square.

Elizabeth Gonzalez has been the front office manager for Crosby Square for three years. She performed clerical functions, including making employee schedules, answering the telephone and sending medical reports.

Maria Villagomez was employed by Dr. Johnson. She traveled to Crosby Square with Dr. Johnson on Mondays. Part of her responsibilities included verifying prescriptions on behalf of Dr. Johnson. She was not authorized to, and did not, verify prescriptions on behalf of Dr. Rafla.

Ms. Villagomez was the only employee named "Maria" who worked in the Crosby Square Clinic.

Dr. Rafla visited Crosby Square approximately once a month to provide pain management consultations. Dr. Rafla's assistant, Myra, always accompanied him when he saw patients at Crosby Square.

Myra gave Dr. Rafla the patient folders and directed patients to the exam room. Dr. Rafla returned the patient folders and any prescriptions he wrote to Myra after the consultation. Myra gave the folders to Ms. Gonzalez to enter the demographic information. Ms. Gonzalez gave the patient the prescriptions from the folder for the patient to take to the pharmacy.

Elizabeth Gonzalez or Lupita Sanchez answered the telephones at Crosby Square.

Ms. Gonzalez did not recall getting telephone calls from Cal-Mex. She does not know anything about medications, and she was not authorized to, and did not, verify prescriptions. She directed anyone who asked questions about prescriptions to call Dr. Rafla.

Mr. Martinez did not work for Dr. Rafla. He was not authorized to prepare or verify Dr. Rafla's prescriptions. Dr. Rafla instructed everyone at Crosby Square to direct any questions that involved him to his office.

Mr. Martinez did not answer telephones for Crosby Square, but he overheard calls that came in from Cal-Mex and was aware that Cal-Mex staff called the office several times on the days Dr. Rafla was there.

Mr. Oduyale was seen in the Crosby Square offices a "couple of times" talking to Myra or Dr. Rafla. Lydia Garcia was seen speaking to Dr. Rafla three to four times.

62. In a declaration dated March 27, 2014, Dr. Rafla declared:

In the past three years, Katherine Ramirez is the only individual at my office who has been authorized to verify a prescription on

my behalf. In the past three years, I have never given anyone authority, other than Katherine Ramirez, to authorize prescriptions or verify prescriptions on my behalf. In the event that a pharmacy contacts the [Crosby] Clinic for authorization or verification of a prescription written by me, the Clinic is instructed to contact my office directly. I do not have [an] agent by the name of "Maria" working for me. In the past three years, I have never given anyone by the name of "Maria" authority to verify prescriptions or authorize prescriptions on my behalf.

In response to a questionnaire provided to Dr. Rafla by respondents' attorney, Dr. Rafla wrote that he had conversations with Cal-Mex employees "1 or 2 times," and he met Mr. Oduyale on one occasion for five minutes. Dr. Rafla identified Katherine as the only employee who could authorize refills "after checking with me" and Myra as his employee whose responsibilities were limited to "paperwork only." He also verified his February 1, 2013 letter in which he wrote that all prescriptions written by him that were filled by Cal-Mex "were either verified by phone or in person by the pharmacist, Sol, of Cal-Mex Pharmacy." Dr. Rafla's statements are contradictory.

VERIFICATION PRACTICES AND PROCEDURES AT CAL-MEX

63. Lydia Garcia, Esteban Martinez and Valerie Banda, each of whom was employed at Cal-Mex, testified at the hearing regarding the policies and practices of Cal-Mex and how copies of prescriptions were copied and produced for Ms. Acosta. Their testimony included the following:

Lydia Garcia has been licensed as a pharmacy technician since March 2002. She has been employed as a pharmacy technician for Cal-Mex since April 2012; Cal-Mex opened one week before she began working there. Her duties include typing prescriptions, conducting inventories, reconciling checks, engaging in customer service, calling for re-fills, and requesting authorization for insurance coverage.

Esteban Martinez (Esteban) worked for Mr. Oduyale at Cal-Mex from February 2012 to April 2013. He did general marketing work for the pharmacy and delivered medications to customers. He also drove patients to doctor's appointments; Cal-Mex did this as a free service for patients, mostly senior citizens who had prescriptions filled at Cal-Mex.

Valerie Banda has been a pharmacy clerk for Cal-Mex for almost three years.

64. Dr. Rafla authorized "Katherine" in his office in Santa Ana to verify his prescriptions. Mr. Oduyale and Cal-Mex employees knew that Myra was Dr. Rafla's assistant and that she traveled to Calexico with him when he saw patients at the Crosby Square Clinic. They believed that Myra was also authorized to verify Dr. Rafla's prescriptions. Ms. Garcia identified an undated page from a notebook that contained telephone numbers for "Mayra" [sic] and "Katherine." Ms. Garcia stated she was told these

were the individuals she could call if there were questions about Dr. Rafla's patients. Ms. Garcia and Mr. Oduyale also believed that the clinic manager, Alex Martinez, could verify prescriptions.

Ms. Garcia stated that Cal-Mex did not dispense medications based on Dr. Rafla's pre-printed form without first obtaining verifications from Dr. Rafla or one of the persons believed to be his agent.

EVALUATION

65. The evidence does not support a finding that Mr. Martinez, erroneously referred to as Felix, was authorized to verify prescriptions or that Mr. Oduyale and Cal-Mex reasonably believed he had such authority. The evidence does not support a finding that Myra was authorized to verify prescriptions; however, the evidence supports a finding that Cal-Mex reasonably believed she was authorized to do so.

Allegation that Respondents Dispensed a Refill Without Authorization from the Prescriber

66. A pharmacist may not dispense a refill of a dangerous drug unless it is authorized by the prescriber orally or the refill is included on the original prescription. (Bus. & Prof. Code § 4063.)

THE BOARD'S INSPECTORS' FINDINGS

67. On November 16, 2012, Dr. Rafla prescribed Motrin 600 mg for patient JP. The original prescription was on a pre-printed, check-off prescription blank and did not authorize refills. On December 12, 2012, respondents dispensed a refill of the Motrin 600 mg to JP. When Ms. Acosta questioned Mr. Oduyale about the refill, he was unable to identify from whom he obtained authorization or explain why the refill was dispensed.

68. In a declaration signed by Dr. Rafla on March 27, 2014, he stated that it was his practice to document each instance in which he authorized a refill of a prescription. Dr. Rafla reviewed JP's files and declared that there were no records in JP's file that indicated a refill for Motrin 600 mg was prescribed or that his office was contacted to request authorization for a refill. He confirmed that the last prescription he wrote for JP for Motrin 600 mg was in November 2012.

RESPONDENTS' RESPONSE

69. Mr. Oduyale agreed that the original prescription for Motrin 600 mg issued by Dr. Rafla for patient JP did not contain authorization for a refill. Mr. Oduyale stated that, when JP learned that the prescription did not indicate a refill was authorized, he became belligerent and alleged that the pharmacy had made an error. JP returned to the Crosby Clinic to complain. Thereafter, Dr. Rafla telephoned Cal-Mex and authorized one refill.

Mr. Oduyale submitted an undated, typed note on blank paper that he represented was a confidential note in the computer records of Cal-Mex. The note confirmed that JP “exploded” when he learned there was no refill on his prescription; that he returned to the clinic and that “aria¹⁰” called the pharmacy to authorize adding one refill to JP’s prescription. Mr. Oduyale asserted that these confidential notes are the way he records matters that occur concerning prescriptions. By email dated March 3, 2014, over a year after the incident, Katherine Ramirez, who was authorized to verify prescriptions for Dr. Rafla, verified that JP’s prescription for Motrin 600 mg was authorized for one refill.

EVALUATION

70. This is another example of the difficulty involved in determining the validity of a prescription when notes are contained in a confidential file on the pharmacy’s computer. The fact that these notes were provided in discovery and were not provided to the board’s inspectors during or following their inspections evidences their ineffectiveness. The creation of a paper trail over one year later is not an efficient way to verify prescriptions and calls into question the credibility of the information. In this instance, Dr. Rafla and Katherine contradict one another in trying to recreate what occurred long after the prescription was written. Although respondents assert that Dr. Rafla confirmed he authorized a refill, the document he signed indicates only that the November prescription for Motrin was authorized, not the refill dispensed in December.

It is noted that the backer to JP’s prescription indicates the origin as “written.” This is also an example of a failure to provide a verification for a pre-printed prescription. There is no notation on the face of the prescription that Dr. Rafla or his agent was contacted to verify the prescription. The backer confirms that a refill was authorized but indicates the origin of the prescription as “written.” Given Mr. Oduyale’s explanation, and the fact that the prescription was required to have been verified, the origin would more accurately have been that the prescription was phoned in.

However, no authority was provided to support a finding that Motrin 600 mg is classified as a dangerous drug. For this reason, the allegation as pled cannot support disciplinary action.

Allegation that Respondents Dispensed Testim Before the Prescription was Written

THE BOARD’S INSPECTORS’ FINDINGS

71. Ms. Acosta found a December 5, 2012, prescription for Testim for patient DF that had a backer suggesting the Testim was dispensed on November 28, 2012. When asked about this prescription, Mr. Oduyale could not explain it. Ms. Acosta stated that she later learned this situation was related to billing problems.

¹⁰ The first letter of each line of the copied note is missing. It is assumed that the note intended to read, “Maria.”

RESPONDENTS' RESPONSE

72. On November 28, 2012, Cal-Mex wrote a prescription for Testim 1% for patient DF. David Johnson was written into the space after "Dr." and "Maria" was handwritten on the prescription under Dr. Johnson's name. The prescription was signed by "Sol." A backer for the prescription submitted by respondents was dated November 28, 2012. Mr. Oduyale testified that Cal-Mex did not have Testim in stock when Dr. Johnson requested it for DF. Mr. Oduyale said he spoke to DF who told Mr. Oduyale that he would wait until the pharmacy could get the Testim. Mr. Oduyale ordered the Testim and billed DF's insurance that day. He created the backer for billing purposes, but Testim was not dispensed on that day.

Pharmacy technician Ms. Garcia placed an order for Testim after receiving the prescription from Dr. Johnson and learning that DF would wait until the pharmacy could get the Testim in stock. An invoice to Cal-Mex from Valley Wholesale Drug shows that Cal-Mex placed an order for Testim on November 28, 2012. On December 5, 2012, a second prescription for the Testim, but with different directions for use, was written on a Cal-Mex prescription pad. A backer for the December prescription was not produced. Cal-Mex pick-up logs indicate that DF picked up the Testim on December 5, 2012.

EVALUATION

Respondents' record keeping is consistently poor. This contributes to confusing and contradictory documents. Regardless of the explanation, there should not be two documents that could constitute the dispensing document. At the very least, if prescriptions must be created for billing purposes, all copies of prescriptions and backers should be kept together with a clear explanation attached to them of why there are two presumptively dispensing documents with different dates. It should not require hours of investigation to determine how the Testim was dispensed. However, the evidence supports a finding that Testim was not dispensed before a prescription was written. For this reason, the evidence does not support disciplinary action.

Allegation that Respondents Dispensed a 90 Day Supply of Oxycodone in 30 Days

73. The prescriber of controlled substances is responsible to write only prescriptions that are for a legitimate medical purpose. A pharmacist, however, has a corresponding responsibility to be aware of, and question, any prescription that appears out of the ordinary. (Health & Saf. Code § 1153, subd. (a).) Even after verifying a prescription, a pharmacist may not "dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose." (Cal. Code Regs., tit. 16, § 1761, subd. (b).)

THE BOARD'S INSPECTORS' FINDINGS

74. On December 6, 2012, respondents dispensed 150 tablets of oxycodone 30 mg – a 30 day supply – to patient BS. On December 20, 2012, fourteen days later, respondents dispensed another 150 tablets of oxycodone 30 mg to BS. On January 4, 2013, fifteen days

after that, respondents again dispensed 150 tablets of oxycodone 30 mg to BS¹¹. The prescriber in this case was located in Victorville, a drive in excess of three hours from Calexico; the patient lived in Apple Valley, a drive of almost three and one-half hours from Calexico; and the patient paid cash for the prescriptions. These factors should have caused respondents to question the validity and medical necessity of the multiple prescriptions. Ms. Acosta noted that use of the CURES reports and PDMP are invaluable when issues such as these arise. The PDMP report allows a pharmacist to see if the patient had been prescribed oxycodone in the past, and if so, if a pattern of abuse was evident. The PDMP report could also alert the pharmacist as to whether the patient was new to the drug and could be uninformed about how to take it and possible side effects. Ms. Acosta stated that the prescription called for a large starting dose of oxycodone which also should have caused Mr. Oduyale to take notice. She stated that, even if the prescriber authorized the prescription, Mr. Oduyale should have questioned it, particularly if he did not know the physician or the patient.

During the January inspection, when initially questioned about the apparent excessive dispensing of medication, Mr. Oduyale told the inspectors that he did not realize the dates were so close, and he did not contact the prescribing physician to confirm the legitimate medical purpose for the multiple prescriptions.

RESPONDENTS' RESPONSE

75. Mr. Oduyale noted that BS was almost 73 years old when she presented the prescriptions to Cal-Mex. He testified that BS told him she required more prescriptions of oxycodone because she was on an extended vacation. Mr. Oduyale stated that oxycodone is prescribed for pain. If a patient's supply ran out before obtaining a new prescription, the pain could return and the patient could suffer withdrawal, either of which could result in discomfort, anxiety, depression and temporary disability.

Mr. Oduyale stated that he contacted Dr. Street, and Dr. Street authorized him to dispense the three prescriptions. Respondents submitted a typed note on blank paper stating "[BS] getting vacation supply won't be back for some time. Talked to Dr. Street to confirm the rx as issued and legitimate."

76. By letter dated January 9, 2014, Dr. Street confirmed the three prescriptions issued to BS and wrote, "As per phone conversation with Pharmacist, Sol Oduyale I requested these prescriptions to be issued as such to cover the patient's medication needs while she was on vacation. No prescriptions were issued during February and her next prescription was issued March 27, 2013."

EVALUATION

77. Ms. Acosta asserted that Mr. Oduyale told her he did not realize that Cal-Mex dispensed a 90-day supply of oxycodone to BS in 30 days and that he did not contact Dr. Street.

¹¹ Oxycodone can be misused and is sometimes sold as a recreational drug.

However, Mr. Oduyale asserted that he was aware of the situation and that he had contacted Dr. Street to receive authorization to dispense the oxycodone as prescribed. In addition to the issue of credibility, this example again emphasizes Cal-Mex and Mr. Oduyale's poor record-keeping. There is no indication on any of the three prescriptions or their backers that Dr. Street was contacted and questioned about prescribing a 90 day supply of oxycodone in 30 days. Instead, respondents rely on a note allegedly entered in Cal-Mex's computer at the time the second prescription was presented by BS¹² but was not provided to Ms. Acosta during the inspection or before the Accusation was filed. And respondents rely on a note from a doctor written over one year after the prescriptions were written. Respondents' evidence to support a claim that they contacted Dr. Street is not credible. Additionally, it is not reasonable that pharmacy records are not clear on their face. It should not require lengthy inquisition to determine how and why a prescription was dispensed.

78. The factors presented by Dr. Street's prescriptions for BS are more than ample to implicate respondents' corresponding responsibility. The fact that BS was 73 years old does not negate her potential to abuse, or re-sell for profit, a dangerous drug. It is inherently suspicious that a person who lives over three hours away; whose doctor's office is over three hours away; and who is unknown to the pharmacist, twice returns to that far away pharmacy to obtain a total of a 90 day supply of oxycodone in 30 days. These are classic factors to be considered by a pharmacist when evaluating his or her corresponding responsibility. If respondents were aware of, and made proper inquiry into, the validity of Dr. Street's prescriptions, their actions in doing so should be clear from the face of the prescriptions, or at least from the backers, and not hidden in a confidential note in the pharmacy's computer.

Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex failed to discharge their corresponding duty.

Allegation that Respondents Provided Altered Documents that Falsely Represent Facts

79. Complainant alleged that respondents provided false documents to the board's inspectors during the course of their investigation. A pharmacist is prohibited from making or signing any document that falsely represents facts. (Bus & Prof. Code § 4301, subd. (g).)

THE BOARD'S INSPECTORS' FINDINGS

80. During their January inspection, the board's inspectors reviewed original prescriptions on non-compliant prescription forms. The backers of at least 20 of these prescriptions showed the origin of the prescription to be "fax" or "written." Mr. Oduyale signed or initialed the backers of 16 of the 20 prescriptions. Ms. Acosta took the prescriptions and backers, along with other prescriptions, with her after her January inspection.

¹² The note references the prescription number for the December 19, 2012 prescription that was filled on December 20, 2012.

Mr. Oduyale told the inspectors that he verified the prescriptions by calling the prescribing physician's office or walking across the street to his office and then re-wrote the prescriptions. There were no notes on the face of the prescriptions or on the backers to indicate the prescriptions were verified. Respondents did not have the verifications for these prescriptions available to show the inspectors during their January inspection. Although the prescriptions were filled between September and December 2012, Cal-Mex told Ms. Acosta that the prescription verifications had been unavailable because the re-written prescriptions were in a separate room being processed.

A few days after the board's inspection, respondents provided re-written prescriptions on Cal-Mex prescription pads and new backers for the 20 prescriptions. Where the original prescriptions had backers that indicated the prescriptions were sent by facsimile or were written, the new backers indicated that the prescriptions were called in by "Maria" or "Rafla."

RESPONDENTS' RESPONSE

81. Mr. Oduyale and Cal-Mex employees adamantly denied altering documents after the board's inspection.

82. Estaban was present during Ms. Acosta's January inspection. He helped look for the prescription records Ms. Acosta wanted to review. He described it as an "overwhelming day" because it was a day that Dr. Rafla was in Calexico, and there were many customers in the pharmacy. He heard Ms. Acosta tell Mr. Oduyale to get the missing prescription records to her as soon as possible.

83. After Ms. Acosta's January inspection, Mr. Oduyale asked Ms. Garcia where the original prescriptions were, and Ms. Garcia told him. Mr. Oduyale asked Estaban to make copies of the newly located records. He asked Ms. Banda to print the prescriptions and labels questioned by the board's inspectors from Cal-Mex's computer. Ms. Banda printed the prescriptions and labels as requested.

The next day, Estaban copied the requested prescriptions on an industrial copier at Mr. Oduyale's copy center. Estaban put a couple of prescriptions on some pages in order to minimize the stack of documents to be sent to Ms. Acosta. He made exact copies of the documents that were found. He returned the copied documents to Mr. Oduyale. Ms. Garcia put the documents in large envelopes and sent them to Ms. Acosta. Several Cal-Mex employees were present while copies of the prescriptions were made. None of the employees saw anyone make any changes to the prescriptions while they were being copied. No notes were created in the records or on the computer after Ms. Acosta left.

EVALUATION

84. Mr. Oduyale testified that a technician who input information from an invalid prescription and then printed a dispensing backer made a mistake. If Mr. Oduyale was correct, this mistake was repeated multiple times. Additionally, Mr. Oduyale's testimony does not

explain why he signed the backers to the invalid prescriptions. The only logical explanation for the state of the records is that these 20 prescriptions were changed and new documents were created after the January inspection.

When the inspectors pointed out the non-conforming prescriptions to Mr. Oduyale, he did not understand why they were non-compliant or how to verify them. Ms. Acosta spoke to Dr. Rafla in January, and she testified that he did not know his forms were non-compliant. Ms. Samari confirmed that Dr. Rafla told her he learned his forms were non-compliant from Ms. Acosta. These facts further support a finding that respondents created documents after Ms. Acosta completed her inspection.

Clear and convincing evidence supports a finding that Mr. Oduyale and Cal-Mex gave documents to Ms. Acosta that were altered and contained false facts.

Expert Testimony on Behalf of Respondents Regarding Pharmacy Practices

85. Phillip K. Evans received his pharmacist license in 1973. He received his juris doctorate degree in 2000. He is studying for a master's degree in pharmacy. He has worked extensively in the pharmaceutical industry and has experience in hospital, retail and government-run pharmacies. He has worked in many pharmacies. He has extensive experience preparing sterile injectable medications. He also has had a career as an attorney. He is currently the pharmacist-in-charge in a retail pharmacy in San Diego.

86. In 1993, Mr. Evans' pharmacist license was suspended for 60 days, and he was placed on probation for three years for improperly increasing the quantity of drugs authorized by a prescribing physician, dispensing refills when refills were not authorized and for increasing the dosage of a prescribed drug without authorization from the prescriber. Mr. Evans recently received a citation from the board relating to his pharmacy license; however, he is disputing the citation.

87. In 2013, Mr. Evans' license to practice law was suspended for two years; however, the suspension was stayed and his license was placed on probation for three years with an actual suspension of six months. Mr. Evans was required to pay restitution to five clients in the total amount of approximately \$3800 and to pay disciplinary costs. In a stipulation to resolve the disciplinary action, Mr. Evans admitted that his misconduct significantly harmed clients and evidenced multiple acts of wrongdoing. The incidents that led to the discipline involved accepting money in advance for services that were not performed. Mr. Evans testified that he was undergoing medical treatment and sold his practice to another attorney who had agreed to provide the services Mr. Evans had contracted to provide. Mr. Evans, nonetheless, accepted responsibility for the misconduct.

88. Mr. Evans has been professionally associated with Mr. Oduyale for approximately 18 years, and they are very close friends. Mr. Evans worked at Cal-Mex for five days in December 2014 and was covering for Mr. Oduyale while this hearing was held.

89. Mr. Evans puts his initials on each prescription he reviews. He would not put his initials on a prescription if there was a problem with the prescription. He observed that the practices at Cal-Mex were standard compared with what he has observed at other pharmacies.

90. Mr. Evans considers a prescription "dispensed" when the medication is handed to the patient, not when the prescription is ready for the patient to pick it up. Until the patient receives the medication, the pharmacist retains possession and control of the medication.

REVIEW OF RECORDS RELATING TO BS

91. Mr. Evans reviewed the prescriptions for oxycodone dispensed to BS. He identified the typed note produced in discovery as being similar to what he has seen in other pharmacies, either in the computer or written on the prescription. He did not see such notes at Cal-Mex during his time there. Mr. Evans said this type of note is readily retrievable.

Mr. Evans testified that it was mandatory to contact the prescribing doctor when the quantity of medication prescribed exceeded expected usage. He agreed that if a patient with a chronic pain condition, who was likely dependent upon medications, was going on vacation, it was reasonable that an increased quantity of medication would be prescribed. If such a patient were to run out of medication, he or she could go through withdrawal, which could be life-threatening. Mr. Evans found the prescribing doctor's letter written one year after the prescriptions were dispensed to be persuasive evidence that Cal-Mex verified the prescriptions.

REVIEW OF RECORDS RELATING TO AS

92. Mr. Evans opined that respondents correctly dispensed 200 tablets of oxycodone 15 mg when the pharmacy did not have sufficient stock to fill the complete prescription because they obtained the prescribing doctor's permission first. Although Mr. Evans stated that it was "most important" that respondents had obtained the prescriber's permission to fill only part of the prescription, he later testified that respondents had acted properly if only the patient had been informed because providing the medication helped the patient.

ALTERED DIRECTIONS

93. As regards to bottle labels with different directions for use than indicated on the prescription, Mr. Evans, as did Mr. Oduyale, stated that these were in error, but Mr. Evans added that all pharmacies make mistakes. Mr. Evans also stated that pharmacists can alter a prescriber's directions when counseling the patient. For example, Mr. Evans stated that there are instances where the directions say to take a medication once a day and he will tell patients not to take the medication if they don't need it. He called this "embellishing" and stated that it was appropriate pharmacy practice. He also testified that it was not necessary to obtain a doctor's authorization to change instructions on a prescription from a standing order (example, one a day) to an "as needed" order. On cross-examination, Mr. Evans said he may not change the instructions on the medicine bottle but, depending on the circumstances, would tell the

patient orally that they should take the medication as needed. Mr. Evans's testimony that such changes are permissible was unpersuasive.

AUDIT OF NORCO-10

94. As part of his duties as a pharmacist, Mr. Evans maintains controlled substance records and performs audits. He stated that his goal in conducting an audit is to zero out, but it does not always happen. A broken tablet or a miscount can result in an audit that does not zero out. Mr. Evans felt that having a 473 count overage indicated a problem in invoicing since Norco-10 comes in bottles of 500; he stated that it was better to be over than under by that amount.

VERIFYING PRESCRIPTIONS

95. Mr. Evans opined that pharmacists generally know a prescriber's staff. He described the process of verifying a prescription as: telephoning the a doctor's office; advising the person answering the phone what the call is about; and receiving an "ok" from the person who answered the telephone. He believes that a doctor's staff can review a patient's chart and give authorization to fill a prescription. He testified that in 40 years of being licensed as a pharmacist he never contacted a doctor to determine who was authorized to verify a prescription, and he never heard of anyone doing that.

When Mr. Evans verifies a prescription he writes on the face of the prescription the date, time and who he spoke to, and he initials the prescription. If he re-wrote the prescription, he would include this information in a note on the prescription or on a piece of paper attached to the prescription.

When shown a pre-printed prescription from Dr. Rafla, Mr. Evans stated he would verify the prescription the first few times he received it from the doctor relating to a particular patient until he was comfortable with the prescription. When shown a prescription re-written by Cal-Mex, he agreed that he would have made more complete notes that what was on the prescription, but disagreed that the prescription did not meet the requirements of a prescription because all of the information needed was on the backer. He believes that as long as the pharmacist is the one who verified a prescription, the pharmacist can document the verification in any way he or she wants.

Mr. Evans did not see pharmacy technicians verify prescriptions while he was filling in at Cal-Mex.

96. Mr. Evans has worked with 4000 to 5000 pharmacists. He believes Mr. Oduyale is a competent and versatile pharmacist and that he has a reputation for honesty and integrity. He described Mr. Oduyale as a better pharmacist than himself.

97. In many ways, Mr. Evans and Mr. Oduyale disagreed as to what was standard and acceptable practice by pharmacists and pharmacies. Overall, Mr. Evans appeared rather

cavalier in his manner of testifying and several times contradicted himself. His testimony was not found to be helpful in determining the issues in this matter.

Allegation that Respondent Oduyale Improperly Extended an Expiration Date for Oxytocin.

EXTENSION OF BEYOND USE DATE AND HOSPITAL INVESTIGATION

98. A pharmacist may not distribute drugs that they knew, or had reason to know, were adulterated or misbranded. (Bus. & Prof. Code § 4169, subd. (a); Health & Saf Code § 111440.) When compounding drugs – combining two or more substances to make one drug product – a pharmacist must assign an expiration date to the compound beyond which the pharmacist, using his professional judgment, determines the product should not be used. This “beyond use date” (BUD) may not exceed the “shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.” Cal. Code Regs., tit. 16, § 1735.2(h.)

99. On February 26, 2014, Mr. Oduyale was working as a pharmacist at Pioneer Memorial Hospital. Jaime Gudino, a pharmacy technician who was licensed for ten years and employed by Pioneer for over three and one-half years, was working with Mr. Oduyale. Mr. Gudino did not know Mr. Oduyale before they worked together at Pioneer, but they became friends and they frequently socialize.

Mr. Gudino worked in six to ten pharmacies before working at Pioneer. He was aware that Mr. Oduyale had a good reputation in the hospital and stated that he was the “go-to guy” for the other pharmacists on staff. Mr. Gudino observed that the nurses on staff asked Mr. Oduyale questions about medications more than they did any other staff pharmacist.

100. Mr. Gudino observed Mr. Oduyale preparing labels for sterile compounded bags of oxytocin¹³ which Pioneer purchased from Cantrell Drug Company. Mr. Gudino told Mr. Oduyale that the labels indicated that the oxytocin bags were expired. Mr. Oduyale disregarded Mr. Gudino’s concern and told him that it was all right, he was going to re-label the bags. Mr. Oduyale told Mr. Gudino that there was an urgent need for oxytocin. Mr. Gudino testified that he saw Mr. Oduyale look at the sterile compound bags but he did not know what Mr. Oduyale was looking for. He did not see Mr. Oduyale researching whether the expiration date could be extended. Mr. Gudino did not question Mr. Oduyale further because Mr. Oduyale was his boss.

¹³ Oxytocin is a medication used in the Obstetrics Department to induce and augment labor and to control post-partum bleeding. Oxytocin is compounded by adding a concentrated form of Oxytocin to a sterile solution which is then administered to the patient intravenously. The oxytocin manufactured by Cantrell added concentrated oxytocin to lactated Ringer’s bags.

HOSPITAL'S INVESTIGATION OF MR. ODUYALE'S EXTENSION OF BEYOND USE DATE

101. John Paul Teague is the Director of Pharmacy (Pharmacist-in-Charge) at Pioneer Hospital. He has worked at Pioneer in a variety of positions since 2005 and has been the Director for almost two years. He has been a licensed pharmacist for approximately seven years. As the Director of Pharmacy, Mr. Teague is responsible for the management and oversight of the hospital's pharmacy operations. Mr. Oduyale reported to Mr. Teague. Mr. Teague occasionally worked with Mr. Oduyale at the hospital and considered him a "pretty good" employee.

102. Mr. Teague overheard pharmacy technicians discussing Mr. Oduyale's re-labeling of expired Cantrell bags, and he interviewed Mr. Gudino. Mr. Gudino told Mr. Teague that he saw Mr. Oduyale re-label the expired bags.

Mr. Teague searched the pharmacy computer logs for February 26, 2014, and could find no documentation that Mr. Oduyale had changed the expiration date of the compounded oxytocin. He expected to find a note in the system that the expiration dates had been changed, why they were changed, and upon what authority they had been extended. Mr. Teague found expired Cantrell bags in an area of the pharmacy designated for products that were to be discarded; there were no expired bags on the pharmacy shelves. He also found unexpired multi-use vials of concentrated oxytocin in the overstock area that were available for pharmacy staff to use to compound oxytocin. Further, Mr. Teague found that oxytocin was compounded by pharmacy staff the next morning, February 27, 2014, without extending an expiration date, thus supporting his belief that sufficient non-expired stock was available in the pharmacy on February 26.

Mr. Teague examined the Pyxis¹⁴ records in the Obstetrics Department and learned that compounded oxytocin bags were placed in Pyxis on regular intervals on February 26, 2014. Except for the bags relabeled by Mr. Oduyale, the compounded bags complied with hospital policy and were correctly compounded. Mr. Teague determined that two oxytocin bags were in the Pyxis machine when Mr. Oduyale put five expired bags in. Six bags of oxytocin were used between when Mr. Oduyale stocked the machine and it was refilled the next day. The first bag of oxytocin was taken 20 minutes after Mr. Oduyale loaded them into machine.

Mr. Teague found small unexpired vials of concentrated oxytocin in the Obstetrics Department's Pyxis machine that were available to use to compound oxytocin. The Obstetrics Department also maintained an emergency supply of oxytocin. Mr. Teague spoke with the physician on call on February 26 and learned that the physician had not been contacted by Mr. Oduyale to advise him that expired sterile compound bags were placed in the Pyxis machine.

¹⁴ Pyxis is the trade name for an automatic, computer-controlled medication dispensing system. Pyxis machines are located in several departments in the hospital. The Pyxis machine records a variety of information, including name of any individual who accesses the machine and the date and time medication is placed in, or withdrawn from, the machine.

Mr. Teague was not aware of any literature that supported Mr. Oduyale's extension of Cantrell's assigned beyond use date.

Mr. Teague interviewed Mr. Oduyale a few days after he learned that Mr. Oduyale had re-labeled the compounded oxytocin. Mr. Oduyale admitted that he had changed the expiration date on the Cantrell bags from February 24, 2014, to February 28, 2014, because there was no stock available. Mr. Teague asked Mr. Oduyale if he documented what he did, including referencing literature that supported his extension of the manufacturer's beyond use date. Mr. Oduyale insisted that he was within his rights to use his professional judgment to extend the date.

Mr. Teague testified that all pharmacy staff personnel received training about the hospital's drug compounding policy and were required to sign a document attesting that they understood the policy. The hospital maintained multiple logs to document the compounding of drugs and impressed upon the pharmacy staff that it was very important to accurately complete the logs. Mr. Teague had discussed with the pharmacy staff the significance of the beyond use date. The hospital maintained extensive policies about expired medications and provided bins in multiple locations for discarded pharmacy waste. He stated that unless the pharmacist was the person who compounded the drug, the expiration date of a compounded product could not be extended because the pharmacist could not know how the expiration date assigned by a manufacturer had been determined.

If, in an emergency situation, the only stock remaining was expired, the pharmacist was to contact the physician on call or the treating physician to give the physician the opportunity to decide if he or she wanted to use the expired product. An expired product may be less sterile, less stable and less potent. It may not provide the therapeutic response relied upon by the physician when treating his or her patient. In some cases, ineffective product could lead to a patient not progressing as expected and result in an otherwise unnecessary cesarean section. Further, if a patient was not progressing on inefficient medication, the physician might order a higher dosage, which could be excessive when full-strength medication was subsequently administered. Although in this case, no harm was reported, a potential for harm was created by extending the expiration dates of the compounding bags.

103. Mr. Oduyale did not have any negative job performance issues at Pioneer prior to February 26, 2014; however, Mr. Teague considered Mr. Oduyale's actions very serious. Mr. Teague found that Mr. Oduyale used poor judgment in extending the expiration dates on the oxytocin without performing research to determine if the extension was supported by empirical data; he failed to document that he had extended the beyond use date; and he failed to advise the physician on call that he had stocked the Pyxis machine with expired compound bags. As a result of this misconduct, Mr. Teague determined to terminate Mr. Oduyale from his employment at Pioneer.

104. On cross-examination, a draft of a letter written by Mr. Teague, dated January 27, 2014, supporting Mr. Oduyale was introduced in evidence. The letter was addressed to the California State Board of Pharmacy and appeared to be originally intended to support Mr.

Oduyale's application for a license for Cal-Mex. In the letter, Mr. Teague wrote that Mr. Oduyale had a reputation for "honesty, integrity and good moral character," and that "[a]s owner of his own pharmacy I believe Sol will continual [sic] to uphold his reputation as an honest, competent and ethical pharmacist." It is noted that the letter was never finalized or signed and was dated approximately one month before the incident that lead to respondent's termination from Pioneer Hospital. Mr. Teague testified that Mr. Oduyale's re-labeling of the expired oxytocin bag changed his opinion that Mr. Oduyale exercised good judgment as a pharmacist.

BOARD'S INVESTIGATION OF MR. ODUYALE'S EXTENSION OF BEYOND USE DATE

105. On April 30, 2014, Ms. Acosta performed a sterile compounding annual renewal inspection at Pioneer Hospital's pharmacy and investigated Mr. Oduyale's conduct in extending the beyond use date of the oxytocin bags. Ms. Acosta testified that ensuring the safety of sterile products, such as the sterile injectable oxytocin, is one of the board's priorities.

106. Ms. Acosta reviewed scientific literature relating to the expiration date of compounded Oxytocin. Lawrence Trissel is the leading expert in the field of sterile injectables, such as oxytocin, and the assignment of beyond use dates. His writings are considered to be the best authority on the subject of sterile injectables. Published research conducted by Trissel, with others, confirmed that "oxytocin in lactated Ringer's injection should be restricted to a use period no greater than 28 days at room temperature to prevent microprecipitate formation¹⁵ and drug loss." In an article by Lisa A. Boothby and others, it is suggested that compounded oxytocin "could have beyond use dates of 31 days" if the bags are refrigerated and if sterility tests are conducted on them." Here, there was no testimony that the bags were refrigerated, and it was established that Mr. Oduyale did not perform sterility tests on the oxytocin bags before he re-labeled them.

107. Ms. Acosta subpoenaed documents from Pioneer and obtained a copy of a packing slip from Cantrell Drug Company dated January 29, 2014. The packing slip indicated that 60 oxytocin bags were delivered to Pioneer Hospital and provided, "BUD: **2/24/2014**" (Bold in the original.).

Ms. Acosta contacted Cantrell for further information. Cantrell personnel advised Ms. Acosta that Mr. Oduyale had not contacted Cantrell before he extended the expiration date of the compounded Oxytocin from February 24 to February 28, 2014; it had never provided data or authorized the extension of the beyond use date past 28 days; and it did not have sterility or stability data that would allow the extension of the beyond use date beyond the assigned 28 days. Cantrell provided a copy of the shipping label and a label attached to the prescription indicating a discard date of February 24, 2014.

¹⁵ Microprecipitates are not visible by the naked eye.

RESPONDENT ODUYALE'S POSITION RELATING TO EXTENSION OF BEYOND USE DATE

108. Mr. Oduyale worked at Pioneer Hospital from 2003 until his termination in early 2014. In a 2012 performance evaluation, Mr. Oduyale received an overall rating of 2.06 out of 3.0 from his supervisor, Santos S. Milosevich. Mr. Milosevich noted that "Sol is a reliable and dependable pharmacist. Sol makes good judgment [sic] and is an integral part of Pharmacy Healthcare team."

In November 2013, Mr. Oduyale received a performance evaluation prepared by Mr. Teague. In that review, Mr. Oduyale received an overall rating of 2.32 out of 3.0. In the performance evaluation, Mr. Teague wrote, "Sol consistently makes himself available to all staff and routinely rounds patient care areas before leaving and closing the pharmacy for the evening. This is not a requirement of our pharmacists but shows his commitment and care for our patients and Pioneer Memorial Hospital staff that we serve. Additional comments included, "Sol can handle matters without requiring assistance, he offers advice and communicates not only with pharmacy staff but our nursing staff as well. Sol offers a wealth of knowledge and experience and is the first to offer his assistance to anybody in need."

109. Mr. Oduyale testified that he received a lot of training regarding sterile injectables. His training covered compounding, mixing concentration vials, pharma-kinetics and the preparation of intravenous bags.

110. Mr. Oduyale testified that, on February 26, 2014, a call came into Pioneer Hospital's pharmacy at approximately 11:15 p.m. from a nurse in the labor and delivery unit requesting oxytocin immediately. Although the pharmacy was scheduled to be closed at 11:00 p.m., Mr. Oduyale responded to the call. He looked for compounded oxytocin bags on the pharmacy's shelves and found more than a dozen there. The beyond use date on all of the bags had expired by one or two days. Mr. Oduyale said he checked the Pyxis machines for other departments to see if oxytocin could be located there. He looked for vials of oxytocin from which he could compound oxytocin bags, but he could not find any. He considered whether he could get oxytocin from another hospital or retail pharmacy but they were closed. He determined that the call for oxytocin was an emergency because the failure to administer oxytocin when needed could injure a baby or cause suffering in the mother. Mr. Oduyale determined that the Cantrell oxytocin bags were compounded on January 29, 2014, and made the decision to extend the beyond use date.¹⁶

111. Mr. Oduyale stated that manufacturers were required to put the prepared date on compounded sterile injectable. He therefore assumed that the January 29, 2014, date on the Cantrell bags reflected the compounded date. No other witness confirmed this assertion.

112. Mr. Oduyale stated that he shook the compound bags and inspected them against the light to see if he could observe any particulates in the fluid; he did not see any. He also squeezed the bags to determine if there was any leakage. The bags looked stable to

¹⁶ Twenty-eight days from January 29, 2014 is February 26, 2014.

him; he had three women in labor; and he decided to extend the beyond use date. Mr. Oduyale also stated that he consulted a website, the name of which he could not recall, on his telephone and a book on intravenous admixture by Trissell. He claimed the website he consulted on his telephone supported a beyond use date of 28 to 31 days. The page of Trissell cited by Mr. Oduyale provides that oxytocin is physically compatible with a lacerated ringer's bag "with little or no loss of oxytocin in 28 days at 23 °C protected by light. Microprecipitate forms and loss of oxytocin occurs after that date." This citation does not support Mr. Oduyale's extension of the beyond use date.

113. Respondents rely on hospital policy that states, "A pharmacist may adjust expiration dates based on current literature and professional judgment." It also says that expiration dates for compounded sterile products "shall not extend beyond the stability period established by the manufacturer or listed in a current, authoritative reference. . . . A pharmacist shall determine if the products are usable after this date." Mr. Oduyale believed this policy gave him discretion to extend the beyond use date of the oxytocin in an emergency situation. He stated he changed the dates on four or five bags.¹⁷

TESTIMONY OF PHARMACY TECHNICIAN RICARDO ARRIQUIVE

114. Ricardo Arriquive has been a licensed pharmacy technician for ten years. He worked at Pioneer Hospital for seven years until his employment there was involuntarily terminated in October 2013. He has worked at Cal-Mex for three months. Mr. Arriquive opined that he would adjust expiration dates on products that he compounded after he researched how long the product remained stable and sterile. If a medication was needed but not in stock, Mr. Arriquive would research the issue and make a decision whether to extend the expiration date. He would not adjust the expiration date on a manufactured compound. He was not authorized to adjust the beyond use date for any product; he was required to get authorization from a pharmacist. He stated that the hospital did not use expired medications, although expired medications were found in the Pyxis machine from time to time. Staff was instructed to pull any medication they saw that was expired. He testified that Labor and Delivery nurses had totes and concentrated oxytocin on the unit. Although Mr. Oduyale's counsel called Mr. Arriquive to testify, Mr. Arriquive's testimony tends to support a finding that Mr. Oduyale should not have extended the beyond use date of the oxytocin.

Mr. Arriquive testified that, having access to medications could be challenging at Pioneer Hospital because Eliva Martinez Gonzalez, a pharmacy technician, put some medications in locked storage so that departments that did not need medications would not be overstocked. It became difficult to get medications at night because Ms. Martinez Gonzalez was not on duty at night and there was not an extra key to the locked medications.

Mr. Arriquive stated that Mr. Oduyale was well-respected at the hospital and even the Directors of Pharmacy came to him for advice. He felt that Mr. Oduyale was the most

¹⁷ Pyxis records show that Mr. Oduyale placed five bags of oxytocin the machine.

knowledgeable pharmacist he had ever worked with. Mr. Arriquive is a social friend of Mr. Oduyale.

TESTIMONY OF ELVIRA MARTINEZ GONZALEZ

115. Elvira Martinez Gonzalez has been a licensed pharmacy technician for sixteen years; she has worked at Pioneer Hospital for thirteen years. Her responsibilities include medical billing, preparing medications, answering the pharmacy telephone, bringing medications to hospital floors, compounding drug products, and acting as buyer for the pharmacy department at the direction of the pharmacist. Ms. Gonzalez worked for Rite Aid several years ago. She testified in response to Mr. Arriquive's testimony.

116. Ms. Gonzalez denied that there was a locked drug cabinet that was accessible only by her and denied that staff was hiding drugs. A cabinet that is located close to her desk was locked a few years ago because narcotics boxes for the Operating Room were stored there. Since Pyxis machines were installed in the hospital, there was no need to lock the cabinet, and Mrs. Gonzalez testified there is no key for the cabinet now. If something is ordered that the hospital does not need or an incorrect item is delivered, Ms. Gonzalez puts those items in the cabinet until they can be returned.

The hospital pharmacy has shelving units on the walls of the pharmacy; each wall contains medications and devices for various purposes. For example, one wall is for intravenous applications, one is for ear related medications, one is inhalation gasses, and one is for emergency room medications. A few feet from the intravenous wall is the overstock wall for compounding. Every Thursday during staff meetings, Ms. Gonzalez asks what items are overstocked and what items need to be ordered. Hospital pharmacists have access to all drugs in the hospital regardless of where they are located.

Pharmacy staff is required to make corrections in Pyxis when they see that the count is not correct. The accuracy in the count is determined by whether each user enters the correct amount of medication being removed and removing the amount entered.

It is not common for someone in the pharmacy department to re-label a compounded drug product to extend the expiration date. The hospital policy is that expired drugs should not be used.

The pharmacy has concentrated vials of oxytocin for compounding in the event there is an unexpected volume in the Labor and Delivery Department or if the bags they have are expired. It takes no more than five minutes to compound a bag of oxytocin. Ms. Gonzalez reviewed pharmacy records and determined that, on February 26, 2014, there were multiple unexpired vials of oxytocin in Pyxis machines and in emergency "totes" (tackle boxes) in the obstetrics department that were available to be compounded. Additionally, a pharmacy technician compounded 5 bags of oxytocin in the morning on February 26. On February 27, 2014, oxytocin was compounded in the pharmacy using vials that were available on February

26. There was no need, emergency or otherwise, to extend the beyond use date of the Cantrell Pitocin bags.

Before this incident, Ms. Gonzalez felt Mr. Oduyale was a hard-working pharmacist with integrity. After this incident, she is not sure how she feels about his abilities as a pharmacist.

Respondent's Expert Testimony Relating to Extension of Beyond Use Date

117. Anna K. Brodsky received a Doctor of Pharmacy degree from the University of Southern California in 2010. She participated in one to two month externships/clerkships in 2006, 2008, 2009 and 2010. From August 2006 to January 2010, Dr. Brodsky worked as an intern pharmacist for CVS Pharmacy. She was a pharmacist for Target Corporation from May 2010 to June 2013, where she received experience compounding medications. From February 2013 through March 2014, Dr. Brodsky was a clinical pharmacist for Absolute Wellcare Pharmacy, LLC., a company that operated long-term care facilities. She served as a panel expert appointed by the Los Angeles County Superior court to assist attorneys in criminal trials in matters relating to pharmacology. Dr. Brodsky has worked for Medico Rx Specialty and Home Infusion as Pharmacy Director since March 2014, where she has administrative duties as well as responsibilities that include dispensing medications. She teaches at the University of Southern California and is a preceptor to pharmacy students. Dr. Brodsky could not recall if she ever compounded oxytocin, but if she had, it would have been limited to when she was a student intern in a hospital setting.

118. Dr. Brodsky was asked to evaluate and render an opinion regarding respondent's extension of the beyond use date of the oxytocin. She was provided a copy of the Cantrell prescription label which indicated "Discard after 2/24/2014" below which was the date "1/29/2014." Dr. Brodsky testified that, in her experience, the January 29, 2014, date on the label represents the date the medication was compounded – or the "make date and that it was reasonable for a pharmacist to assume January 29, 2014, was the make date. She also testified that other literature in the scientific community supports the proposition that oxytocin may remain potent to ninety percent up to 31 days or more, although she qualified her response by saying that more studies were needed. She opined nonetheless, that extending oxytocin by two days past the "beyond use date" is not harmful even if the concentration of drugs was lower. She stated that a nurse might need to adjust the amount given, but that there was nothing to suggest the drug would not work. Dr. Brodsky felt that allowing hospitals to use medications for a longer period helps patients by lowering healthcare costs. She stated that a pharmacist may use his or her professional judgment whether to extend a beyond use date by considering when the drug was compounded and reviewing scientific literature.

119. Dr. Brodsky made the following assumptions when she opined that Mr. Oduyale properly exercised his professional judgment to extend the oxytocin by two days past the beyond use date assigned by Cantrell: Mr. Oduyale inspected the oxytocin bags; research supported the extension of the dates; the oxytocin bags were compounded on January 29, 2014; and February 26 was the 28th day after the product was compounded. In response to a

hypothetical question, Dr. Brodsky opined that if a patient needed oxytocin and the only oxytocin in a hospital pharmacy was expired, the pharmacist should pull the current scientific literature concerning beyond use dates and check the oxytocin bag to confirm there are no precipitates in the bag. If the literature supported a date extension, there were no precipitates visible, the bag was stored under good conditions and the hospital policy allowed the pharmacist to change the date, then the pharmacist could properly exercise his or her professional judgment to extend the date. In this case, Dr. Brodsky testified that, assuming the “make” date was January 29, 2014, the literature supports a beyond use date of February 26, 2014, and the medication would not have changed significantly in the two days the date was extended by Mr. Oduyale. Dr. Brodsky stated that in the balance of risk versus patient need, the patient’s need prevails.

120. Under cross-examination, Dr. Brodsky stated that she could not recall if she ever extended the beyond use date of a manufactured sterile injectable. She acknowledged that she was not aware of any literature that supported a determination that compounded oxytocin bags remained sterile after 28 days. Contrary to her original opinion, Dr. Brodsky testified that, were she to extend the beyond use date of a manufactured sterile injectable, she would do research and send the product to a laboratory to determine if the drugs remained sterile and stable; however, it would take three to seven days to get the results from the laboratory. She agreed that to safely extend the beyond use date of a manufactured drug product it was necessary to know the expiration dates of the components used to compound the drug. She admitted she really did not know what Cantrell’s January 29, 2014, date meant or how they assigned expiration dates. She also acknowledged that a pharmacist could not see microprecipitates by looking at a compounded drug product.

121. Dr. Brodsky subsequently opined that if the “made” date of the compounded oxytocin was other than January 29, 2014, she would follow the beyond use date of February 24, 2014, assigned by Cantrell, and she would not extend that date because it would be more than 28 days after the compound was made. Dr. Brodsky was unaware that Mr. Oduyale had extended the oxytocin beyond use date to February 28, 2014. She stated that it was “probably not” acceptable to extend the beyond use date to February 28 and that no studies supported such an extension. She testified that, if she had compounded a drug product and assigned a beyond use date, she would have assigned the correct date and no one should extend the date she assigned. Dr. Brodsky testified that if the oxytocin was given an expiration date past the beyond use date date assigned by the manufacturer, the drug is not misbranded but the label would contain false or misleading information. Finally, Dr. Brodsky confirmed that she would not extend the beyond use date by four days and that it was not the exercise of good professional judgment to do so without contacting the manufacturer, calling the physician on call, and looking for the medication in other places in the hospital.

EVALUATION

122. Clear and convincing evidence supports a finding that Mr. Oduyale improperly extended the expiration date of five bags of oxytocin. Mr. Oduyale’s claim that the invoice date of the compounded oxytocin was the “made” date was unsupported by any evidence and was

wrong. The Cantrell oxytocin bags were clearly labeled with an expiration date of February 24, 2014. Mr. Oduyale had no way to know the expiration date of the materials used to make them or when the compound was made. The fact that Mr. Oduyale, a pharmacist with many years of experience, believed he could hold a compounded product up to the light to see if there were any microprecipitates in it is alarming.

Mr. Oduyale's assertion that there was no concentrated oxytocin he could use to compound is unfounded and was unanimously disproved by witnesses and hospital records. Pharmacy technicians had compounded oxytocin earlier in the day on February 26 and in the morning of February 27 without using expired products. Although Mr. Oduyale claimed the need for oxytocin was an emergency, no oxytocin was taken from the Pyxis machine for twenty minutes after he stocked it with expired oxytocin.

None of the scientific articles submitted at the hearing supported Mr. Oduyale's assertion that oxytocin remains stable, sterile and potent after 28 days, and none provided a justification for him to extend the beyond use date of the Cantrell bags. Significantly, even Mr. Oduyale's expert reconsidered her opinion when she became aware of the actual facts in this case and withdrew her previously held opinion that Mr. Oduyale had properly exercised his professional judgment to extend the expiration date of the oxytocin.

Clear and convincing evidence supports a finding that Mr. Oduyale improperly extended the expiration date of the Cantrell compounded oxytocin.

Professional Reputation and Character Evidence

CAM TRAN

123. Several witnesses testified at the hearing regarding Mr. Oduyale's professional knowledge and reputation in the community.

124. Cam Tran has been a licensed pharmacist since 2001. She has been the Pharmacy Director at Alvarado Hospital, an acute care hospital in San Diego, for five years. Ms. Tran supervises eight pharmacists. Ms. Tran was a Pharmacy Director for Scripps Hospital from 2006 to 2009 and was the Pharmacy Director at Pioneer Hospital from 2002 to 2006. When she was a new pharmacist, Ms. Tran worked at Rite Aid in Calexico; Mr. Oduyale was her manager. When she worked at Pioneer Hospital, Mr. Oduyale was one of her pharmacists. She has not worked with Mr. Oduyale since 2006.

Ms. Tran stated that Mr. Oduyale is as competent as any other pharmacist she has working for her. She described him as a dedicated pharmacist. Ms. Tran hired Mr. Oduyale to work as a pharmacist at Alvarado Hospital; however, after a few days of training, Mr. Oduyale decided the commute was too long to pursue the job any further. Ms. Tran hired him because she trusted and valued him as a pharmacist. She never heard any complaints about Mr. Oduyale. Ms. Tran testified that she did not know exactly what the hearing was about although she understood the hearing was related to the board of pharmacy.

Ms. Tran stated that when she was at Pioneer Hospital, there were small tackle boxes in the labor and delivery department that had oxytocin in them for emergency use. She testified that she extended the date on a medication on one occasion when a surgeon asked for a medication and there was only one expired product in stock. She called the surgeon and told him the situation. He gave the authorization to use the expired product. She sent a sample to a laboratory the next day and learned the product was fine. She stated that hospital pharmacy practices did not allow a pharmacist to extend the beyond use date; the standard practice is that pharmacists follow what is on the label. She stated that intravenous bag labels always have the expiration date on them and confirmed that the labels may not include information about when the product was made.

VINCENT NGUYEN

125. Vincent Nguyen has been a licensed pharmacist since 2001; he and Ms. Tran are married. He is a floating pharmacist and works on a per diem basis. Mr. Nguyen interned for Mr. Oduyale in 2001; Mr. Oduyale was his preceptor at Rite Aid Pharmacy in Calexico. When Mr. Nguyen became licensed, he worked for Rite Aid with Mr. Oduyale. Mr. Nguyen has worked as a per diem pharmacist at Cal-Mex. He usually fills in for a few days; however, he worked at Cal-Mex for two weeks in late 2014 when Mr. Oduyale returned to Nigeria to attend his mother's funeral.

Mr. Nguyen has worked in many pharmacies. He did not see any differences in the way Cal-Mex was run and how other pharmacies he has worked in are run. Mr. Nguyen believes Mr. Oduyale is a good pharmacist and that he has a reputation as a good man. Mr. Oduyale speaks Spanish for his Spanish-speaking customers. Mr. Nguyen never heard a complaint about Mr. Oduyale or Cal-Mex.

Mr. Nguyen was the pharmacist on duty one of the times that the board's probation monitor, Simin Samari, came to inspect the pharmacy. Ms. Samari was in the pharmacy for approximately one to two hours. She reviewed computer records, hard copies of prescriptions, backers and invoices. Ms. Samari told Mr. Nguyen that there were errors in the manufacturer National Drug Code (NDC) numbers on some prescriptions in the customer pick up area. Several manufacturers may make a generic brand of a medication. The NDC number identifying the manufacturer of the generic dispensed is required to be on each prescription. Ms. Samari educated him about the issue and told him he had to be careful. Mr. Nguyen stated that human errors occurred at Cal-Mex as they do in all pharmacies. Listing the wrong NDC number does not cause harm as long as the correct medication and strength is dispensed. Ms. Samari left a letter explaining a number of record keeping items that needed to be corrected. Mr. Nguyen advised Mr. Oduyale of the letter, and Mr. Oduyale responded to Ms. Samari.

MARCIA NESINIGUEZ

126. Marcia Nesiniguez has been a registered nurse for fourteen years. She is currently a Charge Nurse/Clinical Manager at Pioneer Hospital. She works in the Medical/Surgery Unit and is responsible for the movement of patients and nurse

performance. She also helps in professional development of nurses on the floor. She has worked at Pioneer for six years.

Ms. Nesiniguez met Mr. Oduyale when he was a pharmacist at Pioneer. She stated that a patient care team includes the doctor, the nurse and the pharmacist. Mr. Oduyale was often the night pharmacist for the first five years Ms. Nesiniguez worked for Pioneer.

Ms. Nesiniguez said that Mr. Oduyale was always available to help and educate students and nurses. She felt that Mr. Oduyale was knowledgeable and caring. She had seen him work and had trust in his decisions and recommendations concerning the care and medications needed for patients. He was careful and would look things up if he had questions. She believes he had a good reputation in the hospital. Ms. Nesiniguez is also familiar with Cal-Mex and has personal prescriptions filled there. She has never heard a complaint about the pharmacy.

Ms. Nesiniguez did not read the accusation in this matter and did not know what the hearing was about. She did not know Mr. Oduyale's license was previously on probation and did not know that he had once been arrested with drugs on him. She was not aware of why Mr. Oduyale was terminated from Pioneer Hospital. She relies on the pharmacy to check expiration dates of injectable products and trusts the information they give her.

CECILE MARIE ARELLANO ALCARAZ

127. Cecile Marie Arellano Alcaraz has been a licensed pharmacist in California since 2007. She has worked in retail pharmacies as a manager and on a per diem basis. Ms. Alcaraz met Mr. Oduyale in March 2013 at a professional meeting. She felt Mr. Oduyale was well-rounded as a pharmacist.

In June 2013, Mr. Oduyale requested Ms. Alcaraz to observe Cal-Mex as a paid consultant to see if she had any recommendations about the operation of the pharmacy. Ms. Alcaraz observed how prescriptions were checked and filed. She saw Mr. Oduyale talking to patients and getting information from them. Ms. Alcaraz did not stay long at Cal-Mex, but she sent Mr. Oduyale a note regarding follow through. She also advised him of seminars offered by the board that might be helpful to him.

Ms. Alcaraz understood that it takes time to explain medications and instructions for use, especially to senior citizen patients. She felt Mr. Oduyale's care with this population and his ability to communicate with them in Spanish was a virtue of a good pharmacist. She saw Mr. Oduyale check the computer screen against the prescription label and look at the actual medication. Ms. Alcaraz suggested ways to improve the staff's work load. She discussed that the filing should be more organized. She also suggested updating the temperature log on the refrigerator and providing separate trash bins for empty bottles to better protect patient confidential information.

Ms. Alcaraz felt Cal-Mex was typical of other pharmacies she has worked in and supervised. She did not see anything she felt was being done incorrectly.

OLAYEMI FALOWO

128. Olayemi Falowo has been a pharmacist for 27 years; however, she has only an intern pharmacist license in California. She has had many positions in pharmacies in Minnesota, California and Arizona. She worked with Mr. Oduyale for three years, from 2006 through 2009, at the CVS Pharmacy in Yuma, Arizona, where he was the manager and she was a staff pharmacist. Ms. Falowo opined that Mr. Oduyale was a very good pharmacist, dependable; he went the extra mile and was hard working. He was exceptional amongst all the pharmacists she has worked with.

Ms. Falowo has observed Cal-Mex once a week for approximately four hours for the last two years because she aspires to have her own pharmacy. Mr. Oduyale has been her mentor. She observed all aspects of the pharmacy. From her observations, she opined that Cal-Mex was a good pharmacy. It helps seniors by providing transportation for them and delivers medications at no cost. She observed that Cal-Mex did a good job and she did not observe any violations of pharmacy laws or regulations.

Character and Reputation Evidence – Customers and Community Leaders

129. Respondents submitted approximately 13 character and reputation letters from customers and community leaders. These letters described Mr. Oduyale as “a very caring man,” “charismatic,” “a pleasure to work with,” “reliable,” “hard working,” “community minded,” “professional,” “generous,” “ethical,” “dedicated,” “diligent,” “compassionate,” and “knowledgeable.” Additionally, respondents submitted approximately nine letters from Cal-Mex customers who wrote glowingly about exceptional services they have received from Mr. Oduyale and Cal-Mex. Respondents also submitted over 20 customer surveys that were returned to Cal-Mex. In each survey, Cal-Mex was rated “5” on a scale of one to five. Comments from customers included that the staff was friendly and helpful and that Mr. Oduyale provided excellent service.

HILDY CARRILLO

130. Hildy Carrillo has been the Executive Director of the Calexico Chamber of Commerce for 15 years. Through this position she has become familiar with the reputations of businesses in Calexico. She sometimes receives complaints about other pharmacies, but she has not received any about Cal-Mex. She has known Mr. Oduyale for 20 years and believes him to be a well-respected and honest member of the business community. She is aware that he has generously sponsored events for senior citizens. She is aware that Cal-Mex’s license was on probation, but she did not know what the hearing she was attending was about.

JOHN RENISON

131. John Renison has served for almost 20 years in many community and public service positions in Imperial County and the City of Calexico including Mayor, City Councilman and County Supervisor. He also held a management position with San Diego

State University for 16 years. He is familiar with Calexico's local businesses and their reputations in the community. He has known Mr. Oduyale since the mid-1990s and believes him to be a good-hearted, community minded businessman who is always willing to help the economically disadvantaged in the community. Mr. Renison noted that more than 40 percent of the citizens in the area receive government assistance, and the unemployment rate is at 26 percent. He commented that it is important to the community when local businesses reach out to help. Mr. Renison described Mr. Oduyale and Cal-Mex Pharmacy as above reproach, honest, and having integrity; he has not heard any complaints about Cal-Mex. Mr. Renison did not know what the hearing for which he was providing testimony was about; he had not read the accusation. He knew that Cal-Mex was on probation, but he did not know why. He did not know that Mr. Oduyale's license had been on probation, why his license was on probation, or that Mr. Oduyale was terminated from Pioneer Hospital.

Other Matters Impacting the Level of Discipline

132. Simin Samari has been a licensed pharmacist in California since 1989. She has been an inspector with the board since 2005. For the past several years, Ms. Samari has been on the probation team. Her caseload is 65-70 probationers each quarter. Her duties include inspecting pharmacies and answering probationers' questions. Her goal is to help pharmacists do well in their probation.

When Ms. Samari is first assigned a probationer, she conducts inspections three to four times a year. She then reduces the number of inspections to approximately two a year. As a member of the probation team, she does not investigate complaints against pharmacies or pharmacists. As a probation monitor, Ms. Samari inspects to make sure the probationer is compliant with rules and regulations governing pharmacists and pharmacies and with the terms and conditions of probation.

133. In an inspection conducted in April 2012, one month after Cal-Mex opened, Ms. Samari observed that the pharmacy appeared to be in disarray and unorganized. The inspection report noted three areas that the pharmacy was required to improve. Ms. Samari discussed the deficiencies with Mr. Oduyale and how to correct them.

134. In an inspection report concerning an inspection conducted on July 5, 2012, Ms. Samari noted compliance with the previous inspection requirements. Ms. Samari found the pharmacy was still unorganized.

135. Ms. Samari inspected Cal-Mex on February 12, 2013 shortly after the board's inspection by Ms. Acosta and Mr. Mutrux. She reviewed the controlled and non-controlled substance books and controlled substance records. In the report for this inspection, Ms. Samari discussed Dr. Rafla's pre-printed prescriptions. Ms. Samari educated Mr. Oduyale about these and told him that all prescriptions must be written on board approved prescription pads. Ms. Samari also spoke to Dr. Rafla and advised him that the pre-printed prescriptions he was using did not comply with California requirements. Dr. Rafla acknowledged that he had spoken with

Ms. Acosta and had stopped using pre-printed prescription blanks. Although Ms. Samari testified that she still found the pharmacy cluttered, she did not note that on the report.

136. On June 27, 2013, Ms. Samari inspected Cal-Mex. She reviewed the controlled and non-controlled substance books and controlled substance records. She issued a reminder to "Keep the pharmacy clean and organized."

137. On January 30, 2014, Ms. Samari inspected Cal-Mex. Mr. Nguyen was the pharmacist on duty. She reviewed the controlled and non-controlled substance books and controlled substance records. On this inspection, Ms. Samari found two medications in the will-call area for which the description of the dispensed medication on the label did not match the medication in the bottle. Mismatched medication can be an indicator of billing fraud. A brand name drug is generally much more expensive than a generic brand of the same drug. A pharmacy engaged in billing fraud could bill for the more expensive drug but dispense the less expensive generic brand. Mr. Oduyale was instructed to provide a statement to Ms. Samari explaining how he planned to prevent this error from happening again.

Mr. Oduyale responded that the medications prescribed and dispensed were correct once the error was realized. He stated that the error occurred because NDC numbers on the label did not match the NDC from the original container. He stated that a special training meeting was held for all the pharmacy staff to educate them about the issue.

138. Ms. Samari inspected Cal-Mex on July 1, 2014. She found five prescriptions ready to be dispensed where the medication in the bottle did not match the description on the label. This was the same error noted in her previous inspection. In this inspection Mr. Oduyale told Ms. Samari that he was no longer accepting prescriptions for controlled substances if the doctor is outside the area and the patient is not known to him.

139. On March 5, 2015, Ms. Samari inspected Cal-Mex. The previous issue regarding label descriptions not matching the medication appeared to be corrected. However, in this inspection, Ms. Samari found "numerous" medications with labels indicating drug expiration dates in December 2016; however, the prescriptions were filled with medications whose expiration dates were earlier than that shown on the label. For example, one prescription with a label that indicated an expiration date of December 2016, was filled from stock that had an expiration date of June 2015. Potency and sterility decrease after the manufacturer's expiration date. Ms. Samari issued a non-compliance notice to Cal-Mex based on her findings.

140. Ms. Samari testified that respondents failed to file two recent quarterly reports as required by the terms and conditions of probation. Mr. Oduyale, however, stated that he was not aware that he was required to continue to file quarterly reports because, absent the current administrative proceedings, Cal-Mex's probation would have terminated.

Ms. Samari opined that Cal-Mex was not a good probationer. Cal-Mex and Mr. Oduyale, its pharmacist in charge, were given ample opportunities to comply with the rules and regulations governing pharmacies and pharmacists, but they have not demonstrated an ability to comply. She stated that there may have been additional deficiencies in the pharmacy that she

spoke to Mr. Oduyale about but did not include in her report in order to give respondents a chance to improve.

Allegations of Poor Quality of the Board's Investigation

141. Respondents claim that the board's inspections were of such a poor quality that the inspectors' findings are suspect and should be disregarded. Respondents refer to claims alleged in the originally filed Accusation and Petition to Revoke Probation but dropped in the First Amended Accusation and Petition and a cause for discipline dismissed at the hearing as evidence of the poor quality of the investigations. Respondents argue that the board's inspectors should have taken affirmative actions to determine that the dropped claims were not meritorious.

Costs

142. The board filed a Certification of Costs of Investigation by Agency Executive Officer; a Certification of Investigative Costs with Declaration of Christine Acosta; an Amended Certification of Investigative Costs with Declaration of Brandon Mutrux; and a Certification of Prosecution Costs with Declaration of Nicole R. Trama seeking to recover costs of investigation and prosecution pursuant to Business and Professions Code section 125.3.

The certification of prosecution costs filed by the Attorney General sought recovery of costs in the amount of \$26,920.00 and was supported by a billing summary detailing the professionals who worked on the matter, the date the professional worked on the matter, the tasks performed, the amount of time billed for the activity and the hourly rate of the professional who performed the work. The total amount sought included \$1,700.00 which was an estimate of additional hours that would be incurred by the prosecution in preparation of the case up to the commencement of the hearing. The costs sought by the Attorney General are reasonable.

The certifications of investigative costs with declarations from Ms. Acosta and Mr. Mutrux sought the recovery of \$25,066.50. The certifications listed the total of investigative hours spent working on the case, the hourly rate charged and a breakdown of activities by categories; the total number of hours worked on the matter was divided into investigation, travel, report preparation and hearing preparation. These certifications did not detail the date the activities were performed or the time spent performing those activities on each date. Due to the lack of specificity, it cannot be determined whether the costs claimed for investigative hours are reasonable.

Ms. Acosta testified that this matter was a difficult case with many documents that she was required to review. She did not know if the costs claimed included time she accompanied the DEA to Cal-Mex in April 2014. She did not pro-rate the amount of costs claimed by the amount of time devoted to claims that were later dismissed.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Complainant bears the burden of proof of establishing that the charges in the accusation and petition to revoke probation are true.

2. With respect to the accusation portion of the pleadings, the standard of proof required is “clear and convincing evidence.” (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) The obligation to establish charges by clear and convincing evidence is a heavy burden. It requires a finding of high probability; it is evidence so clear as to leave no substantial doubt, or sufficiently strong evidence to command the unhesitating assent of every reasonable mind. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

3. With respect to the charges in the petition to revoke probation, the standard of proof is preponderance of the evidence. (*Sandarg v. Dental Bd. of California* (2010) 184 Cal.App.4th 1434, 1441.) A preponderance of the evidence means that the evidence on one side outweighs the evidence on the other side, not necessarily in number of witnesses or quantity, but in its effect on those to whom it is addressed. In other words, it refers to evidence that has more convincing force than that opposed to it. (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

4. The board’s highest priority in exercising its licensing, regulatory, and disciplinary functions is protection of the public. Whenever the protection of the public is inconsistent with other interests sought to be promoted, protection of the public shall be paramount. (Bus. & Prof. Code, § 4001.1)

5. Business and Professions Code section 4063 regulates how a prescription can be refilled. It provides:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

6. Business and Professions Code section 4022 defines “dangerous drug” as “any drug . . . unsafe for self-use in humans or animals. Subdivision (a) provides that a dangerous drug is “Any drug that bears the legend: “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import. Subdivision (c) provides that a dangerous drug includes, “Any other drug . . . that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.”

7. Business and Professions Code section 4071 provides:

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

This section shall not apply to orders for Schedule II controlled substances

8. Business and Professions Code section 4073, subdivision (a), regulates how a pharmacist can make substitutions in filling a prescription. It provides:

A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

9. Business and Professions Code section 4081, subdivision (a), requires a pharmacy to maintain records of the “manufacture and sale, acquisition, receipt, shipment, or disposition of dangerous drugs” for three years. The records must be “at all times during business hours open to inspection by authorized officers of the law” The subdivision also requires that every pharmacy maintain a current inventory of dangerous drugs.

10. Business and Professions Code section 4169, subdivision (a), provides, in part:

(a) A person or entity shall not do any of the following:

[¶] . . . [¶]

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs . . . after the beyond use date on the label.

11. Business and Professions Code section 4301, provides, in 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:

[¶] . . . [¶]

(c) Gross negligence.

[¶] . . . [¶]

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

[¶] . . . [¶]

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

[¶] . . . [¶]

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

12. Business and Professions Code section 4306.5 provides in part:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

13. Health and Safety Code section 11153, subdivision (a), provides:

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

14. Health and Safety Code section 11164 provides, in part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time

request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

[¶] . . . [¶]

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

15. Health and Safety Code section 11165 provides, in part:

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) 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.

[¶] . . . [¶]

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall 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 specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate 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.

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

16. Health and Safety Code section 11172 provides, "No person shall antedate or postdate a prescription."

17. Health and Safety Code section 111440 provides, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

18. Health and Safety Code section 111335 provides, "Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

19. Health and Safety Code section 110290 provides:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any

combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered

20. Health and Safety Code section 111455 provides that, "It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded."

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

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

22. California Code of Regulations, title 16, section 1717.3 regulates the use of pre-printed forms and provides:

(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

[¶] . . . [¶]

(c) "Preprinted multiple check-off prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "check-off," indicates a prescription order for that drug.

23. California Code of Regulations, title 16, section 1718 requires a pharmacy to maintain a current inventory which "shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332." Controlled substances inventories "shall be available for inspection upon request for at least 3 years after the date of the inventory."

24. California Code of Regulations, title 16, section 1735.2 regulates when and how medications can be compounded. Subdivision (h) provides:

Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment

of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

25. California Code of Regulations, title 16, section 1761, subdivision (a) provides:

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

Disciplinary Guidelines

26. The Board of Pharmacy Disciplinary Guidelines, October 2007, provide that the board “serves the public by: protecting the health, safety, and welfare of the people of California with integrity and honesty”

27. The Guidelines provide that the following factors should be considered when determining the level of discipline to be imposed in a disciplinary case:

1. Actual or potential harm to the public.
2. Actual or potential harm to any consumer.
3. Prior disciplinary record, including level of compliance with disciplinary order(s).
4. Prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s).
5. Number and/or variety of current violations.
6. Nature and severity of the act(s), offense(s) or crime(s) under consideration.
7. Aggravating evidence.
8. Mitigating evidence.

9. Rehabilitation evidence.
10. Compliance with terms of any criminal sentence, parole, or probation.
11. Overall criminal record.
12. If applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code.
13. Time passed since the act(s) or offense(s).
14. Whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct.
15. Financial benefit to the respondent from the misconduct.

Evaluation

28. Pharmacists occupy positions that require trustworthiness, honesty, clear-headedness, and the exercise of impeccable judgment; they have access to confidential personal and financial information as well as highly regulated medications and devices. Pharmacies are a highly regulated industry because they possess and control dangerous drugs and devices. Lax practices and the failure to comply with the rules and regulations regarding pharmacies and pharmacists allow for a high potential for abuse and significant harm to individuals and the public. Pharmacies with a reputation for skirting the legalities of dispensing medications have a high potential to create great harm to their communities.

CAUSES FOR DISCIPLINE ALLEGED AGAINST CAL-MEX AND MR. ODUYALE

29. Cause exists under Business and Professions Code sections 4301, subdivision (o) and 4081, subdivision (a), and California Code of Regulations, title 16, section 1718 to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they failed to maintain adequate records of the acquisition and disposition of the controlled substance of Norco 10 and failed to keep a current accurate inventory as described in the Findings of Fact above.

30. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11165, subdivision (d), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing

evidence established that respondents engaged in unprofessional conduct when they failed to submit required controlled substance dispensing reports to the Department of Justice on a weekly basis as described in the Findings of Fact above.

31. Cause exists under Business and Professions Code sections 4301, subdivision (o), and 4073, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed an incorrect quantity of oxycodone without obtaining the approval of the prescriber for the substitution as described in the Findings of Fact above.

32. Cause exists under Business and Professions Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1716, to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they improperly deviated from the usage instructions provided by the prescriber as discussed in the Findings of Fact above.

33. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11164, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions for controlled substances which were not written on a controlled substance form as required by law as discussed in the Findings of Fact above.

34. Cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1717.3, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions for controlled substances which were written on pre-printed, multiple check-off prescription blanks as discussed in the Findings of Fact above.

35. Cause does not exist under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code sections 11164, subdivision (a)(1) and 11172, to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence failed to establish that respondents dispensed a controlled substance where the prescription was written after the medication was dispensed as discussed in the Findings of Fact above.

36. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11164, subdivision (b)(3), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they failed to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions on multiple occasions as discussed in the Findings of Fact above.

37. Cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1761, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they dispensed prescriptions containing significant errors, omissions, irregularities, uncertainties, ambiguities or alterations as discussed in the Findings of Fact above.

38. Cause does not exist under Business and Professions Code sections 4301, subdivision (o), and 4063, to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence failed to establish that Motrin 600 mg is a dangerous drug as discussed in the Findings of Fact above.

39. Cause exists under Business and Professions Code section 4301, subdivision (o), and Health and Safety Code section 11153, subdivision (a), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they failed to implement corresponding responsibility when dispensing a 90 day supply of a controlled substance in 30 days as discussed in the Findings of Fact above.

40. Cause exists under Business and Professions Code section 4301, subdivision (g), to impose discipline on Cal-Mex's pharmacy permit and Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondents engaged in unprofessional conduct when they provided altered documents to the board's inspector that falsely represented the existence of facts as discussed in the Findings of Fact above.

CAUSES FOR DISCIPLINE ALLEGED AGAINST MR. ODUYALE

41. Cause exists under Business and Professions Code sections 4301 and 4306.5, subdivision (b), to impose discipline on Mr. Oduyale's pharmacist's license. Respondent argued that a statute imposing discipline for the failure to exercise "best professional judgment" is unconstitutionally void for vagueness. Administrative agencies are not empowered to declare a statute unconstitutional. (Cal. Const., art. III, sec. 3.5.) Further, the provisions of the Business and Professions Code are not void for vagueness as applied in this case. Clear and convincing evidence established that respondent Oduyale engaged in unprofessional conduct when he failed to exercise or implement his best professional judgment as it relates to the matters alleged in the First, Third through Seventh, Ninth, Tenth, Twelfth and Thirteenth Causes for Discipline in the Accusation and as discussed in the Findings of Fact above.

42. Cause exists under Business and Professions Code sections 4301, subdivision (o), and 4169, subdivision (a), and Health and Safety Code section 111440, to impose discipline on Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondent Oduyale engaged in unprofessional conduct when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Findings of Fact above. The extension of

the beyond use date by re-labeling the product constituted a misbranding of the compounded oxytocin.

43. Cause exists under Business and Professions Code section 4301, subdivision (j), and California Code of Regulations, title 16, section 1735.2 subdivision (h), to impose discipline on Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondent Oduyale engaged in unprofessional conduct when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Findings of Fact above.

44. Cause exists under Business and Professions Code section 4301, subdivision (c), to impose discipline on Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondent Oduyale engaged in gross negligence when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date as discussed in the Findings of Fact above.

45. Cause exists under Business and Professions Code section 4301, subdivision (g), to impose discipline on Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondent Oduyale engaged in misconduct when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date by relabeling the product as discussed in the Findings of Fact above. The relabeling of the compounded oxytocin constituted the making of a document that falsely represents the existence of a state of facts.

46. Cause exists under Business and Professions Code sections 4301 and 4306.5, subdivision (a) to impose discipline on Mr. Oduyale's pharmacist's license. Clear and convincing evidence established that respondent Oduyale engaged in misconduct and misused his education, experience and training when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date by relabeling the product, verifying its quality, and dispensing the product for patient use as discussed in the Findings of Fact above.

47. Cause exists under Business and Professions Code sections 4301 and 4306.5, subdivision (b) to impose discipline on Mr. Oduyale's pharmacist's license. Respondent argued that a statute imposing discipline for the failure to exercise "best professional judgment" is unconstitutionally void for vagueness. Administrative agencies are not empowered to declare a statute unconstitutional. (Cal. Const., art. III, sec. 3.5.) Further, the provisions of the Business and Professions Code are not void for vagueness as applied in this case. Clear and convincing evidence established that respondent Oduyale engaged in misconduct and failed to exercise his best professional judgment when he improperly, and without authority, extended the expiration date of compounded oxytocin beyond the manufacturer's beyond use date by relabeling the product, verifying its quality, and dispensing the product for patient use as discussed in the Findings of Fact above.

PETITION TO REVOKE CAL-MEX'S PROBATION

48. In 2011, Cal-Mex's application for a pharmacy permit was granted, the permit was immediately revoked, the revocation stayed, and Cal-Mex was placed on 35 months of probation under certain terms and conditions. Under Condition 11 of the terms and conditions of probation, the board retained jurisdiction to revoke Cal-Mex's probation if Cal-Mex failed to comply with all of the terms and conditions of probation.

49. Cause exists under Condition 1 to revoke Cal-Mex's probation. Condition 1 of Cal-Mex's probation requires that Cal-Mex "and its officers shall obey all state and federal laws and regulations." The preponderance of the evidence established that Mr. Oduyale, and thereby Cal-Mex, did not obey all state and federal laws and regulations.

50. Cause exists under Condition 13 to revoke Cal-Mex's probation. Condition 13 of Cal-Mex's probation required that Cal-Mex "maintain and make available for inspection a separate file of all records pertaining to the acquisition and disposition of all controlled substances." The preponderance of the evidence established that Mr. Oduyale, and thereby Cal-Mex, did not comply with Condition 13.

Discipline Determination

51. The purpose of an administrative proceeding seeking the revocation or suspension of an occupational license or registration or revocation of probation is not to punish the individual; the purpose is to protect the public from dishonest, immoral, disreputable or incompetent practitioners. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

52. The determination of whether respondent Cal-Mex's pharmacy permit or Mr. Oduyale's pharmacy license should be revoked or suspended includes an evaluation of the criteria set forth in the board's disciplinary Guidelines. In this case, it is fortuitous that there is no evidence of actual harm occurring to Cal-Mex's customers or Pioneer Hospital patients. However, to establish a nexus between misconduct and fitness to practice a profession, patient harm is not required. The laws are designed to protect the public before a licensee harms any patient rather than after harm has occurred. (*Griffiths v. Superior Court* (2002) 96 Cal.App.4th 757, 771-772.) The multiple instances of failure to comply with laws and regulations applicable to pharmacies and pharmacists are serious and present a significant potential of harm to the public.

Both Mr. Oduyale and Cal-Mex have a prior disciplinary record; however, Cal-Mex's disciplinary record is based entirely upon Mr. Oduyale's past misconduct. Although it is Cal-Mex that is on probation, it is Mr. Oduyale's continued misconduct and failure to comply with pharmacy laws and regulations that has threatened Cal-Mex's pharmacy permit. It is not possible to neatly separate Cal-Mex and Mr. Oduyale. Cal-Mex and Mr. Oduyale were given correction notices and warnings by Cal-Mex's probation inspector, Ms. Samari. The pattern that was established was that Cal-Mex would remedy one problem and on the

next inspection there would be a new violation. However, on some occasions the prior violation would reappear.

There are 22 causes for discipline including those alleged in the Petition to Revoke Probation, although several causes overlap and/or relate to the same misconduct. The seriousness of the violations is underscored by the undeniable evidence that, for all his years of experience, Mr. Oduyale does not appear to understand the basic principles of operating a pharmacy and is incapable of running an orderly and compliant pharmacy. The finding in 2006 that he “played fast and loose with some of the rules” is equally applicable in this proceeding. The re-labeling of oxytocin shows a lack of understanding of compounding, expiration dates, the requirement to document and notify others when medications are altered, and hospital policies.

As relates to the record keeping and multiple versions of prescriptions, the only conclusions that can be drawn are that the pharmacy is out of control. There simply is no good explanation of how documents obtained in the January inspection were re-produced as different documents several days later, and then as something new again several months later. Record keeping deficiencies and the failure of attention to detail were present in 2005, in the inspections of Ms. Samari in 2012, in the inspections of Ms. Acosta in 2013, in the DEA inspection in 2014, and in inspections conducted in 2015. Mr. Oduyale does not seem capable of getting these issues under control.

The lack of understanding and inability to conform to the rules, regulations and policies applying to pharmacies and pharmacists allow no other determination but that, without significant additional training and education, Mr. Oduyale is not a competent pharmacist.

These findings are not an indictment of Mr. Oduyale as a person. By all accounts, including reports by the board’s inspectors, Mr. Oduyale is a kind and generous man who cares about his customers and community. Unfortunately, those qualities need to be matched with an ability to understand and comply with complex rules and regulations governing pharmacies and pharmacists. Pharmacies and pharmacists are heavily regulated for good reason. They possess and control dangerous drugs and devices that can make them targets of drug abusing employees, customers and members of the public. A failure to maintain complete control and an inability to demonstrate complete control through clear and organized files, invites abuse and presents a significant potential of harm to the public.¹⁸ Only the outright revocation of Mr. Oduyale’s license will protect the public.

53. Although Cal-Mex is the respondent on probation, the allegations against it in the prior action and the present action are solely based upon the actions of Mr. Oduyale. In fact, the pharmacy was placed on probation before it ever opened because of the prior discipline of Mr. Oduyale. Calexico has an underserved population. Testimony in this hearing established that the loss of the pharmacy would be a detriment to the community and

¹⁸ No evidence was presented to suggest that there currently is diversion or theft of drugs occurring at Cal-Mex.

those it serves. Perhaps under the guidance of a more detail-oriented pharmacist, the pharmacy can continue to be a benefit to the community. The board's "highest priority" of protecting the public can be accomplished by revoking Cal-Mex's permit, staying the revocation, and placing Cal-Mex on four years' probation. Because Mr. Oduyale's license is revoked, he will no longer be able to serve as a pharmacist-in-charge, or as any other category of pharmacist, in Cal-Mex. Cal-Mex will be required to obtain and designate a new pharmacist-in-charge who will be responsible for ensuring that Cal-Mex complies with the terms and conditions of probation, including all state and federal regulations. This level of discipline comports with the board's recommended guidelines.

The Reasonable Costs of Investigation and Prosecution

54. Under Business and Professions Code section 125.3, complainant may request that an administrative law judge "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."

55. The Office of Administrative Hearings has enacted regulations for use when evaluating an agency's request for costs under Business and Professions Code section 125.3. (Cal. Code Regs., tit. 1, § 1042.) Under the regulations, a cost request must be accompanied by a declaration or certification of costs. The declaration "may be executed by the agency or its designee and shall describe the general tasks performed, the time spent on each task and the method of calculating the cost." Alternatively, the agency may provide a bill or invoice. (Cal. Code Regs., tit. 1, § 1042, subd. (b)(1).) For services provided by persons who are not agency employees, the declaration must be executed by the person providing the service and must describe the general tasks performed, the time spent on each task and the hourly rate. In lieu of the declaration, the agency may attach copies of the time and billing records submitted by the service provider. (Cal. Code Regs., tit. 1, § 1042, subd. (b)(2).)

56. Complainant seeks costs related to the investigation and prosecution of this matter in the amount of \$51,986.50, based on \$25,066.50 for investigative costs and \$26,920.00 for costs incurred by the Attorney General's Office. Under Business and Professions Code section 125.3, costs awarded may not exceed the reasonable costs of investigation and enforcement of the case with respect to the licensing act violations. In this case, complainant filed an accusation and petition to revoke probation. All of the charges alleged in the Accusation and Petition were allegations that respondents violated the rules, regulations and policies that govern pharmacies and pharmacists.

57. The Certification of Investigative Costs submitted by Ms. Acosta and Mr. Mutrux listed a total of hours spent on the case and the hourly rate charged for activities they performed in the investigation and prosecution of the case. The total hours was then broken down into four categories: Investigation; travel; report preparation; and hearing preparation. For example, Ms. Acosta's certification seeks costs for 187.5 hours at the rate of \$102.00 per hour. Of the total hours, 79 hours were for:

Investigation which included:

- (1) Reviewing and prioritizing assignment upon receipt.
- (2) Communicating with complainant.
- (3) Contacting and interviewing witness(es) and/or the licensee.
- (4) Preparing correspondence and/or declarations.
- (5) Collecting, organizing, and evaluating documentation and other physical evidence.
- (6) Performing audit(s).
- (7) Inspection.
- (8) Research.
- (9) Conferencing with supervisor.
- (10) Other _____.

8.25 hours were attributed to travel; 80.75 hours were attributed to report preparation; and 8 hours were attributed to hearing preparation. No other information regarding investigative services or expenses was included. Mr. Mutrux's certification was on an identical form, but his total number of hours were fewer and the numbers were distributed differently.

58. Neither the inspectors' nor complainant's certification contained information regarding, the specific tasks performed, the date they were performed, or how long each task took. It is impossible to determine which part of the claimed charges, if any, related to claims that were dismissed or not pursued, or the DEA inspection which was not part of this case. Ms. Acosta candidly admitted she did not know if the costs claimed included the time she spent at the DEA inspection. Because the certification did not comply with the regulation, it is impossible to determine if the costs claimed are permissible charges under Business and Professions Code section 125.3, or to determine the reasonableness of the costs being sought. As a result, complainant's request for investigation costs must be denied.

59. The Certification of Prosecution Costs was prepared by Deputy Attorney General Nicole R. Trama and requested costs of enforcement in the amount of \$26,920.00. The certification included an attached breakdown of tasks by the professional who performed them, their general nature, the amount of time spent, and the amount charged. The certification complied with the OAH regulation. Based on a review of the accusation and petition to revoke probation, it is found that the charges related to abandoned or dismissed claims constituted a negligible portion of the case. The time-consuming aspects of this matter involved sorting out multiple versions of prescription documents resulting from respondents' poor record-keeping. The reasonable cost of enforcement by the Attorney General's Office is found to be \$26,920.00.

60. Other factors that must be considered when determining costs are discussed in *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32. In *Zuckerman*, the California Supreme Court decided, in part, that in order to determine whether the reasonable costs of investigation and prosecution should be awarded or reduced, the Administrative Law Judge must decide: (a) whether the licensee has been successful at hearing in getting charges

dismissed or reduced; (b) the licensee's subjective good faith belief in the merits of his or her position; (c) whether the licensee has raised a colorable challenge to the proposed discipline; (d) the financial ability of the licensee to pay; and (e) whether the scope of the investigation was appropriate to the alleged misconduct.

Respondents presented substantial evidence of their subjective good faith belief in the merits of their positions and, in fact, respondents' successfully defended some of the claims while others were dismissed.

Respondent Cal-Mex raised a colorable challenge to the proposed discipline and successfully achieved a reduction in the severity of the discipline sought to be imposed; however, Mr. Oduyale did not. Mr. Oduyale stated that he would have a financial challenge paying the full cost recovery requested. He testified that he had two children in college at a cost of \$8,000 per child per semester. He also represented that the pharmacy was his sole source of income and that it had not yet turned a profit but was breaking even. He stated that he was behind in rent because he had not realized any income from which to pay the rent. He also stated that he had unpaid debts in an unknown amount to drug companies for supplies he purchased from them. He further asserted that he was sustaining a loss on rental property he owns. There was some testimony at the hearing that Mr. Oduyale owns several businesses. In fact, there was testimony that photocopies of Cal-Mex documents provided to Ms. Acosta were made on a photocopy machine in one of Mr. Oduyale's other businesses. After consideration of all of the relevant factors, it is determined that it is reasonable to require respondents Cal-Mex and Mr. Oduyale to pay \$20,000.00 in costs. Respondents are jointly and severally liable for the costs. These costs shall be paid prior to Mr. Oduyale filing an application for reinstatement of his license.

ORDER

1. Pharmacist License Number 42719 issued to Olugbenga Solomon Oduyale is revoked.

2. Olugbenga Solomon Oduyale and Cal-Mex Special Services, Inc., dba Cal-Mex Pharmacy are ordered to pay costs to the board in the amount of \$20,000.00.

3. Pharmacy Permit number PHY 50374, issued to respondent Cal-Mex Special Services, Inc., dba Cal-Mex Pharmacy is revoked; however, the revocation is stayed and respondent is placed on probation for four years upon the following terms and conditions:

1. Obey All Laws. Respondent owner shall obey all state and federal laws and regulations.

2. Report Violations. 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 Cal-Mex's pharmacy permit 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.

3. 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.

4. 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.

5. Cooperate with Board Staff. Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

6. 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 \$20,000.00. Respondent owner and the probation monitor may agree on a payment plan. Once a payment plan has been agreed upon, there shall be no deviation from this plan absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

7. 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.

8. Status of License. Respondent owner shall, at all times while on probation, maintain Cal-Mex's 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 Cal-Mex's permit, and Cal-Mex shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent Cal-Mex's permit 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.

9. 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.

10. 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.

11. Owners and Officers: Knowledge of the Law. Respondent Cal-Mex 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.

12. 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.

13. 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.

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

15. Separate File of Records. Respondent owner 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.

16. Report of Controlled Substances. Respondent owner shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

Dated: May 27, 2015


SUSAN J. BOYLE
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
12 Case No. 4724

13 In the Matter of the Accusation and Petition to
Revoke Probation Against:

**FIRST AMENDED ACCUSATION AND
PETITION TO REVOKE PROBATION**

14 **CAL-MEX SPECIAL SERVICES, INC.,**
DBA CAL-MEX PHARMACY
15 **337 Paulin Avenue, Suite 1A**
Calexico, CA 92231

16 **Pharmacy Permit No. PHY 50374**

17 **and**

18 **OLUGBENGA SOLOMON ODUYALE**
19 **2209 E. 27th Street**
Yuma, AZ 85365

20 **Pharmacist License No. RPH 42719**

21 Respondents.

22
23 Complainant alleges:

24 **PARTIES**

25 1. Virginia Herold (Complainant) brings this First Amended Accusation and Petition to
26 Revoke Probation solely in her official capacity as the Executive Officer of the Board of
27 Pharmacy, Department of Consumer Affairs.

1 2. On or about August 19, 2011, the Board of Pharmacy issued Pharmacy Permit
2 Number PHY 50374 to Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy
3 with Olugbenga Solomon Oduyale as President and Pharmacist-in-Charge (PIC) (Respondent).
4 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
5 herein and will expire on August 1, 2015, unless renewed.

6 3. In a disciplinary action entitled "In the Matter of the Statement of Issues Against
7 Calmex Special Services, Inc., dba Cal-Mex Pharmacy," Case No. 4009, the Board of Pharmacy
8 issued a Decision and Order effective July 20, 2011, in which Respondent's Pharmacy Permit was
9 revoked. However, the revocation was stayed and Respondent's Pharmacy Permit was placed on
10 probation for thirty-five (35) months with certain terms and conditions. A copy of that Decision
11 and Order is attached as Exhibit A and is incorporated by reference.

12 4. On or about August 8, 1989, the Board of Pharmacy issued Pharmacist License
13 Number 42719 to Olugbenga Solomon Oduyale (Respondent). The Pharmacist License was in
14 full force and effect at all times relevant to the charges brought herein and will expire on October
15 31, 2014, unless renewed.

16 **JURISDICTION AND STATUTORY PROVISIONS FOR ACCUSATION**

17 5. This First Amended Accusation is brought before the Board of Pharmacy (Board),
18 Department of Consumer Affairs, under the authority of the following laws. All section
19 references are to the Business and Professions Code ("Code") unless otherwise indicated.

20 6. Section 4011 of the Code provides that the Board shall administer and enforce both
21 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
22 Act [Health & Safety Code, § 11000 et seq.].

23 7. Section 4300(a) of the Code provides that every license issued by the Board may be
24 suspended or revoked.

25 8. Section 4300.1 of the Code states:

26 The expiration, cancellation, forfeiture, or suspension of a board-issued
27 license by operation of law or by order or decision of the board or a court of law,
28 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

1 proceed with any investigation of, or action or disciplinary proceeding against, the
licensee or to render a decision suspending or revoking the license.

2 **STATUTORY PROVISIONS**

3 9. Section 4022 of the Code states:

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

6 (a) Any drug that bears the legend: "Caution: federal law prohibits
7 dispensing without prescription," "Rx only," or words of similar import.

8 (b) Any device that bears the statement: "Caution: federal law restricts this
9 device to sale by or on the order of a _____," "Rx only," or words of similar import,
the blank to be filled in with the designation of the practitioner licensed to use or
order use of the device.

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

12 10. Section 4063 of the Code states:

13 No prescription for any dangerous drug or dangerous device may be refilled
14 except upon authorization of the prescriber. The authorization may be given orally
15 or at the time of giving the original prescription. No prescription for any dangerous
drug that is a controlled substance may be designated refillable as needed.

16 11. Section 4073 of the Code states in pertinent part:

17 (a) A pharmacist filling a prescription order for a drug product prescribed by
18 its trade or brand name may select another drug product with the same active
19 chemical ingredients of the same strength, quantity, and dosage form, and of the
20 same generic drug name as determined by the United States Adopted Names
(USAN) and accepted by the federal Food and Drug Administration (FDA), of
those drug products having the same active chemical ingredients.

21

22 (d) This section shall apply to all prescriptions, including those presented
23 by or on behalf of persons receiving assistance from the federal government or
24 pursuant to the California Medical Assistance Program set forth in Chapter 7
(commencing with Section 14000) of Part 3 of Division 9 of the Welfare and
Institutions Code.

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12. Section 4081 of the Code states:

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

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

13. Section 4169 of the Code states in pertinent part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

....

14. 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

1 misrepresentation or issued by mistake. Unprofessional conduct shall include, but
2 is not limited to, any of the following:

3

4 (c) Gross negligence.

5

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

8

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

14

15 15. Section 4306.5 of the Code states in pertinent part:

16 Unprofessional conduct for a pharmacist may include any of the following:

17 (a) Acts or omissions that involve, in whole or in part, the inappropriate
18 exercise of his or her education, training, or experience as a pharmacist, whether or
19 not the act or omission arises in the course of the practice of pharmacy or the
20 ownership, management, administration, or operation of a pharmacy or other entity
21 licensed by the board.

22 (b) Acts or omissions that involve, in whole or in part, the failure to
23 exercise or implement his or her best professional judgment or corresponding
24 responsibility with regard to the dispensing or furnishing of controlled substances,
25 dangerous drugs, or dangerous devices, or with regard to the provision of services.

26 (c) Acts or omissions that involve, in whole or in part, the failure to
27 consult appropriate patient, prescription, and other records pertaining to the
28 performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully
maintain and retain appropriate patient-specific information pertaining to the
performance of any pharmacy function.

16. Health and Safety Code section 111330 states that any drug or device is misbranded if
its labeling is false or misleading in any particular.

1 17. Health and Safety Code section 111440 states that it is unlawful for any person to
2 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

3 18. Health and Safety Code section 11153 provides in pertinent part:

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

16 19. Health and Safety Code section 11164 provides in pertinent part:

17 Except as provided in Section 11167, no person shall prescribe a controlled
18 substance, nor shall any person fill, compound, or dispense a prescription for a
19 controlled substance, unless it complies with the requirements of this section.

20 (a) Each prescription for a controlled substance classified in Schedule II,
21 III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled
22 substance prescription form as specified in Section 11162.1 and shall meet the
23 following requirements:

24 (1) The prescription shall be signed and dated by the prescriber in ink and
25 shall contain the prescriber's address and telephone number; the name of the
26 ultimate user or research subject, or contact information as determined by the
27 Secretary of the United States Department of Health and Human Services; refill
28 information, such as the number of refills ordered and whether the prescription is a
first-time request or a refill; and the name, quantity, strength, and directions for
use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom
the controlled substance is prescribed. If the prescriber does not specify this
address on the prescription, the pharmacist filling the prescription or an employee
acting under the direction of the pharmacist shall write or type the address on the
prescription or maintain this information in a readily retrievable form in the
pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section
11162.1, any controlled substance classified in Schedule III, IV, or V may be
dispensed upon an oral or electronically transmitted prescription, which shall be

1 produced in hard copy form and signed and dated by the pharmacist filling the
2 prescription or by any other person expressly authorized by provisions of the
3 Business and Professions Code. Any person who transmits, maintains, or receives
any electronically transmitted prescription shall ensure the security, integrity,
authority, and confidentiality of the prescription.

4 (2) The date of issue of the prescription and all the information required for a
5 written prescription by subdivision (a) shall be included in the written record of the
6 prescription; the pharmacist need not include the address, telephone number,
7 license classification, or federal registry number of the prescriber or the address of
the patient on the hard copy, if that information is readily retrievable in the
pharmacy.

8 (3) Pursuant to an authorization of the prescriber, any agent of the
9 prescriber on behalf of the prescriber may orally or electronically transmit a
10 prescription for a controlled substance classified in Schedule III, IV, or V, if in
these cases the written record of the prescription required by this subdivision
specifies the name of the agent of the prescriber transmitting the prescription.

11 (c) The use of commonly used abbreviations shall not invalidate an
12 otherwise valid prescription.

13 (d) Notwithstanding any provision of subdivisions (a) and (b),
14 prescriptions for a controlled substance classified in Schedule V may be for more
than one person in the same family with the same medical need.

15 (e) This section shall become operative on January 1, 2005.

16 20. Health and Safety Code section 11165 provides in pertinent part:

17

18 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV
19 controlled substance, as defined in the controlled substances schedules in federal
20 law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,
21 respectively, of Title 21 of the Code of Federal Regulations, the dispensing
pharmacy or clinic shall provide the following information to the Department of
Justice on a weekly basis and in a format specified by the Department of Justice:

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

25 (2) The prescriber's category of licensure and license number; federal
26 controlled substance registration number; and the state medical license number of
27 any prescriber using the federal controlled substance registration number of a
government-exempt facility.

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

2 (4) NDC (National Drug Code) number of the controlled substance
3 dispensed.

4 (5) Quantity of the controlled substance dispensed.

5 (6) ICD-9 (diagnosis code), if available.

6 (7) Number of refills ordered.

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

9 (9) Date of origin of the prescription.

10 (10) Date of dispensing of the prescription.

11 21. Health and Safety Code section 11172 provides that no person shall antedate or
12 postdate a prescription.

13 STATE REGULATORY PROVISIONS

14 22. California Code of Regulations, title 16, section 1716 states:

15 Pharmacists shall not deviate from the requirements of a prescription
16 except upon the prior consent of the prescriber or to select the drug product in
accordance with Section 4073 of the Business and Professions Code.

17 Nothing in this regulation is intended to prohibit a pharmacist from
18 exercising commonly-accepted pharmaceutical practice in the compounding or
dispensing of a prescription.

19 23. California Code of Regulations, title 16, section 1717.3 states:

20 (a) No person shall dispense a controlled substance pursuant to a preprinted
21 multiple check-off prescription blank.

22 (b) A person may dispense a dangerous drug, that is not a controlled
23 substance, pursuant to a preprinted multiple checkoff prescription blank and may
24 dispense more than one dangerous drug, that is not a controlled substance,
pursuant to such a blank if the prescriber has indicated on the blank the number of
dangerous drugs he or she has prescribed.

25 (c) "Preprinted multiple checkoff prescription blank," as used in this
26 section means any form listing more than one dangerous drug where the intent is
that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription
order for that drug.

27 24. California Code of Regulations, title 16, section 1718 states:

28 "Current Inventory" as used in Sections 4081 and 4332 of the Business and

1 Professions Code shall be considered to include complete accountability for all
2 dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

3 The controlled substances inventories required by Title 21, CFR, Section
4 1304 shall be available for inspection upon request for at least 3 years after the
5 date of the inventory.

6 25. California Code of Regulations, title 16, section 1735.2 provides in part:

7

8 (h) Every compounded drug product shall be given an expiration date
9 representing the date beyond which, in the professional judgment of the
10 pharmacist performing or supervising the compounding, it should not be used.
11 This "beyond use date" of the compounded drug product shall not exceed 180 days
12 from preparation or the shortest expiration date of any component in the
13 compounded drug product, unless a longer date is supported by stability studies of
14 finished drugs or compounded drug products using the same components and
15 packaging. Shorter dating than set forth in this subsection may be used if it is
16 deemed appropriate in the professional judgment of the responsible pharmacist.

17

18 26. California Code of Regulations, title 16, section 1761 states:

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

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

27 **COST RECOVERY**

28 27. Section 125.3 of the Code provides, in pertinent part, that the 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, with failure of the licentiate to comply subjecting the license to not being
renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
included in a stipulated settlement.

29 **DRUGS**

30 28. Ambien, is a brand name for zolpidem, a Schedule IV controlled substance pursuant
31 to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to
32

1 Business and Professions Code section 4022. It is a sedative used for the short-term treatment of
2 insomnia.

3 29. Hydrocodone/acetaminophen, also known by the brand names Vicodin, Norco,
4 Zydone, Maxidone, Lortab, Lorcet, Hydrocet, Co-Gesic, and Anexsia, is a narcotic Schedule III
5 controlled substance as designated by Health and Safety Code section 11056(e)(4), and is a
6 dangerous drug pursuant to Business and Professions Code section 4022. Hydrocodone is used as
7 a narcotic analgesic in the relief of pain.

8 30. Lorazepam, is a Schedule IV controlled substance pursuant to Health and Safety
9 Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions
10 Code section 4022.

11 31. Oxycodone, is a Schedule II controlled substance pursuant to Health and Safety Code
12 section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code
13 section 4022.

14 32. Oxytocin is a dangerous drug pursuant to Business and Professions Code section
15 4022.

16 33. Temazepam, is a Schedule IV controlled substance pursuant to Health and Safety
17 Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions
18 Code section 4022.

19 **FACTUAL ALLEGATIONS: BOARD OF PHARMACY INSPECTION(S)**

20 34. On or about January 28, 2013, Board inspectors performed a routine inspection of
21 Cal-Mex Pharmacy located at 337 Paulin Avenue, Ste. 1A, in Calexico, California. The President
22 and Pharmacist-in-Charge (PIC) Oduyale was present during the inspection. During the
23 inspection, the Board inspectors reviewed hundreds of prescriptions, invoices from wholesalers,
24 and the quality assurance binder, among other items. Following the inspection, Board inspectors
25 continued the investigation of Respondents by interviewing and obtaining statements from
26 pharmacy personnel, including Respondent PIC Oduyale, and reviewing additional
27 documentation provided by Respondents.

28

1 35. Respondent PIC Oduyale provided the Board inspector with an audit of the
 2 hydrocodone/acetaminophen 10mg/325mg inventory that was acquired and dispensed by
 3 Respondent Cal-Mex Pharmacy between May 1, 2012 and January 28, 2013. According to
 4 Respondent PIC Oduyale's audit, Respondent Cal-Mex Pharmacy's total acquisition of
 5 hydrocodone/acetaminophen 10mg/325mg was 8,040 tablets and it's total disposition of
 6 hydrocodone/acetaminophen 10mg/325mg was 8,073 tablets, (an overage of 33 tablets).
 7 However, the Board inspector's audit of the inventory and records showed Respondent Cal-Mex
 8 Pharmacy's total acquisition of hydrocodone/acetaminophen 10mg/325mg was 8,040 tablets and
 9 it's total disposition of hydrocodone/acetaminophen 10mg/325mg was 8,663 tablets of
 10 hydrocodone/acetaminophen 10mg/325mg during that time period, (an overage of 623 tablets) as
 11 follows:

Audit Performed By:	Total Acquisition	Total Disposition	Variance	Overage
PIC Oduyale	8,040 tablets	8,073 tablets	33	33 tablets
Board Inspector	8,040 tablets	8,663 tablets	623	623 tablets

13
 14 Thus, Respondents dispensed 590 more tablets of hydrocodone/acetaminophen 10 mg/325mg
 15 than accounted for on Respondent PIC Oduyale's audit. Additionally, Respondent PIC Oduyale
 16 removed from the pharmacy's inventory 630 tablets on August 27, 2012 but was unable to
 17 provide an explanation for these removals to the Board inspector.

18 36. Between November 2012 and January 2013, Respondent Cal-Mex Pharmacy
 19 purchased drugs from River City Pharma located in Cincinnati, Ohio, even though River City
 20 Pharma did not hold an Out-of-State Wholesaler's license with the Board of Pharmacy.
 21 Respondent Cal-Mex Pharmacy purchased the following drugs from River City Pharma during
 22 that time period:

Date	Invoice Number	Dangerous Drug	Amount
11/13/2012	1055611-IN	Nystatin topical	2
11/13/2012	1055611-IN	Valacyclovir HCL 500mg tabs	1
11/14/2012	1056190-IN	Ciprofloxacin HCl 500mg tabs	2
11/14/2012	1056190-IN	Nystatin topical powder	6

1	1/8/2013	1078725-IN	Nystatin topical powder	6
2	1/21/2013	1084697-IN	Novolin 70/30 100U inj.	4
3	1/21/2013	1084697-IN	Novolin R U100	4
4	1/21/2013	1084697-IN	Nystatin topical powder	5
5	1/21/2013	1084697-IN	Celebrex 200mg Caps	3
6	1/21/2013	1084697-IN	Fluticasone 50mcg spray	6
7	1/21/2013	1084697-IN	Gabapentin 600mg tabs	2
8	1/21/2013	1084697-IN	Gabapentin 800mg tabs	1

9 37. Respondent Cal-Mex Pharmacy did not report to the Department of Justice (CURES)
10 its controlled substance dispensing on a weekly basis from March 21, 2012 to November 2013.
11 In fact, on December 3, 2013, Respondents reported 252 prescriptions from March 2, 2012 to
12 November 2013.

13 38. After completing a review of prescriptions dispensed by Respondents, Board
14 inspectors discovered that Respondent Cal-Mex Pharmacy did not dispense the correct quantity
15 when substituting oxycodone 15mg number 200 for a prescription written for oxycodone 30mg
16 number 120. The original prescription (RX No. 20013 written on August 8, 2012) provided
17 patient AS with 3,600 mg (a 30 day supply), however, it was dispensed for 3,000 mg (a 25 day
18 supply) without notification or consent of the prescriber.

19 39. Additionally, Respondents deviated from requirements in filling four prescriptions
20 without documentation of prior consent of the prescriber as follows:

21	RX #	Date Written	Date Filled	Patient	Drug Written For	Amount	Original/Rewrite Signature	Filled For
22	20013	8/8/12	8/9/12	AS	Oxycodone 30 mg	120	Oxycodone 30 mg number 120 (1 tab four times a day)	Oxycodone 15 mg number 200 (take 2 tabs four times a day)
23	40269	12/17/12	10/17/12	MF	Lorazepam 0.5mg	75	Every 8-12 hours	Every 8-12 hours as needed for pain
24	40270	10/17/12	10/17/12	EL	Hydrocodone/APAP 10/325mg	90	Rewrite: every 8 hours as needed	Every 8 hours
25	40416	12/5/12	12/5/12	EH	Ambien 5mg	50	Every night at bed for 7 weeks	Every night at bed as needed for sleep
26								
27								
28								

40. Respondent Cal-Mex Pharmacy also dispensed twenty-four prescriptions for controlled substances not written on controlled substance forms. Respondent PIC Oduyale informed the Board inspector that prescriptions were brought in by patients on an 8.5x11" white paper, not a controlled substance form, which was preprinted multiple check-off prescription blanks. Respondent PIC Oduyale told the Board inspector that all prescriptions were verified; however, he did not provide the required hard copy forms. From September 10, 2012 to November 16, 2012, Respondents dispensed the following prescriptions using original prescriptions provided by the patients, which were not written on controlled substance forms:

	RX #	Date Written	Date Filled	Patient	Drug Written For	Amount
1.	40202	9/7/12	9/10/12	GN	Zolpidem 10 mg	60
2.	40203	9/7/12	9/10/12	RA	Hydrocodone/APAP 10/325	60
3.	40204	9/7/12	9/10/12	MM	Hydrocodone/APAP 10/325	60
4.	40205	Unknown	9/11/12	EC	Hydrocodone/APAP 10/325	60
5.	40207	9/7/12	9/11/12	AC	Zolpidem 10 mg	60
6.	40209	9/7/12	9/11/12	BR	Zolpidem 10 mg	60
7.	40210	9/7/12	9/11/12	SB	Zolpidem 10 mg	60
8.	40211	9/7/12	9/11/12	MM	Hydrocodone/APAP 10/325	60
9.	40212	9/7/12	9/11/12	JR	Hydrocodone/APAP 10/325	60
10.	40214	9/7/12	9/11/12	EL	Hydrocodone/APAP 10/325	60
11.	40215	9/7/12	9/11/12	EF	Hydrocodone/APAP 10/325	60
12.	40216	9/7/12	9/11/12	EF	Zolpidem 10 mg	60
13.	40324	11/16/12	11/16/12	RG	Hydrocodone/APAP 7.5/750	60
14.	40331	11/16/12	11/16/12	NM	Zolpidem 10 mg	60
15.	40356	11/16/12	11/16/12	AC	Hydrocodone/APAP 10/325	60
16.	40357	11/16/12	11/16/12	MM	Hydrocodone/APAP 10/325	60
17.	40358	11/16/12	11/16/12	MR	Hydrocodone/APAP 10/325	60
18.	40359	11/16/12	11/16/12	MR	Zolpidem 10 mg	60
19.	40364	11/16/12	11/16/12	JF	Hydrocodone/APAP 10/325	60
20.	40366	11/16/12	11/16/12	SB	Zolpidem 10 mg	60
21.	40367	11/16/12	11/16/12	EF	Hydrocodone/APAP 10/325	60
22.	40368	11/16/12	11/16/12	RN	Hydrocodone/APAP 10/325	60
23.	40369	11/16/12	11/16/12	MN	Hydrocodone/APAP 10/325	60
24.	40370	11/16/12	11/16/12	EC	Hydrocodone/APAP 10/325	60

41. A review of prescriptions also revealed that Respondent Cal-Mex Pharmacy filled a post-dated prescription. Specifically, RX Number 40393 was filled by Respondent Cal-Mex Pharmacy on November 28, 2012 for patient DF for 1 box of Testim Gel 1%; however, the prescriber wrote the prescription on December 5, 2012 (7 days after it was filled.) When Board inspectors asked Respondent PIC Oduyale for an explanation about the discrepancies in the dates, Respondent PIC Oduyale was unable to provide an explanation or any documentation supporting

1 the discrepancies in dates. Therefore, Respondent Cal-Mex Pharmacy filled a postdated
 2 prescription without consulting the prescriber for clarification.

3 42. Respondent Cal-Mex Pharmacy also filled thirty-nine prescriptions from oral
 4 transmission but failed to obtain the name of the agent of the prescriber transmitting or "calling
 5 in" the prescription as follows:

	RX Number	Date Written	Date Filled	Patient	Drug	Amount	
6	1	40321	11/16/12	11/16/12	AR	Hydrocodone/APAP 10/325	60
7	2	40322	11/16/12	11/16/12	MH	Hydrocodone/APAP 10/325	60
8	3	40323	11/16/12	11/16/12	MH	Zolpidem 10 mg	60
9	4	40326	11/16/12	11/16/12	ML	Hydrocodone/APAP 10/325	60
10	5	40329	11/16/12	11/16/12	RC	Hydrocodone/APAP 10/325	60
11	6	40332	11/16/12	11/16/12	NM	Hydrocodone/APAP 7.5/750	60
12	7	40333	11/16/12	11/16/12	BR	Hydrocodone/APAP 10/325	60
13	8	40334	11/16/12	11/16/12	BR	Zolpidem 10 mg	60
14	9	40335	11/16/12	11/16/12	BM	Hydrocodone/APAP 10/325	60
15	10	40336	11/16/12	11/16/12	TG	Hydrocodone/APAP 10/325	60
16	11	40337	11/16/12	11/16/12	TG	Zolpidem 10 mg	60
17	12	40338	11/16/12	11/16/12	GN	Hydrocodone/APAP 7.5/750	60
18	13	40339	11/16/12	11/19/12	DL	Hydrocodone/APAP 10/325	60
19	14	40341	11/16/12	11/16/12	ED	Hydrocodone/APAP 10/325	60
20	15	40342	11/16/12	11/16/12	JP	Hydrocodone/APAP 10/325	60
21	16	40344	11/16/12	11/16/12	FF	Hydrocodone/APAP 10/325	60
22	17	40345	11/16/12	11/16/12	GJ	Hydrocodone/APAP 10/325	60
23	18	40347	11/16/12	11/16/12	MB	Hydrocodone/APAP 5/500	60
24	19	40348	11/16/12	11/16/12	ML	Hydrocodone/APAP 10/325	60
25	20	40349	11/16/12	11/16/12	FA	Hydrocodone/APAP 10/325	60
26	21	40351	11/16/12	11/16/12	AL	Hydrocodone/APAP 10/325	60
27	22	40353	11/16/12	11/16/12	MR	Hydrocodone/APAP 10/325	60
28	23	40354	11/16/12	11/16/12	MR	Zolpidem 10 mg	60
29	24	40355	11/16/12	11/16/12	OP	Hydrocodone/APAP 5/500	60
30	25	40360	11/16/12	11/16/12	RC	Hydrocodone/APAP 10/325	60
31	26	40361	11/16/12	11/16/12	JC	Hydrocodone/APAP 7.5/750	60
32	27	10362	11/16/12	11/16/12	JT	Hydrocodone/APAP 10/325	60
33	28	40363	11/16/12	11/16/12	EC	Hydrocodone/APAP 10/325	60
34	29	40365	11/16/12	11/16/12	SB	Hydrocodone/APAP 10/325	60
35	30	40371	11/16/12	11/16/12	CQ	Hydrocodone/APAP 10/325	60
36	31	40372	11/16/12	11/16/12	EL	Hydrocodone/APAP 10/325	60
37	32	40374	11/16/12	11/16/12	CS	Hydrocodone/APAP 10/325	60
38	33	40320	11/16/12	11/16/12	JA	Hydrocodone/APAP 5/500	60
39	34	40372	11/16/12	11/16/12	EL	Hydrocodone/APAP 10/325	60
40	35	40374	11/16/12	11/16/12	CS	Hydrocodone/APAP 10/325	60
41	36	40304	11/7/12	11/7/12	EH	Ambien 5 mg	30
42	37	40361	11/16/12	11/16/12	JC	Hydrocodone/APAP 7.5/750	60
43	38	40414	12/15/12	12/15/12	JP	Temazepam 15mg	35
44	39	40416	15/5/12	12/5/12	EH	Ambien 5 mg	50

43. Respondent Cal-Mex Pharmacy also refilled prescriptions without obtaining the
 authorization of the prescriber. Specifically, RX number 603306 for patient JP was written on

1 November 16, 2012 for Motrin 600mg, with no refills authorized on the original prescription.
2 Respondents' records show that Respondent Cal-Mex Pharmacy dispensed RX number 603306 to
3 patient JP on November 16, 2012 and was re-filled on December 12, 2012. Board inspectors
4 asked Respondent PIC Oduyale about the prescription; however, Respondent PIC Oduyale was
5 unable to explain when or who received the authorization for the December 12, 2012 refill.

6 44. Respondent Cal-Mex Pharmacy also dispensed approximately a 90 day supply of a
7 controlled substance within approximately 30 days to patient BS. Prescription records
8 demonstrated that on December 6, 2012, Respondent Cal-Mex Pharmacy dispensed to patient BS
9 pursuant to RX number 20049, 150 tablets of oxycodone 30mg with a thirty day estimated
10 supply. Fourteen days later on December 20, 2012, Respondent Cal-Mex Pharmacy dispensed to
11 patient BS pursuant to RX number 20059, 150 tablets of oxycodone 30mg, which is another thirty
12 day estimated supply. Fifteen days later on January 4, 2013, Respondent Cal-Mex Pharmacy
13 again dispensed to patient BS pursuant to RX number 20066, 150 tablets of oxycodone 30mg,
14 which is yet another thirty day estimated supply. Board inspectors asked Respondent PIC
15 Oduyale about the excessive dispensing of medication to this patient. He admitted that he did not
16 contact the physician to approve the dispensing and also did not notice the dates when he was
17 dispensing the medication.

18 45. Board inspectors also reviewed several original prescriptions that were filled by
19 Respondent Cal-Mex Pharmacy. The original prescriptions showed that all of the prescriptions'
20 origins were by fax or written prescription. Board inspectors questioned Respondent PIC
21 Oduyale about the verifications for these prescriptions. Respondent PIC Oduyale told Board
22 inspectors that verifications for these prescriptions were obtained by either calling or walking
23 over to the prescriber's office. Although requested, Respondents did not provide the verifications
24 for these prescriptions to Board inspectors during the January 28, 2013 inspection. However, on
25 February 1, 2013, Respondents provided the requested verifications to Board inspectors with
26 edited "backers" (dispensing information on the back of the original prescription). The
27 verifications provided by Respondents contained discrepancies when compared to the originals
28 obtained by Board inspectors. The verifications showed that the prescriptions were phoned in by

1 a person, many of them noted that Dr. Ralfa¹ as the verifier (as opposed to fax or written
 2 prescription as reflected on the originals.) Board inspectors noted the following discrepancies
 3 when comparing the originals to the edited backers provided by Respondents:

RX No.	Date Written	Date Filled	Drug	Amount	Original	Edited Backer
40269	12/17/12	10/17/12	Lorazepam 0.5mg	75	-Front says Call in: Cal-Mex -Backer shows Origin: fax	-Backer says phone in by: Maria
40270	10/17/12	10/17/12	Hydrocodone/APAP 10/325 mg	90	-Backer shows Origin: fax	-Backer says phone in by: Maria
40271	10/17/12	10/17/12	Alprazolam .25 mg	30	-Backer shows Origin: fax	-Backer says phone in by: Maria
40303	11/7/12	11/7/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40304	11/7/12	11/7/12	Ambien 5mg	30	-Backer says Origin: written	-Backer says phone in by: Maria
40393	12/5/12	11/28/12	Testim Gel 1%	1box	-Backer says Origin: written	-Backer says phone in by: Maria
40416	12/5/12	12/5/12	Ambien 5mg	50	-Backer shows Origin: fax	-Backer says phone in by: Maria
Unknown	12/5/12	12/5/12	Hydrocodone/APAP 5/500 mg	100	-Backer shows Origin: fax	-Backer says phone in by: Maria
40213	9/7/12	9/11/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40320	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40321	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40322	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40325	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40326	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
40327	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40328	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40329	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40333	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40334	11/16/12	11/16/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
40335	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla

¹ When Dr. Ralfa was questioned by Board inspectors, he stated that he only "sporadically" spoke to Cal-Mex and he did not know or recognize Respondent PIC Oduyale's name.

1	40336	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
2	40338	11/16/12	11/16/12	Hydrocodone/APAP 7.5/750 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
3	40339	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
4	40342	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
5	40343	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
6	40344	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
7	40345	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
8	40347	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
9	40348	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
10	40349	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
11	40351	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
12	40352	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
13	40353	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
14	40354	11/16/12	11/16/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
15	40360	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
16	40362	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
17	40363	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
18	40362	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
19	40371	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
20	40372	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
21	40374	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
22	40320	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
23	40372	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
24	40374	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla

25 46. In April 2014, a Board of Pharmacy inspector assisted the Drug Enforcement Agency
26 (DEA) in an inspection of Respondent Cal-Mex Pharmacy. During the investigation, the
27 inspector discovered that Respondents were still filling prescriptions for out-of-area prescribers or
28 patients paying with large amounts of cash. Respondents had also failed to file prescriptions as

1 required, in that Respondent filed Schedule II controlled substance prescriptions with Schedule
2 III, IV, and V controlled substance prescriptions, non-controlled substance prescriptions, and
3 dangerous drug prescriptions. Respondent Cal-Mex Pharmacy was also disorganized and
4 Respondent PIC Oduyale could not find the required DEA daily reports from April 21, 2014,
5 invoices, a proper DEA inventory, or a completed perpetual inventory.

6 **FIRST CAUSE FOR DISCIPLINE**

7 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Failure to Maintain
8 Adequate Records of Acquisition & Disposition & Failure to Keep Current Inventory)

9 47. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
10 violation of section 4081, subdivision (a), and California Code of Regulations, title 16, section
11 1718, for failure to maintain records of acquisition and disposition and failure to keep a current
12 inventory for hydrocodone/acetaminophen 10 mg/325 mg from May 1, 2012 through January 28,
13 2013, as set forth in paragraph 35, which is incorporated herein by reference.

14 **SECOND CAUSE FOR DISCIPLINE**

15 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Purchasing From
16 Unlicensed Out-of-State Distributor)

17 48. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
18 violation of section 4169, subdivision (a), in that Respondents purchased twelve prescription
19 medications on four different days from an unlicensed Out-of-State Wholesaler, River City
20 Pharma, from November 13, 2012 to January 21, 2013, as set forth in paragraph 36, which is
21 incorporated herein by reference.

22 **THIRD CAUSE FOR DISCIPLINE**

23 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Failure to Report to
24 CURES)

25 49. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
26 violation of section Health and Safety Code section 11165, subdivision (d), for failing to report to
27 the Department of Justice its controlled substance dispensing on a weekly basis from March 21,
28 2012 to November, 2013, as set forth in paragraph 37, which is incorporated herein by reference.

1 **FOURTH CAUSE FOR DISCIPLINE**

2 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Inappropriate Substitution)

3 50. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
4 violation of section 4073, subdivision (a), in that on August 9, 2012, Respondents failed to
5 dispense the correct quantity when substituting oxycodone 15mg number 200 for a prescription
6 written for oxycodone 30mg number 120, as set forth in paragraph 38, which is incorporated
7 herein by reference.

8 **FIFTH CAUSE FOR DISCIPLINE**

9 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Variation From
10 Prescription)

11 51. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
12 violation of California Code of Regulations, title 16, section 1716, in that Respondents deviated
13 from the requirements of four prescriptions without documentation of prior consent of the
14 prescriber, as set forth in paragraph 39, which is incorporated herein by reference.

15 **SIXTH CAUSE FOR DISCIPLINE**

16 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Dispense From
17 a Required Controlled Substance Prescription Form)

18 52. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
19 violation of Health and Safety Code section 11164, subdivision (a), in that Respondents dispensed
20 twenty-four prescriptions for controlled substances which were not written on a controlled
21 substance form as required by law, as set forth in paragraph 40, which is incorporated herein by
22 reference.

23 **SEVENTH CAUSE FOR DISCIPLINE**

24 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Filling Controlled
25 Substances From Preprinted Multiple Check-off Prescription Blanks)

26 53. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
27 violation of California Code of Regulations, title 16, section 1717.3, subdivision (a), in that
28 Respondents dispensed twenty-four prescriptions for controlled substances pursuant to a

1 preprinted multiple check-off prescription form, as set forth in paragraph 40, which is
2 incorporated herein by reference.

3 **EIGHTH CAUSE FOR DISCIPLINE**

4 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Dispensing Postdated
5 Prescription Without Documentation that Prescriber was Contacted)

6 54. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
7 violation of Health and Safety Code section 11164, subdivision (a)(1), in that Respondents
8 dispensed a prescription for controlled substances where the prescription was written after the
9 medication was dispensed (postdated), which is prohibited under Health and Safety Code section
10 11172, and without documentation that the prescriber was contacted for correction, as set forth in
11 paragraph 41, which is incorporated herein by reference.

12 **NINTH CAUSE FOR DISCIPLINE**

13 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Document the
14 Name of Agent Transmitting Oral Prescriptions)

15 55. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
16 violation of Health and Safety Code section 11164, subdivision (b)(3), in that Respondents failed
17 to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions
18 for thirty nine prescriptions, as set forth in paragraph 42, which is incorporated herein by
19 reference.

20 **TENTH CAUSE FOR DISCIPLINE**

21 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Dispensing Erroneous or
22 Uncertain Prescriptions)

23 56. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
24 violation of California Code of Regulations, title 16, section 1761, subdivision (a), in that
25 Respondents dispensed prescriptions containing significant errors, omissions, irregularities,
26 uncertainties, ambiguities or alterations as set forth in paragraphs 40-42, which are incorporated
27 herein by reference, and as follows:
28

1 a. Respondents dispensed twenty-four prescriptions for controlled substances pursuant
2 to a preprinted multiple check-off prescription blank, not controlled substance forms.

3 b. Respondents dispensed a prescription for controlled medication where the
4 prescription was written after the medication was dispensed (postdated) without documentation
5 the prescriber was contacted for verification.

6 c. Respondents dispensed thirty-nine oral prescriptions for controlled medications which
7 lacked the name of the agent of the prescriber transmitting the prescription.

8 **ELEVENTH CAUSE FOR DISCIPLINE**

9 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Unauthorized Refill)

10 57. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
11 violation of Business and Professions Code section 4063 in that Respondents dispensed
12 prescription number 603306 to patient JP on December 12, 2012 without the authorization of the
13 prescriber, as set forth in paragraph 43, which is incorporated herein by reference.

14 **TWELFTH CAUSE FOR DISCIPLINE**

15 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Implement
16 Corresponding Responsibility)

17 58. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
18 violation of Health and Safety Code section 11153, subdivision (a), in that Respondents failed to
19 implement corresponding responsibility when dispensing within thirty days, an approximately
20 ninety days supply of controlled substance medication to patient BS, which lacked a legitimate
21 medical purpose, as set forth in paragraph 44, which is incorporated herein by reference.

22 **THIRTEENTH CAUSE FOR DISCIPLINE**

23 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Knowingly Making a
24 Document that Falsely Represents the Existence or Nonexistence of Facts)

25 59. Respondents are subject to disciplinary action under section 4301, subdivision (g) for
26 knowingly making a document that falsely represents the existence or nonexistence of facts, in
27 that Respondents provided to the Board altered documents which falsely represented the
28 existence of facts, as set forth in paragraph 45, which is incorporated herein by reference.

1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 (Against Respondent PIC Oduyale: Failure to Implement Best Professional Judgment)

3 60. Respondent is subject to disciplinary action under section 4301 for unprofessional
4 conduct as defined by Business and Professions Code section 4306.5, subdivision (b), for failing
5 to exercise or implement his best professional judgment, as set forth in paragraphs 34-45, which
6 are incorporated herein by reference, and as follows:

7 a. Respondent failed to keep a current inventory for hydrocodone/acetaminophen
8 10mg/325mg;

9 b. Respondent purchased twelve prescription medications on four different days from an
10 unlicensed out of state wholesaler, River City Pharma, from November 13, 2012 through January
11 21, 2013;

12 c. Respondent failed to report to the Department of Justice Respondent Cal Mex
13 Pharmacy's controlled substance dispensing on a weekly basis;

14 d. Respondent dispensed four prescriptions which deviated from the requirements of the
15 prescriber's prescription;

16 e. Respondent dispensed prescription number 603306 to patient JP for Motrin 600mg
17 on December 12, 2012 without the authorization of the prescriber;

18 f. Respondent failed to dispense the correct quantity when substituting oxycodone 15mg
19 number 200 for a prescription written for oxycodone 30mg number 120;

20 g. Respondent dispensed twenty-four prescriptions from September 10, 2012 to
21 November 16, 2012 pursuant to an improper preprinted multiple check-off prescription blank;

22 h. Respondent dispensed twenty-four prescriptions for controlled substances not written
23 on a controlled substance form, as required;

24 i. Respondent dispensed thirty-nine oral prescriptions for controlled medications which
25 lacked the name of the agent of the prescriber transmitting the prescription;

26 j. Respondent dispensed a prescription for controlled medication where the prescription
27 was written after the medication was dispensed (postdated) without documentation the prescriber
28 was contacted for correction;

- 1 k. Respondent dispensed sixty-five erroneous or uncertain prescriptions;
- 2 l. Respondent failed to implement corresponding responsibility when dispensing within
- 3 thirty days, an approximate ninety day supply of a oxycodone 30mg to patient BS, which lacked a
- 4 legitimate medical purpose.
- 5 m. Respondent knowingly provided the Board with altered documents which falsely
- 6 represented the existence of a state of facts.

7 **FACTUAL ALLEGATIONS: PIONEERS MEMORIAL HEALTHCARE HOSPITAL**

- 8 61. Respondent Oduyale was employed as a pharmacist at Pioneers Memorial Healthcare
- 9 District (Pioneers) located in Brawley, California.
- 10 62. On or about February 26, 2014 at approximately 11:00 p.m., Respondent Oduyale
- 11 was working with a pharmacy technician at Pioneers. The pharmacy technician observed
- 12 Respondent Oduyale working on labels for the intravenous compounded bags. The pharmacy
- 13 technician informed Respondent Oduyale that the compounded bag labels indicated that the
- 14 contents of the bags had expired. Respondent Oduyale stated, "that's okay, I'll just re-label
- 15 them." The pharmacy technician reported the incident and the PIC of Pioneers conducted an
- 16 internal investigation. The PIC of Pioneers discovered that five bags of oxytocin 20 units in
- 17 1000ml of lactated ringers (LR) (oxytocin 20 units/LR 1000 ml) expired on February 24, 2014
- 18 but they were relabeled by PIC Oduyale with an expiration date of February 28, 2014 (4 days
- 19 beyond the assigned beyond-use-date (BUD) by the compounder). The investigation also
- 20 revealed that Respondent restocked the Pyxis machine with these five bags so that they could be
- 21 dispensed to patients. The PIC of Pioneers then confronted Respondent Oduyale on March 7,
- 22 2014. Respondent Oduyale told the PIC that re-labeled the expired bags because the pharmacy
- 23 did not have the stock to compound more bags. Respondent Oduyale was terminated from
- 24 Pioneers for gross negligence.

25 **FIFTEENTH CAUSE FOR DISCIPLINE**

26 (Against Respondent Oduyale: Misbranding and Offering for Sale Misbranded Drugs)

- 27 63. Respondent Oduyale is subject to disciplinary action under section 4301, subdivision
- 28 (o) for violation of section 4169(a) and Health and Safety Code section 111440, for selling or

1 transferring a misbranded drug, in that while working as a pharmacist at Pioneers, Respondent
2 Oduyale misbranded five intravenous bags of oxytocin 20 units/LR 1000 ml and then loaded
3 them into an automatic dispensing cabinet for immediate retrieval and administration by a nurse
4 in the labor and delivery department, thereby offering it for sale, as set forth in paragraphs 61-62,
5 which are incorporated herein by reference.

6 **SIXTEENTH CAUSE FOR DISCIPLINE**

7 (Against Respondent Oduyale: Unlawful Extension of the BUD)

8 64. Respondent Oduyale is subject to disciplinary action under section 4301, subdivision
9 (j) for violation of California Code of Regulations section 1735.2(h), for giving an expiration date
10 to five bags of oxytocin 20 units/LR 1000 ml, beyond the BUD provided by the compounder,
11 without any supporting stability or sterility studies, as set forth in paragraphs 61-61, which are
12 incorporated herein by reference.

13 **SEVENTEENTH CAUSE FOR DISCIPLINE**

14 (Against Respondent Oduyale: Gross Negligence)

15 65. Respondent Oduyale is subject to disciplinary action under section 4301, subdivision
16 (c) for gross negligence, in that while working as a pharmacist at Pioneers, Respondent Oduyale
17 was grossly negligent when he relabeled, verified, and dispensed five intravenous bags of
18 oxytocin 20 units/LR 1000 ml with a BUD which was four days greater than the compounder's
19 expiration date, as set forth in paragraphs 61-62, which are incorporated herein by reference.

20 **EIGHTEENTH CAUSE FOR DISCIPLINE**

21 (Against Respondent Oduyale: Falsely Representing the Existence of a State of Facts)

22 66. Respondent Oduyale is subject to disciplinary action under section 4301, subdivision
23 (g) for knowingly making a document that falsely represents the existence of a state of facts, in
24 that while working as a pharmacist at Pioneers, Respondent Oduyale knowingly relabeled, with a
25 false BUD five intravenous bags of oxytocin 20 units/LR 1000 ml, as set forth in paragraphs 61-
26 62, which are incorporated herein by reference.

1 **NINETEENTH CAUSE FOR DISCIPLINE**

2 (Against Respondent Oduyale: Misuse of Education)

3 67. Respondent Oduyale is subject to disciplinary action under section 4301, for violation
4 of section 4306.5, subdivision (a), in that while working as a pharmacist at Pioneers, Respondent
5 Oduyale committed an act which was an inappropriate exercise of his education, training and
6 experience as a pharmacist when he relabeled, verified, and dispensed five intravenous bags of
7 oxytocin 20 units/LR 1000 ml with a BUD which was four days greater than the compounder's
8 expiration date, as set forth in paragraphs 61-62, which are incorporated herein by reference.

9 **TWENTIETH CAUSE FOR DISCIPLINE**

10 (Against Respondent Oduyale: Failure to Use Best Professional Judgment)

11 68. Respondent Oduyale is subject to disciplinary action under section 4301, for violation
12 of section 4306.5, subdivision (b), in that while working as a pharmacist at Pioneers, Respondent
13 Oduyale failed to exercise or implement his best professional judgment with regard to the
14 dispensing or furnishing of dangerous drugs when he relabeled, verified, and dispensed five
15 intravenous bags of oxytocin 20 units/LR 1000 ml with a BUD which was four days greater than
16 the compounder's expiration date, as set forth in paragraphs 61-62, which are incorporated herein
17 by reference.

18 **JURISDICTION FOR PETITION TO REVOKE PROBATION**

19 69. This Petition to Revoke Probation is brought against Respondent Cal-Mex Special
20 Services, Inc., doing business as Cal-Mex Pharmacy, before the Board of Pharmacy (Board),
21 Department of Consumer Affairs under Probation Term and Condition Number 11 of the
22 Decision and Order *In the Matter of the Statement of Issues Against Cal-Mex Special Services,*
23 *Inc., dba Cal-Mex Pharmacy*, Case No. 4009. That term and condition states:

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

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

10 **FIRST CAUSE TO REVOKE PROBATION**

11 (Obey All Laws)

12 70. At all times after the effective date of Respondent Cal-Mex Pharmacy's probation,
13 Condition 1 stated, in pertinent part:

14 **Obey All Laws**

15 Respondent and its officers shall obey all state and federal laws and
16 regulations.

17

18 71. Respondent Cal-Mex Pharmacy's probation is subject to revocation because
19 Respondent Cal-Mex Pharmacy failed to comply with Probation Condition 1, referenced above,
20 in that it violated state laws and regulations as set forth in paragraphs 35-46 above, which are
21 incorporated herein by reference.

22 **SECOND CAUSE TO REVOKE PROBATION**

23 (Separate File of Records)

24 72. At all times after the effective date of Respondent Cal-Mex Pharmacy's probation,
25 Condition 13 stated, in pertinent part:

26 **Separate File of Records**

27 Respondent shall maintain and make available for inspection a separate file of
28 all records pertaining to the acquisition and disposition of all controlled
substances. Failure to maintain such file or make it available for inspection shall
be considered a violation of probation.

73. Respondent Cal-Mex Pharmacy's probation is subject to revocation because
Respondent Cal-Mex Pharmacy failed to comply with Probation Condition 13, referenced above,

1 in that it failed to maintain and make available for inspection a separate file of all records
2 pertaining to the acquisition and disposition of all controlled substances, as set forth in paragraphs
3 35-46 above, which are incorporated herein by reference.

4 DISCIPLINARY CONSIDERATIONS

5 74. To determine the degree of discipline, if any, to be imposed on Respondent PIC
6 Oduyale, Complainant alleges On August 1, 2006, in a disciplinary action entitled *In the Matter*
7 *of the Accusation Against Olugbenga Solomon Oduyale*, Case No. 2733, the Board of Pharmacy
8 issued a Decision and Order effective August 31, 2006, adopting the Proposed Decision of the
9 Administrative Law Judge dated May 17, 2006, providing that Respondent PIC Oduyale's
10 Pharmacist License was revoked; however, the revocation was stayed and Respondent PIC
11 Oduyale was placed on probation for three years. On August 30, 2006, the Board granted a stay
12 of the Decision and granted Respondent PIC Oduyale's Petition for Reconsideration based solely
13 on the issue of whether the probation condition of "supervision" should be eliminated. On
14 November 21, 2006, in its Decision After Reconsideration, the Board adopted the proposed
15 decision dated May 17, 2006, with the exception of the "supervision" paragraph, which was
16 modified to read, "Respondent shall not supervise any ancillary personnel, including, but not
17 limited to, registered pharmacy technicians or exemptees, of any entity licensed by the board."
18 All other provisions of the probation conditions were to remain in full force and effect and the
19 Decision After Reconsideration became effective on December 21, 2006. Respondent PIC
20 Oduyale's three year probationary term was completed on December 20, 2009.

21 PRAYER

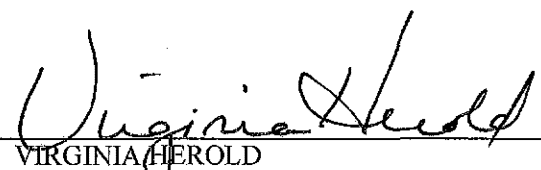
22 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
23 Accusation and Petition to Revoke Probation, and that following the hearing, the Board of
24 Pharmacy issue a decision:

- 25 1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4009
26 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY
27 50374 issued to Cal-Mex Special Services, Inc., doing business as Cal-Mex;

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- 2. Revoking or suspending Pharmacy Permit No. PHY 50374, issued to Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy;
- 3. Revoking or suspending Pharmacist License Number 42719 to Olugbenga Solomon Oduyale;
- 4. Ordering Cal-Mex Special Services, Inc., doing business as Cal-Mex to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
- 5. Ordering Olugbenga Solomon Oduyale to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
- 6. Taking such other and further action as deemed necessary and proper.

DATED: 7/11/14



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

SD2013705458
Final Revised.docx

Exhibit A

Decision and Order

Board of Pharmacy Case No. 4009

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

In the Matter of the Statement of Issues Against:

Case No. 4009

**CALMEX SPECIAL SERVICES, INC., dba
CAL-MEX PHARMACY**
337 Paulin Ave., Ste. 1A
Calexico, CA 92231

Pharmacy Permit Applicant

Respondent.

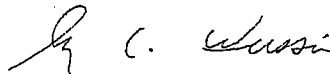
DECISION AND ORDER

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

This decision shall become effective on August 19, 2011.

It is so ORDERED July 20, 2011.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 LINDA K. SCHNEIDER
Supervising Deputy Attorney General
3 KAREN L. GORDON
Deputy Attorney General
4 State Bar No. 137969
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2073
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Statement of Issues
12 Against:

Case No. 4009

13 **CALMEX SPECIAL SERVICES, INC., dba**
14 **CAL-MEX PHARMACY,**
337 Paulin Ave., Suite 1A
15 **Calexico, CA 92231**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

16 Respondent.

17
18 In the interest of a prompt and speedy settlement of this matter, consistent with the public
19 interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,
20 the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will
21 be submitted to the Board for approval and adoption as the final disposition of the Statement of
22 Issues.

23
24 **PARTIES**

25 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
26 She brought this action solely in her official capacity and is represented in this matter by Kamala
27 D. Harris, Attorney General of the State of California, by Karen L. Gordon, Deputy Attorney
28 General.

1 Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed
2 except by a writing executed by an authorized representative of each of the parties.

3 13. In consideration of the foregoing admissions and stipulations, the parties agree that
4 the Board may, without further notice or formal proceeding, issue and enter the following
5 Disciplinary Order:

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that upon satisfaction of all statutory and regulatory
8 requirements for issuance of a license, a license shall be issued to Respondent Calmex Special
9 Services, Inc. dba Cal-Mex Pharmacy, and immediately revoked; the order of revocation is stayed
10 and Respondent is placed on probation for thirty-five (35) months upon the following terms and
11 conditions.

12 1. **Obey All Laws**

13 Respondent and its officers shall obey all state and federal laws and regulations.

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

- 16 an arrest or issuance of a criminal complaint for violation of any provision of the
17 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
18 substances laws
- 19 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
20 criminal complaint, information or indictment
- 21 a conviction of any crime
- 22 discipline, citation, or other administrative action filed by any state or federal agency
23 which involves Respondent's pharmacy permit or which is related to the practice of
24 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
25 charging for any drug, device or controlled substance.

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

27 ///

1 **2. Report to the Board**

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

10 **3. Interview with the Board**

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

16 **4. Cooperate with Board Staff**

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

20 **5. Probation Monitoring Costs**

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

25 **6. Status of License**

26 Respondent shall, at all times while on probation, maintain current licensure with the board.
27 If Respondent submits an application to the board, and the application is approved, for a change
28 of location, change of permit or change of ownership, the board shall retain continuing

1 jurisdiction over the license, and the Respondent shall remain on probation as determined by the
2 board. Failure to maintain current licensure shall be considered a violation of probation.

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

7 **7. License Surrender While on Probation/Suspension**

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

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

17 Respondent shall also, by the effective date of this decision, arrange for the continuation of
18 care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing
19 patients that specifies the anticipated closing date of the pharmacy and that identifies one or more
20 area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary
21 in the transfer of records or prescriptions for ongoing patients. Within five days of its provision
22 to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the
23 board. For the purposes of this provision, "ongoing patients" means those patients for whom the
24 pharmacy has on file a prescription with one or more refills outstanding, or for whom the
25 pharmacy has filled a prescription within the preceding sixty (60) days.

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

1 Respondent shall reimburse the board for its costs of investigation and prosecution prior to
2 the acceptance of the surrender.

3 **8. Notice to Employees**

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

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

17 **9. Owners and Officers: Knowledge of the Law**

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

24 **10. Posted Notice of Probation**

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

28 ///

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

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

6 11. Violation of Probation

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

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

19 12. Completion of Probation

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

22 13. Separate File of Records

23 Respondent shall maintain and make available for inspection a separate file of all records
24 pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such
25 file or make it available for inspection shall be considered a violation of probation.

26 14. Pharmacist-in-Charge

27 Respondent will be acceptable to the Board as Pharmacist-in-Charge of Cal-Mex Pharmacy.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Ronald S. Marks. I understand the stipulation and the effect it will have on the pharmacy permit issued to Respondent Calmex Special Services, Inc. dba Cal-Mex Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5-29-11 *Olugbenga S. Oduyale*
OLUGBENGA S. ODUYALE, President
CALMEX SPECIAL SERVICES, INC. dba
CAL-MEX PHARMACY
Respondent

APPROVAL

I have read and fully discussed with Olugbenga S. Oduyale, President of Respondent Calmex Special Services, Inc. dba Cal-Mex Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 5/29/11 *Ronald S. Marks*
RONALD S. MARKS, Esq.
Attorney for Respondent

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ENDORSEMENT

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

Dated: May 31, 2011

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General



KAREN L. GORDON
Deputy Attorney General
Attorneys for Complainant

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6 San Diego, CA 92186-5266
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7 Facsimile: (619) 645-2061
Attorneys for Complainant
8

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

11 Case No. 4724

12 In the Matter of the Accusation and Petition to
Revoke Probation Against:

**ACCUSATION AND PETITION TO
REVOKE PROBATION**

13 **CAL-MEX SPECIAL SERVICES, INC.,**
14 **DBA CAL-MEX PHARMACY**
337 Paulin Avenue, Suite 1A
15 Calexico, CA 92231

16 **Pharmacy Permit No. PHY 50374**

17 **and**

18 **OLUGBENGA SOLOMON ODUYALE**
2209 E. 27th Street
19 Yuma, AZ 85365

20 **Pharmacist License No. RPH 42719**

21 Respondents.

22
23 Complainant alleges:

24 **PARTIES**

25 1. Virginia Herold (Complainant) brings this Accusation and Petition to Revoke
26 Probation solely in her official capacity as the Executive Officer of the Board of Pharmacy,
27 Department of Consumer Affairs.
28

1 2. On or about August 19, 2011, the Board of Pharmacy issued Pharmacy Permit
2 Number PHY 50374 to Cal-Mex Special Services, Inc., doing business as Cal-Mex Pharmacy
3 with Olugbenga Solomon Oduyale as President and Pharmacist-in-Charge (PIC) (Respondent).
4 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
5 herein and will expire on August 1, 2013, unless renewed.

6 3. In a disciplinary action entitled "In the Matter of the Statement of Issues Against
7 Calmex Special Services, Inc., dba Cal-Mex Pharmacy," Case No. 4009, the Board of Pharmacy
8 issued a Decision and Order effective July 20, 2011, in which Respondent's Pharmacy Permit was
9 revoked. However, the revocation was stayed and Respondent's Pharmacy Permit was placed on
10 probation for thirty-five (35) months with certain terms and conditions. A copy of that Decision
11 and Order is attached as Exhibit A and is incorporated by reference.

12 4. On or about August 8, 1989, the Board of Pharmacy issued Pharmacist License
13 Number 42719 to Olugbenga Solomon Oduyale (Respondent). The Pharmacist License was in
14 full force and effect at all times relevant to the charges brought herein and will expire on October
15 31, 2014, unless renewed.

16 **JURISDICTION AND STATUTORY PROVISIONS FOR ACCUSATION**

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

20 6. Section 4011 of the Code provides that the Board shall administer and enforce both
21 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
22 Act [Health & Safety Code, § 11000 et seq.].

23 7. Section 4300(a) of the Code provides that every license issued by the Board may be
24 suspended or revoked.

25 8. Section 4300.1 of the Code states:

26 The expiration, cancellation, forfeiture, or suspension of a board-issued
27 license by operation of law or by order or decision of the board or a court of law,
28 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

1 proceed with any investigation of, or action or disciplinary proceeding against, the
licensee or to render a decision suspending or revoking the license.

2 **STATUTORY PROVISIONS**

3 9. Section 4022 of the Code states:

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

6 (a) Any drug that bears the legend: "Caution: federal law prohibits
7 dispensing without prescription," "Rx only," or words of similar import.

8 (b) Any device that bears the statement: "Caution: federal law restricts this
9 device to sale by or on the order of a _____," "Rx only," or words of similar import,
the blank to be filled in with the designation of the practitioner licensed to use or
10 order use of the device.

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

12 10. Section 4063 of the Code states:

13 No prescription for any dangerous drug or dangerous device may be refilled
14 except upon authorization of the prescriber. The authorization may be given orally
15 or at the time of giving the original prescription. No prescription for any dangerous
drug that is a controlled substance may be designated refillable as needed.

16 11. Section 4073 of the Code states in pertinent part:

17 (a) A pharmacist filling a prescription order for a drug product prescribed by
18 its trade or brand name may select another drug product with the same active
19 chemical ingredients of the same strength, quantity, and dosage form, and of the
20 same generic drug name as determined by the United States Adopted Names
(USAN) and accepted by the federal Food and Drug Administration (FDA), of
those drug products having the same active chemical ingredients.

21

22 (d) This section shall apply to all prescriptions, including those presented
23 by or on behalf of persons receiving assistance from the federal government or
24 pursuant to the California Medical Assistance Program set forth in Chapter 7
(commencing with Section 14000) of Part 3 of Division 9 of the Welfare and
25 Institutions Code.

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12. Section 4081 of the Code states:

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

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

13. Section 4169 of the Code states in pertinent part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

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14. 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

1 misrepresentation or issued by mistake. Unprofessional conduct shall include, but
2 is not limited to, any of the following:

3

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

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

12

13 15. Section 4306.5 of the Code states in pertinent part:

14 Unprofessional conduct for a pharmacist may include any of the following:

15 (a) Acts or omissions that involve, in whole or in part, the inappropriate
16 exercise of his or her education, training, or experience as a pharmacist, whether or
17 not the act or omission arises in the course of the practice of pharmacy or the
18 ownership, management, administration, or operation of a pharmacy or other entity
19 licensed by the board.

20 (b) Acts or omissions that involve, in whole or in part, the failure to
21 exercise or implement his or her best professional judgment or corresponding
22 responsibility with regard to the dispensing or furnishing of controlled substances,
23 dangerous drugs, or dangerous devices, or with regard to the provision of services.

24 (c) Acts or omissions that involve, in whole or in part, the failure to
25 consult appropriate patient, prescription, and other records pertaining to the
26 performance of any pharmacy function.

27 (d) Acts or omissions that involve, in whole or in part, the failure to fully
28 maintain and retain appropriate patient-specific information pertaining to the
performance of any pharmacy function.

16. Health and Safety Code section 11153 provides in pertinent part:

25 (a) A prescription for a controlled substance shall only be issued for a
26 legitimate medical purpose by an individual practitioner acting in the usual course
27 of his or her professional practice. The responsibility for the proper prescribing
28 and dispensing of controlled substances is upon the prescribing practitioner, but a
corresponding responsibility rests with the pharmacist who fills the prescription.
Except as authorized by this division, the following are not legal prescriptions: (1)

1 an order purporting to be a prescription which is issued not in the usual course of
2 professional treatment or in legitimate and authorized research; or (2) an order for
3 an addict or habitual user of controlled substances, which is issued not in the
4 course of professional treatment or as part of an authorized narcotic treatment
5 program, for the purpose of providing the user with controlled substances,
6 sufficient to keep him or her comfortable by maintaining customary use.

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17. Health and Safety Code section 11164 provides in pertinent part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

1 (3) Pursuant to an authorization of the prescriber, any agent of the
2 prescriber on behalf of the prescriber may orally or electronically transmit a
3 prescription for a controlled substance classified in Schedule III, IV, or V, if in
these cases the written record of the prescription required by this subdivision
specifies the name of the agent of the prescriber transmitting the prescription.

4 (c) The use of commonly used abbreviations shall not invalidate an
5 otherwise valid prescription.

6 (d) Notwithstanding any provision of subdivisions (a) and (b),
7 prescriptions for a controlled substance classified in Schedule V may be for more
than one person in the same family with the same medical need.

8 (e) This section shall become operative on January 1, 2005.

9 18. Health and Safety Code section 11165 provides in pertinent part:

10

11 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV
12 controlled substance, as defined in the controlled substances schedules in federal
13 law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,
14 respectively, of Title 21 of the Code of Federal Regulations, the dispensing
pharmacy or clinic shall provide the following information to the Department of
Justice on a weekly basis and in a format specified by the Department of Justice:

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

18 (2) The prescriber's category of licensure and license number; federal
19 controlled substance registration number; and the state medical license number of
20 any prescriber using the federal controlled substance registration number of a
government-exempt facility.

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

22 (4) NDC (National Drug Code) number of the controlled substance
23 dispensed.

24 (5) Quantity of the controlled substance dispensed.

25 (6) ICD-9 (diagnosis code), if available.

26 (7) Number of refills ordered.

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

1 (9) Date of origin of the prescription.

2 (10) Date of dispensing of the prescription.

3 19. Health and Safety Code section 11172 provides that no person shall antedate or
4 postdate a prescription.

5 **STATE REGULATORY PROVISIONS**

6 20. California Code of Regulations, title 16, section 1716 states:

7 Pharmacists shall not deviate from the requirements of a prescription
8 except upon the prior consent of the prescriber or to select the drug product in
accordance with Section 4073 of the Business and Professions Code.

9 Nothing in this regulation is intended to prohibit a pharmacist from
10 exercising commonly-accepted pharmaceutical practice in the compounding or
dispensing of a prescription.

11 21. California Code of Regulations, title 16, section 1717.3 states:

12 (a) No person shall dispense a controlled substance pursuant to a preprinted
13 multiple check-off prescription blank.

14 (b) A person may dispense a dangerous drug, that is not a controlled
15 substance, pursuant to a preprinted multiple checkoff prescription blank and may
16 dispense more than one dangerous drug, that is not a controlled substance,
pursuant to such a blank if the prescriber has indicated on the blank the number of
dangerous drugs he or she has prescribed.

17 (c) "Preprinted multiple checkoff prescription blank," as used in this
18 section means any form listing more than one dangerous drug where the intent is
that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription
order for that drug.

19 22. California Code of Regulations, title 16, section 1718 states:

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

22 The controlled substances inventories required by Title 21, CFR, Section
23 1304 shall be available for inspection upon request for at least 3 years after the
date of the inventory.

24 23. California Code of Regulations, title 16, section 1761 states:

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

27 (b) Even after conferring with the prescriber, a pharmacist shall not
28 compound or dispense a controlled substance prescription where the pharmacist

1 knows or has objective reason to know that said prescription was not issued for a
2 legitimate medical purpose.

3 **COST RECOVERY**

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

10 **DRUGS**

11 25. Ambien, is a brand name for zolpidem, a Schedule IV controlled substance pursuant
12 to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to
13 Business and Professions Code section 4022. It is a sedative used for the short-term treatment of
14 insomnia.

15 26. Hydrocodone/acetaminophen, also known by the brand names Vicodin, Norco,
16 Zydone, Maxidone, Lortab, Lorcet, Hydrocet, Co-Gesic, and Anexsia, is a narcotic Schedule III
17 controlled substance as designated by Health and Safety Code section 11056(e)(4), and is a
18 dangerous drug pursuant to Business and Professions Code section 4022. Hydrocodone is used as
19 a narcotic analgesic in the relief of pain.

20 27. Lorazepam, is a Schedule IV controlled substance pursuant to Health and Safety
21 Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions
22 Code section 4022.

23 28. Oxycodone, is a Schedule II controlled substance pursuant to Health and Safety Code
24 section 11055, subdivision (b), and a dangerous drug pursuant to Business and Professions Code
25 section 4022.

26 29. Temazepam, is a Schedule IV controlled substance pursuant to Health and Safety
27 Code section 11057, subdivision (d), and a dangerous drug pursuant to Business and Professions
28 Code section 4022.

1 **FACTUAL ALLEGATIONS**

2 30. On or about January 28, 2013, Board inspectors performed a routine inspection of
3 Cal-Mex Pharmacy located at 337 Paulin Avenue, Ste. 1A, in Calexico, California. The President
4 and Pharmacist-in-Charge (PIC) Oduyale was present during the inspection. During the
5 inspection, the Board inspectors reviewed hundreds of prescriptions, invoices from wholesalers,
6 and the quality assurance binder, among other items. Following the inspection, Board inspectors
7 continued the investigation of Respondents by interviewing and obtaining statements from
8 pharmacy personnel, including Respondent PIC Oduyale, and reviewing additional
9 documentation provided by Respondents.

10 31. Respondent PIC Oduyale provided the Board inspector with an audit of the
11 hydrocodone/acetaminophen 10mg/325mg inventory that was acquired and dispensed by
12 Respondent Cal-Mex Pharmacy between May 1, 2012 and January 28, 2013. According to
13 Respondent PIC Oduyale's audit, Respondent Cal-Mex Pharmacy's total acquisition of
14 hydrocodone/acetaminophen 10mg/325mg was 8,040 tablets and it's total disposition of
15 hydrocodone/acetaminophen 10mg/325mg was 8,073 tablets, (an overage of 33 tablets).
16 However, the Board inspector's audit of the inventory and records showed Respondent Cal-Mex
17 Pharmacy's total acquisition of hydrocodone/acetaminophen 10mg/325mg was 8,040 tablets and
18 it's total disposition of hydrocodone/acetaminophen 10mg/325mg was 8,663 tablets of
19 hydrocodone/acetaminophen 10mg/325mg during that time period, (an overage of 623 tablets) as
20 follows:

Audit Performed By:	Total Acquisition	Total Disposition	Variance	Overage
PIC Oduyale	8,040 tablets	8,073 tablets	33	33 tablets
Board Inspector	8,040 tablets	8,663 tablets	623	623 tablets

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23 Thus, the Board inspector discovered that Respondents dispensed 590 more tablets of
24 hydrocodone/acetaminophen 10 mg/325mg than accounted for on Respondent PIC Oduyale's
25 audit. Additionally, Respondent PIC Oduyale removed from the pharmacy's inventory 630
26 tablets on August 27, 2012 but was unable to provide an explanation for these removals to the
27 Board inspector.

1 32. The Board inspector also discovered that Respondent Cal-Mex Pharmacy was
 2 purchasing drugs from River City Pharma located in Cincinnati, Ohio. River City Pharma did not
 3 hold an Out-of-State Wholesaler's license with the Board of Pharmacy between November 2012
 4 and January 2013. Respondent Cal-Mex Pharmacy purchased the following drugs from River
 5 City Pharma during that time period:

Date	Invoice Number	Dangerous Drug	Amount
11/13/2012	1055611-IN	Nystatin topical	2
11/13/2012	1055611-IN	Valacyclovir HCL 500mg tabs	1
11/14/2012	1056190-IN	Ciprofloxacin HCl 500mg tabs	2
11/14/2012	1056190-IN	Nystatin topical powder	6
1/8/2013	1078725-IN	Nystatin topical powder	6
1/21/2013	1084697-IN	Novolin 70/30 100U inj.	4
1/21/2013	1084697-IN	Novolin R U100	4
1/21/2013	1084697-IN	Nystatin topical powder	5
1/21/2013	1084697-IN	Celebrex 200mg Caps	3
1/21/2013	1084697-IN	Fluticasone 50mcg spray	6
1/21/2013	1084697-IN	Gabapentin 600mg tabs	2
1/21/2013	1084697-IN	Gabapentin 800mg tabs	1

19 33. Board inspectors also discovered that Respondent Cal-Mex Pharmacy (who received
 20 its DEA registration on August 19, 2011) did not report to the Department of Justice any of its
 21 controlled substance dispensing from August 19, 2011 to April 19, 2012 and did not report
 22 weekly from April 19, 2012 to April 23, 2013.

23 34. After completing a review of prescriptions dispensed by Respondents, Board
 24 inspectors discovered that Respondent Cal-Mex Pharmacy did not dispense the correct quantity
 25 when substituting oxycodone 15mg number 200 for a prescription written for oxycodone 30mg
 26 number 120. The original prescription (RX No. 20013 written on August 8, 2012) provided
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1 patient AS with 3,600 mg (a 30 day supply), however, it was dispensed for 3,000 mg (a 25 day
2 supply) without notification or consent of the prescriber.

3 35. Additionally, Board inspectors discovered that Respondents deviated from
4 requirements in filling four prescriptions without documentation of prior consent of the prescriber
5 as follows:

RX #	Date Written	Date Filled	Patient	Drug Written For	Amount	Original/Rewrite Signature	Filled For
20013	8/8/12	8/9/12	AS	Oxycodone 30 mg	120	Oxycodone 30 mg number 120 (1 tab four times a day)	Oxycodone 15 mg number 200 (take 2 tabs four times a day)
40269	12/17/12	10/17/12	MF	Lorazepam 0.5mg	75	Every 8-12 hours	Every 8-12 hours as needed for pain
40270	10/17/12	10/17/12	EL	Hydrocodone/APAP 10/325mg	90	Rewrite: every 8 hours as needed	Every 8 hours
40416	12/5/12	12/5/12	EH	Ambien 5mg	50	Every night at bed for 7 weeks	Every night at bed as needed for sleep

13 36. Respondent Cal-Mex Pharmacy also dispensed twenty-four prescriptions for
14 controlled substances not written on controlled substance forms. Respondent PIC Oduyale
15 informed the Board inspector that prescriptions were brought in by patients on an 8.5x11" white
16 paper, not a controlled substance form, which was preprinted multiple check-off prescription
17 blanks. Respondent PIC Oduyale told the Board inspector that all prescriptions were verified;
18 however, he did not provide the required hard copy forms. From September 10, 2012 to
19 November 16, 2012, Respondents dispensed the following prescriptions using original
20 prescriptions provided by the patients, which were not written on controlled substance forms:

	RX #	Date Written	Date Filled	Patient	Drug Written For	Amount	
21	1.	40202	9/7/12	9/10/12	GN	Zolpidem 10 mg	60
22	2.	40203	9/7/12	9/10/12	RA	Hydrocodone/APAP 10/325	60
23	3.	40204	9/7/12	9/10/12	MM	Hydrocodone/APAP 10/325	60
24	4.	40205	Unknown	9/11/12	EC	Hydrocodone/APAP 10/325	60
25	5.	40207	9/7/12	9/11/12	AC	Zolpidem 10 mg	60
26	6.	40209	9/7/12	9/11/12	BR	Zolpidem 10 mg	60
27	7.	40210	9/7/12	9/11/12	SB	Zolpidem 10 mg	60
28	8.	40211	9/7/12	9/11/12	MM	Hydrocodone/APAP 10/325	60
	9.	40212	9/7/12	9/11/12	JR	Hydrocodone/APAP 10/325	60
	10.	40214	9/7/12	9/11/12	EL	Hydrocodone/APAP 10/325	60
	11.	40215	9/7/12	9/11/12	EF	Hydrocodone/APAP 10/325	60
	12.	40216	9/7/12	9/11/12	EF	Zolpidem 10 mg	60
	13.	40324	11/16/12	11/16/12	RG	Hydrocodone/APAP 7.5/750	60

14.	40331	11/16/12	11/16/12	NM	Zolpidem 10 mg	60
15.	40356	11/16/12	11/16/12	AC	Hydrocodone/APAP 10/325	60
16.	40357	11/16/12	11/16/12	MM	Hydrocodone/APAP 10/325	60
17.	40358	11/16/12	11/16/12	MR	Hydrocodone/APAP 10/325	60
18.	40359	11/16/12	11/16/12	MR	Zolpidem 10 mg	60
19.	40364	11/16/12	11/16/12	JF	Hydrocodone/APAP 10/325	60
20.	40366	11/16/12	11/16/12	SB	Zolpidem 10 mg	60
21.	40367	11/16/12	11/16/12	EF	Hydrocodone/APAP 10/325	60
22.	40368	11/16/12	11/16/12	RN	Hydrocodone/APAP 10/325	60
23.	40369	11/16/12	11/16/12	MN	Hydrocodone/APAP 10/325	60
24.	40370	11/16/12	11/16/12	EC	Hydrocodone/APAP 10/325	60

37. A review of prescriptions also revealed to Board inspectors that two prescriptions were filled by Respondent Cal-Mex Pharmacy before the prescriber even wrote the prescription. Specifically, RX Number 40393 was filled by Respondent Cal-Mex Pharmacy on November 28, 2012 for patient DF for 1 box of Testim Gel 1%; however, the prescriber wrote the prescription on December 5, 2012 (7 days after it was filled.) In addition, RX Number 40233 was filled by Respondent Cal-Mex Pharmacy on September 21, 2012 for patient ES for 60 tablets of Tylenol #3; however, the prescriber wrote the prescription on October 3, 2012 (11 days after it was filled.) When Board inspectors asked Respondent PIC Oduyale for an explanation about the discrepancies in the dates, Respondent PIC Oduyale was unable to provide an explanation or any documentation supporting the discrepancies in dates. Therefore, Board inspectors determined that Respondent Cal-Mex Pharmacy filled postdated prescriptions without consulting the prescriber for clarification.

38. Board inspectors also discovered that Respondent Cal-Mex Pharmacy filled thirty-nine prescriptions from oral transmission but failed to obtain the name of the agent of the prescriber transmitting or "calling in" the prescription as follows:

	RX Number	Date Written	Date Filled	Patient	Drug	Amount
1	40321	11/16/12	11/16/12	AR	Hydrocodone/APAP 10/325	60
2	40322	11/16/12	11/16/12	MH	Hydrocodone/APAP 10/325	60
3	40323	11/16/12	11/16/12	MH	Zolpidem 10 mg	60
4	40326	11/16/12	11/16/12	ML	Hydrocodone/APAP 10/325	60
5	40329	11/16/12	11/16/12	RC	Hydrocodone/APAP 10/325	60
6	40332	11/16/12	11/16/12	NM	Hydrocodone/APAP 7.5/750	60
7	40333	11/16/12	11/16/12	BR	Hydrocodone/APAP 10/325	60
8	40334	11/16/12	11/16/12	BR	Zolpidem 10 mg	60
9	40335	11/16/12	11/16/12	BM	Hydrocodone/APAP 10/325	60
10	40336	11/16/12	11/16/12	TG	Hydrocodone/APAP 10/325	60
11	40337	11/16/12	11/16/12	TG	Zolpidem 10 mg	60
12	40338	11/16/12	11/16/12	GN	Hydrocodone/APAP 7.5/750	60

13	40339	11/16/12	11/19/12	DL	Hydrocodone/APAP 10/325	60
14	40341	11/16/12	11/16/12	ED	Hydrocodone/APAP 10/325	60
15	40342	11/16/12	11/16/12	JP	Hydrocodone/APAP 10/325	60
16	40344	11/16/12	11/16/12	FF	Hydrocodone/APAP 10/325	60
17	40345	11/16/12	11/16/12	GJ	Hydrocodone/APAP 10/325	60
18	40347	11/16/12	11/16/12	MB	Hydrocodone/APAP 5/500	60
19	40348	11/16/12	11/16/12	ML	Hydrocodone/APAP 10/325	60
20	40349	11/16/12	11/16/12	FA	Hydrocodone/APAP 10/325	60
21	40351	11/16/12	11/16/12	AL	Hydrocodone/APAP 10/325	60
22	40353	11/16/12	11/16/12	MR	Hydrocodone/APAP 10/325	60
23	40354	11/16/12	11/16/12	MR	Zolpidem 10 mg	60
24	40355	11/16/12	11/16/12	OP	Hydrocodone/APAP 5/500	60
25	40360	11/16/12	11/16/12	RC	Hydrocodone/APAP 10/325	60
26	40361	11/16/12	11/16/12	JC	Hydrocodone/APAP 7.5/750	60
27	10362	11/16/12	11/16/12	JT	Hydrocodone/APAP 10/325	60
28	40363	11/16/12	11/16/12	EC	Hydrocodone/APAP 10/325	60
29	40365	11/16/12	11/16/12	SB	Hydrocodone/APAP 10/325	60
30	40371	11/16/12	11/16/12	CQ	Hydrocodone/APAP 10/325	60
31	40372	11/16/12	11/16/12	EL	Hydrocodone/APAP 10/325	60
32	40374	11/16/12	11/16/12	CS	Hydrocodone/APAP 10/325	60
33	40320	11/16/12	11/16/12	JA	Hydrocodone/APAP 5/500	60
34	40372	11/16/12	11/16/12	EL	Hydrocodone/APAP 10/325	60
35	40374	11/16/12	11/16/12	CS	Hydrocodone/APAP 10/325	60
36	40304	11/7/12	11/7/12	EH	Ambien 5 mg	30
37	40361	11/16/12	11/16/12	JC	Hydrocodone/APAP 7.5/750	60
38	40414	12/15/12	12/15/12	JP	Temazepam 15mg	35
39	40416	15/5/12	12/5/12	EH	Ambien 5 mg	50

39. Respondent Cal-Mex Pharmacy also refilled prescriptions without obtaining the authorization of the prescriber. Specifically, RX number 603306 for patient JP was written on November 16, 2012 for Motrin 600mg, with no refills authorized on the original prescription. Respondents' records show that Respondent Cal-Mex Pharmacy dispensed RX number 603306 to patient JP on November 16, 2012 and was re-filled on December 12, 2012. Board inspectors asked Respondent PIC Oduyale about the prescription; however, Respondent PIC Oduyale was unable to explain when or who received the authorization for the December 12, 2012 refill.

40. Respondent Cal-Mex Pharmacy also dispensed approximately a 90 day supply of a controlled substance within approximately 30 days to patient BS. Prescription records demonstrated that on December 6, 2012, Respondent Cal-Mex Pharmacy dispensed to patient BS pursuant to RX number 20049, 150 tablets of oxycodone 30mg with a thirty day estimated supply. Fourteen days later on December 20, 2012, Respondent Cal-Mex Pharmacy dispensed to patient BS pursuant to RX number 20059, 150 tablets of oxycodone 30mg, which is another thirty day estimated supply. Fifteen days later on January 4, 2013, Respondent Cal-Mex Pharmacy

1 again dispensed to patient BS pursuant to RX number 20066, 150 tablets of oxycodone 30mg,
 2 which is yet another thirty day estimated supply. Board inspectors asked Respondent PIC
 3 Oduyale about the excessive dispensing of medication to this patient. He admitted that he did not
 4 contact the physician to approve the dispensing and also did not notice the dates when he was
 5 dispensing the medication.

6 41. Board inspectors also reviewed several original prescriptions that were filled by
 7 Respondent Cal-Mex Pharmacy. The original prescriptions showed that all of the prescriptions'
 8 origins were by fax or written prescription. Board inspectors questioned Respondent PIC
 9 Oduyale about the verifications for these prescriptions. Respondent PIC Oduyale told Board
 10 inspectors that verifications for these prescriptions were obtained by either calling or walking
 11 over to the prescriber's office. Although requested, Respondents did not provide the verifications
 12 for these prescriptions to Board inspectors during the January 28, 2013 inspection. However, on
 13 February 1, 2013, Respondents provided the requested verifications to Board inspectors with
 14 edited "backers" (dispensing information on the back of the original prescription). The
 15 verifications provided by Respondents contained discrepancies when compared to the originals
 16 obtained by Board inspectors. The verifications showed that the prescriptions were phoned in by
 17 a person, many of them noted that Dr. Ralfa¹ as the verifier (as opposed to fax or written
 18 prescription as reflected on the originals.) Board inspectors noted the following discrepancies
 19 when comparing the originals to the edited backers provided by Respondents:

RX No.	Date Written	Date Filled	Drug	Amount	Original	Edited Backer
40269	12/17/12	10/17/12	Lorazepam 0.5mg	75	-Front says Call in: Cal-Mex -Backer shows Origin: fax	-Backer says phone in by: Maria
40270	10/17/12	10/17/12	Hydrocodone/APAP 10/325 mg	90	-Backer shows Origin: fax	-Backer says phone in by: Maria
40271	10/17/12	10/17/12	Alprazolam .25 mg	30	-Backer shows Origin: fax	-Backer says phone in by: Maria
40303	11/7/12	11/7/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria

26 _____
 27 ¹ When Dr. Ralfa was questioned by Board inspectors, he stated that he only
 28 "sporadically" spoke to Cal-Mex and he did not know or recognize Respondent PIC Oduyale's name.

1	40304	11/7/12	11/7/12	Ambien 5mg	30	-Backer says Origin: written	-Backer says phone in by: Maria
2	40393	12/5/12	11/28/12	Testim Gel 1%	1box	-Backer says Origin: written	-Backer says phone in by: Maria
3	40416	12/5/12	12/5/12	Ambien 5mg	50	-Backer shows Origin: fax	-Backer says phone in by: Maria
4	Unknown	12/5/12	12/5/12	Hydrocodone/APAP 5/500 mg	100	-Backer shows Origin: fax	-Backer says phone in by: Maria
5	40213	9/7/12	9/11/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
6	40320	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
7	40321	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
8	40322	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
9	40325	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
10	40326	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Maria
11	40327	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
12	40328	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
13	40329	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
14	40333	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
15	40334	11/16/12	11/16/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
16	40335	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
17	40336	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
18	40338	11/16/12	11/16/12	Hydrocodone/APAP 7.5/750 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
19	40339	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
20	40342	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
21	40343	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
22	40344	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
23	40345	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
24	40347	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
25	40348	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
26	40349	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
27	40351	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
28	40352	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla

1	40353	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
2	40354	11/16/12	11/16/12	Zolpidem 10 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
3	40360	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
4	40362	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
5	40363	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
6	40362	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
7	40371	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
8	40372	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
9	40374	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
10	40320	11/16/12	11/16/12	Hydrocodone/APAP 5/500 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
11	40372	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla
12	40374	11/16/12	11/16/12	Hydrocodone/APAP 10/325 mg	60	-Backer says Origin: written	-Backer says phone in by: Rafla

FIRST CAUSE FOR DISCIPLINE

(Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Failure to Maintain Adequate Records of Acquisition & Disposition & Failure to Keep Current Inventory)

42. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4081, subdivision (a), and California Code of Regulations, title 16, section 1718, for failure to maintain records of acquisition and disposition and failure to keep a current inventory for hydrocodone/acetaminophen 10 mg/325 mg from May 1, 2012 through January 28, 2013, as set forth in paragraph 31, which is incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Purchasing From Unlicensed Out-of-State Distributor)

43. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of section 4169, subdivision (a), in that Respondents purchased twelve prescription medications on four different days from an unlicensed Out-of-State Wholesaler, River City

1 Pharma, from November 13, 2012 to January 21, 2013, as set forth in paragraph 32, which is
2 incorporated herein by reference.

3 **THIRD CAUSE FOR DISCIPLINE**

4 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Failure to Report to
5 CURES)

6 44. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
7 violation of section Health and Safety Code section 11165, subdivision (d), for failing to report to
8 the Department of Justice any of its controlled substance dispensing from August 19, 2011 to
9 April 19, 2012 and failing to report weekly from April 19, 2012 to April 23, 2013, as set forth in
10 paragraph 33, which is incorporated herein by reference.

11 **FOURTH CAUSE FOR DISCIPLINE**

12 (Against Respondent PIC Oduyale & Respondent Cal-Mex Pharmacy: Inappropriate Substitution)

13 45. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
14 violation of section 4073, subdivision (a), in that on August 9, 2012, Respondents failed to
15 dispense the correct quantity when substituting oxycodone 15mg number 200 for a prescription
16 written for oxycodone 30mg number 120, as set forth in paragraph 34, which is incorporated
17 herein by reference.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Variation From
20 Prescription)

21 46. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
22 violation of California Code of Regulations, title 16, section 1716, in that Respondents deviated
23 from the requirements of four prescriptions without documentation of prior consent of the
24 prescriber, as set forth in paragraph 35, which is incorporated herein by reference.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Dispense From
3 a Required Controlled Substance Prescription Form)

4 47. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
5 violation of Health and Safety Code section 11164, subdivision (a), in that Respondents dispensed
6 twenty-four prescriptions for controlled substances which were not written on a controlled
7 substance form as required by law, as set forth in paragraph 36, which is incorporated herein by
8 reference.

9 **SEVENTH CAUSE FOR DISCIPLINE**

10 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Dispensing Postdated
11 Prescriptions Without Documentation that Prescriber was Contacted)

12 48. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
13 violation of Health and Safety Code section 11164, subdivision (a)(1), in that Respondents
14 dispensed two prescriptions for controlled substances where the prescriptions were written after
15 the medication was dispensed (postdated), which is prohibited under Health and Safety Code
16 section 11172, and without documentation that the prescriber was contacted for correction, as set
17 forth in paragraph 37, which is incorporated herein by reference.

18 **EIGHTH CAUSE FOR DISCIPLINE**

19 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Document the
20 Name of Agent Transmitting Oral Prescriptions)

21 49. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
22 violation of Health and Safety Code section 11164, subdivision (b)(3), in that Respondents failed
23 to document or obtain the name of the agent of the prescriber who transmitted oral prescriptions
24 for thirty nine prescriptions, as set forth in paragraph 38, which is incorporated herein by
25 reference.
26
27
28

1 **NINTH CAUSE FOR DISCIPLINE**

2 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Filing Controlled
3 Substances From Preprinted Multiple Check-off Prescription Blanks)

4 50. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
5 violation of California Code of Regulations, title 16, section 1717.3, subdivision (a), in that
6 Respondents dispensed twenty-four prescriptions for controlled substances pursuant to a
7 preprinted multiple check-off prescription form, as set forth in paragraph 36, which is
8 incorporated herein by reference.

9 **TENTH CAUSE FOR DISCIPLINE**

10 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Dispensing Erroneous or
11 Uncertain Prescriptions)

12 51. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
13 violation of California Code of Regulations, title 16, section 1761, subdivision (a), in that
14 Respondents dispensed prescriptions containing significant errors, omissions, irregularities,
15 uncertainties, ambiguities or alterations as set forth in paragraphs 36-38, which are incorporated
16 herein by reference, and as follows:

17 a. Respondents dispensed twenty-four prescriptions for controlled substances pursuant
18 to a preprinted multiple check-off prescription blank, not controlled substance forms.

19 b. Respondents dispensed two prescriptions for controlled medications where the
20 prescriptions were written after the medication was dispensed (postdated) without documentation
21 the prescriber was contacted for verification.

22 c. Respondents dispensed thirty-nine oral prescriptions for controlled medications which
23 lacked the name of the agent of the prescriber transmitting the prescription.

24 **ELEVENTH CAUSE FOR DISCIPLINE**

25 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Unauthorized Refill)

26 52. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
27 violation of Business and Professions Code section 4063 in that Respondents dispensed
28

1 prescription number 603306 to patient JP on December 12, 2012 without the authorization of the
2 prescriber, as set forth in paragraph 39, which is incorporated herein by reference.

3 **TWELFTH CAUSE FOR DISCIPLINE**

4 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Failure to Implement
5 Corresponding Responsibility)

6 53. Respondents are subject to disciplinary action under section 4301, subdivision (o) for
7 violation of Health and Safety Code section 11153, subdivision (a), in that Respondents failed to
8 implement corresponding responsibility when dispensing within thirty days, an approximately
9 ninety days supply of controlled substance medication to patient BS, which lacked a legitimate
10 medical purpose, as set forth in paragraph 40, which is incorporated herein by reference.

11 **THIRTEENTH CAUSE FOR DISCIPLINE**

12 (Against Respondent PIC Oduyale and Respondent Cal-Mex Pharmacy: Knowingly Making a
13 Document that Falsely Represents the Existence or Nonexistence of Facts)

14 54. Respondents are subject to disciplinary action under section 4301, subdivision (g) for
15 knowingly making a document that falsely represents the existence or nonexistence of facts, in
16 that Respondents provided to the Board altered documents which falsely represented the
17 existence of facts, as set forth in paragraph 41, which is incorporated herein by reference.

18 **FOURTEENTH CAUSE FOR DISCIPLINE**

19 (Against Respondent PIC Oduyale: Failure to Implement Best Professional Judgment)

20 55. Respondent is subject to disciplinary action under section 4301 for unprofessional
21 conduct as defined by Business and Professions Code section 4306.5, subdivision (b), for failing
22 to exercise or implement his best professional judgment, as set forth in paragraphs 30-41, which
23 are incorporated herein by reference, and as follows:

24 a. Respondent failed to keep a current inventory for hydrocodone/acetaminophen
25 10mg/325mg from May 1, 2012 through January 28, 2013;

26 b. Respondent purchased twelve prescription medications on four different days from an
27 unlicensed out of state wholesaler, River City Pharma, from November 13, 2012 through January
28 21, 2013;

1 c. Respondent failed to report to the Department of Justice Respondent Cal Mex
2 Pharmacy's controlled substance dispensing from August 19, 2011 to April 19, 2012;

3 d. Respondent failed to report to the Department of Justice Respondent Cal Mex
4 Pharmacy's controlled substance dispensing on a weekly basis from April 19, 2012 to April 23,
5 2013;

6 e. Respondent dispensed four prescriptions which deviated from the requirements of the
7 prescriber's prescription;

8 f. Respondent dispensed prescription number 603306 to patient JP for Motrin 600mg
9 on December 12, 2012 without the authorization of the prescriber;

10 g. Respondent failed to dispense the correct quantity when substituting oxycodone 15mg
11 number 200 for a prescription written for oxycodone 30mg number 120;

12 h. Respondent dispensed twenty-four prescriptions from September 10, 2012 to
13 November 16, 2012 pursuant to an improper preprinted multiple check-off prescription blank;

14 i. Respondent dispensed twenty-four prescriptions for controlled substances not written
15 on a controlled substance form, as required;

16 j. Respondent dispensed thirty-nine oral prescriptions for controlled medications which
17 lacked the name of the agent of the prescriber transmitting the prescription;

18 k. Respondent dispensed two prescriptions for controlled medications where the
19 prescriptions were written after the medication was dispensed (postdated) without documentation
20 the prescriber was contacted for correction;

21 l. Respondent dispensed sixty-five erroneous or uncertain prescriptions;

22 m. Respondent failed to implement corresponding responsibility when dispensing within
23 thirty days, an approximate ninety day supply of a oxycodone 30mg to patient BS, which lacked a
24 legitimate medical purpose.

25 n. Respondent knowingly provided the Board with altered documents which falsely
26 represented the existence of a state of facts.

27

28

1 **JURISDICTION FOR PETITION TO REVOKE PROBATION**

2 56. This Petition to Revoke Probation is brought against Respondent Cal-Mex Special
3 Services, Inc., doing business as Cal-Mex Pharmacy, before the Board of Pharmacy (Board),
4 Department of Consumer Affairs under Probation Term and Condition Number 11 of the
5 Decision and Order *In the Matter of the Statement of Issues Against Cal-Mex Special Services,*
6 *Inc., dba Cal-Mex Pharmacy*, Case No. 4009. That term and condition states:

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

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

22 **CAUSE TO REVOKE PROBATION**

23 (Obey All Laws)

24 57. At all times after the effective date of Respondent Cal-Mex Pharmacy's probation,
25 Condition 1 stated, in pertinent part:

26 **Obey All Laws**

27 Respondent and its officers shall obey all state and federal laws and
28 regulations.

.....

29 58. Respondent Cal-Mex Pharmacy's probation is subject to revocation because
30 Respondent Cal-Mex Pharmacy failed to comply with Probation Condition 1, referenced above,
31 in that it violated state laws and regulations as set forth in paragraphs 30-55 above, which are
32 incorporated herein by reference.

1 **DISCIPLINARY CONSIDERATIONS**

2 59. To determine the degree of discipline, if any, to be imposed on Respondent PIC
3 Oduyale, Complainant alleges On August 1, 2006, in a disciplinary action entitled *In the Matter*
4 *of the Accusation Against Olugbenga Solomon Oduyale*, Case No. 2733, the Board of Pharmacy
5 issued a Decision and Order effective August 31, 2006, adopting the Proposed Decision of the
6 Administrative Law Judge dated May 17, 2006, providing that Respondent PIC Oduyale's
7 Pharmacist License was revoked; however, the revocation was stayed and Respondent PIC
8 Oduyale was placed on probation for three years. On August 30, 2006, the Board granted a stay
9 of the Decision and granted Respondent PIC Oduyale's Petition for Reconsideration based solely
10 on the issue of whether the probation condition of "supervision" should be eliminated. On
11 November 21, 2006, in its Decision After Reconsideration, the Board adopted the proposed
12 decision dated May 17, 2006, with the exception of the "supervision" paragraph, which was
13 modified to read, "Respondent shall not supervise any ancillary personnel, including, but not
14 limited to, registered pharmacy technicians or exemptees, of any entity licensed by the board."
15 All other provisions of the probation conditions were to remain in full force and effect and the
16 Decision After Reconsideration became effective on December 21, 2006. Respondent PIC
17 Oduyale's three year probationary term was completed on December 20, 2009.

18 **PRAYER**

19 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
20 Accusation and Petition to Revoke Probation, and that following the hearing, the Board of
21 Pharmacy issue a decision:

- 22 1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 4009
23 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY
24 50374 issued to Cal-Mex Special Services, Inc., doing business as Cal-Mex;
- 25 2. Revoking or suspending Pharmacy Permit No. PHY 50374, issued to Cal-Mex
26 Special Services, Inc., doing business as Cal-Mex Pharmacy;
- 27 3. Revoking or suspending Pharmacist License Number 42719 to Olugbenga Solomon
28 Oduyale;

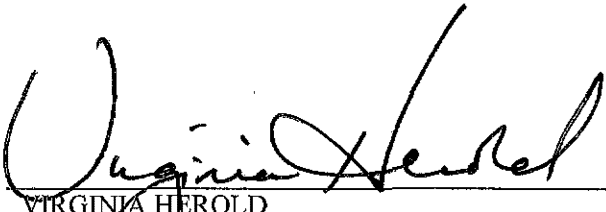
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4. Ordering Cal-Mex Special Services, Inc., doing business as Cal-Mex to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Ordering Olugbenga Solomon Oduyale to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

6. Taking such other and further action as deemed necessary and proper.

DATED: 7/3/13



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

SD2013705458
70724831.doc

Exhibit A

Decision and Order

Board of Pharmacy Case No. 4009

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

In the Matter of the Statement of Issues Against:

Case No. 4009

**CALMEX SPECIAL SERVICES, INC., dba
CAL-MEX PHARMACY**
337 Paulin Ave., Ste. 1A
Calexico, CA 92231

Pharmacy Permit Applicant

Respondent.

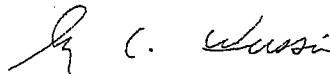
DECISION AND ORDER

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

This decision shall become effective on August 19, 2011.

It is so ORDERED July 20, 2011.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER
Board President

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Attorney General of California
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7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Statement of Issues
12 Against:

Case No. 4009

13 **CALMEX SPECIAL SERVICES, INC., dba**
14 **CAL-MEX PHARMACY,**
337 Paulin Ave., Suite 1A
15 **Calexico, CA 92231**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

16 Respondent.

17
18 In the interest of a prompt and speedy settlement of this matter, consistent with the public
19 interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,
20 the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will
21 be submitted to the Board for approval and adoption as the final disposition of the Statement of
22 Issues.

23
24 **PARTIES**

25 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
26 She brought this action solely in her official capacity and is represented in this matter by Kamala
27 D. Harris, Attorney General of the State of California, by Karen L. Gordon, Deputy Attorney
28 General.

1 2. Calmex Special Services, Inc. dba Cal-Mex Pharmacy (Respondent) is represented in
2 this proceeding by attorney Ronald S. Marks, whose address is: 21900 Burbank Blvd., Suite 300
3 Woodland Hills, CA 91367

4 3. On or about June 25, 2010, the Board of Pharmacy (Board), received an application
5 for a pharmacy permit from Calmex Special Services, Inc., dba Cal-Mex Pharmacy (Respondent).
6 On or about June 15, 2010, Olugbenga S. Oduyale, President of Cal-Mex Special Services, Inc.
7 (Cal-Mex); Anna Murillo, Secretary of Cal-Mex; and Oluwatoyin Oduyale, Cal-Mex Board
8 Member; each certified under penalty of perjury to the truthfulness of all statements, answers, and
9 representations in the application. Olugbenga S. Oduyale indicated on the application that he will
10 be the Pharmacist-in-Charge of Cal-Mex Pharmacy. The Board denied the application on
11 November 22, 2010.

12 JURISDICTION

13 4. Statement of Issues No. 4009 was filed before the Board of Pharmacy (Board), and is
14 currently pending against Respondent. The Statement of Issues and all other statutorily required
15 documents were properly served on Respondent on May 13, 2011. A copy of Statement of Issues
16 No. 4009 is attached as Exhibit A and incorporated herein by reference.

17 ADVISEMENT AND WAIVERS

18 5. Respondent has carefully read, fully discussed with counsel, and understands the
19 charges and allegations in Statement of Issues No. 4009. Respondent has also carefully read,
20 fully discussed with counsel, and understands the effects of this Stipulated Settlement and
21 Disciplinary Order.

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

1 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
2 every right set forth above.

3 CULPABILITY

4 8. Respondent admits that the license of Olugbenga Solomon Oduyale, RPH 42719, was
5 placed on probation for a term of three (3) years effective December 21, 2006 in case number
6 2733.

7 9. Respondent agrees that its pharmacy permit application is subject to denial and it
8 agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order
9 below.

10 CONTINGENCY

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

20 11. The parties understand and agree that facsimile copies of this Stipulated Settlement
21 and Disciplinary Order, including facsimile signatures thereto, shall have the same force and
22 effect as the originals.

23 12. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
24 integrated writing representing the complete, final, and exclusive embodiment of their agreement,
25 along with the letter dated May 29, 2011 from Karen Gordon to Ron Marks, which indicates the
26 dates the decision of the board and the permit will be issued. This Stipulated Settlement and
27 Disciplinary Order supersedes any and all prior or contemporaneous agreements, understandings,
28 discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and

1 Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed
2 except by a writing executed by an authorized representative of each of the parties.

3 13. In consideration of the foregoing admissions and stipulations, the parties agree that
4 the Board may, without further notice or formal proceeding, issue and enter the following
5 Disciplinary Order:

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that upon satisfaction of all statutory and regulatory
8 requirements for issuance of a license, a license shall be issued to Respondent Calmex Special
9 Services, Inc. dba Cal-Mex Pharmacy, and immediately revoked; the order of revocation is stayed
10 and Respondent is placed on probation for thirty-five (35) months upon the following terms and
11 conditions.

12 1. **Obey All Laws**

13 Respondent and its officers shall obey all state and federal laws and regulations.

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

- 16 an arrest or issuance of a criminal complaint for violation of any provision of the
17 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
18 substances laws
- 19 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
20 criminal complaint, information or indictment
- 21 a conviction of any crime
- 22 discipline, citation, or other administrative action filed by any state or federal agency
23 which involves Respondent's pharmacy permit or which is related to the practice of
24 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
25 charging for any drug, device or controlled substance.

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

27 ///

1 **2. Report to the Board**

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

10 **3. Interview with the Board**

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

16 **4. Cooperate with Board Staff**

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

20 **5. Probation Monitoring Costs**

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

25 **6. Status of License**

26 Respondent shall, at all times while on probation, maintain current licensure with the board.
27 If Respondent submits an application to the board, and the application is approved, for a change
28 of location, change of permit or change of ownership, the board shall retain continuing

1 jurisdiction over the license, and the Respondent shall remain on probation as determined by the
2 board. Failure to maintain current licensure shall be considered a violation of probation.

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

7 **7. License Surrender While on Probation/Suspension**

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

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

17 Respondent shall also, by the effective date of this decision, arrange for the continuation of
18 care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing
19 patients that specifies the anticipated closing date of the pharmacy and that identifies one or more
20 area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary
21 in the transfer of records or prescriptions for ongoing patients. Within five days of its provision
22 to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the
23 board. For the purposes of this provision, "ongoing patients" means those patients for whom the
24 pharmacy has on file a prescription with one or more refills outstanding, or for whom the
25 pharmacy has filled a prescription within the preceding sixty (60) days.

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

1 Respondent shall reimburse the board for its costs of investigation and prosecution prior to
2 the acceptance of the surrender.

3 **8. Notice to Employees**

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

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

17 **9. Owners and Officers: Knowledge of the Law**

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

24 **10. Posted Notice of Probation**

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

28 ///

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

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

6 11. Violation of Probation

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

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

19 12. Completion of Probation

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

22 13. Separate File of Records

23 Respondent shall maintain and make available for inspection a separate file of all records
24 pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such
25 file or make it available for inspection shall be considered a violation of probation.

26 14. Pharmacist-in-Charge

27 Respondent will be acceptable to the Board as Pharmacist-in-Charge of Cal-Mex Pharmacy.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Ronald S. Marks. I understand the stipulation and the effect it will have on the pharmacy permit issued to Respondent Calmex Special Services, Inc. dba Cal-Mex Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5-29-11 *Olugbenga S. Oduyale*
OLUGBENGA S. ODUYALE, President
CALMEX SPECIAL SERVICES, INC. dba
CAL-MEX PHARMACY
Respondent

APPROVAL

I have read and fully discussed with Olugbenga S. Oduyale, President of Respondent Calmex Special Services, Inc. dba Cal-Mex Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 5/29/11 *Ronald S. Marks*
RONALD S. MARKS, Esq.
Attorney for Respondent

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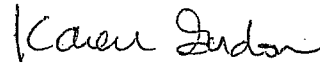
ENDORSEMENT

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

Dated: May 31, 2011

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General



KAREN L. GORDON
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Statement of Issues No. 4009

1 KAMALA D. HARRIS
Attorney General of California
2 LINDA K. SCHNEIDER
Supervising Deputy Attorney General
3 KAREN L. GORDON
Deputy Attorney General
4 State Bar No. 137969
110 West "A" Street, Suite 1100
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 645-2073
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Statement of Issues Against:

Case No. 4009

12 **CALMEX SPECIAL SERVICES, INC., dba**
13 **CAL-MEX PHARMACY,**
14 **337 Paulin Ave., Suite 1A**
Calexico, CA 92231

STATEMENT OF ISSUES

15 Respondent.

16
17 Complainant alleges:

18 **PARTIES**

- 19 1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official
20 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 21 2. On or about June 25, 2010, the Board of Pharmacy, Department of Consumer Affairs
22 received an application for a pharmacy permit from Calmex Special Services, Inc., dba Cal-Mex
23 Pharmacy (Respondent). On or about June 15, 2010, Olugbenga S. Oduyale, President of Cal-
24 Mex Special Services, Inc. (Cal-Mex); Anna Murillo, Secretary of Cal-Mex; and Oluwatoyin
25 Oduyale, Cal-Mex Board Member; each certified under penalty of perjury to the truthfulness of
26 all statements, answers, and representations in the application. Olugbenga S. Oduyale indicated
27 on the application that he will be the Pharmacist-in-Charge of Cal-Mex Pharmacy. The Board
28 denied the application on November 22, 2010.

JURISDICTION

1
2 3. This Statement of Issues is brought before the Board of Pharmacy (Board),
3 Department of Consumer Affairs, under the authority of the following laws. All section
4 references are to the Business and Professions Code unless otherwise indicated.

5 4. Section 4011 of the Code provides that the Board shall administer and enforce both
6 the Pharmacy Law [Bus. & Prof. Code, section 4000 et seq.] and the Uniform Controlled
7 Substances Act [Health & Safety Code, section 11000 et seq.].

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

9 ...

10 (c) The board may refuse a license to any applicant guilty of
11 unprofessional conduct. The board may, in its sole discretion, issue a probationary
12 license to any applicant for a license who is guilty of unprofessional conduct and who
13 has met all other requirements for licensure. The board may issue the license subject
14 to any terms or conditions not contrary to public policy, including, but not limited to,
15 the following:

- 16 (1) Medical or psychiatric evaluation.
- 17 (2) Continuing medical or psychiatric treatment.
- 18 (3) Restriction of type or circumstances of practice.
- 19 (4) Continuing participation in a board-approved rehabilitation program.
- 20 (5) Abstention from the use of alcohol or drugs.
- 21 (6) Random fluid testing for alcohol or drugs.
- 22 (7) Compliance with laws and regulations governing the practice of
23 pharmacy.

24 STATUTORY PROVISIONS

25 6. Section 475 of the Code states, in pertinent part:

26 (a) Notwithstanding any other provisions of this code, the provisions of
27 this division shall govern the denial of licenses on the grounds of:

- 28 (1) Knowingly making a false statement of material fact, or knowingly
omitting to state a material fact, in an application for a license.
- (2) Conviction of a crime.
- (3) Commission of any act involving dishonesty, fraud or deceit with the
intent to substantially benefit himself or another, or substantially injure another.

1 (4) Commission of any act which, if done by a licentiate of the business
or profession in question, would be grounds for suspension or revocation of license.

2 7. Section 480 of the Code states, in pertinent part:

3 (a) A board may deny a license regulated by this code on the grounds
4 that the applicant has one of the following:

5

6 (3)(A) Done any act that if done by a licentiate of the business or
profession in question, would be grounds for suspension or revocation of license.

7 8. Section 4022 states:

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

10 (a) Any drug that bears the legend: "Caution: federal law prohibits
dispensing without prescription," "Rx only," or words of similar import.

11 (b) Any device that bears the statement: "Caution: federal law restricts
12 this device to sale by or on the order of a _____," "Rx only," or words of
similar import, the blank to be filled in with the designation of the practitioner
13 licensed to use or order use of the device.

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

15 9. Section 4059.5 states, in pertinent part:

16 (a) Except as otherwise provided in this chapter, dangerous drugs or
17 dangerous devices may only be ordered by an entity licensed by the board and shall
be delivered to the licensed premises and signed for and received by a pharmacist.
18 Where a licensee is permitted to operate through a designated representative, the
designated representative shall sign for and receive the delivery.

19

20 10. Section 4076 states, in pertinent part:

21 (a) A pharmacist shall not dispense any prescription except in a
22 container that meets the requirements of state and federal law and is correctly labeled
with all of the following:

23 (1) Except where the prescriber or the certified nurse-midwife who
24 functions pursuant to a standardized procedure or protocol described in Section
2746.51, the nurse practitioner who functions pursuant to a standardized procedure
25 described in Section 2836.1 or protocol, the physician assistant who functions
pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a
26 standardized procedure or protocol described in Section 3640.5, or the pharmacist
who functions pursuant to a policy, procedure, or protocol pursuant to either Section
27 4052.1 or 4052.2 orders otherwise, either the manufacturer's trade name of the drug
or the generic name and the name of the manufacturer. Commonly used abbreviations
28 may be used. Preparations containing two or more active ingredients may be
identified by the manufacturer's trade name or the commonly used name or the

principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

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

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

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

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

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11. Section 4081 states, in pertinent part:

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

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

12. Section 4125 states:

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

13. Section 4169 provides in pertinent part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

....

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

1
2 (5) Fail to maintain records of the acquisition or disposition of
3 dangerous drugs or dangerous devices for at least three years.

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

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

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

14 15. Section 4332 of the Code states:

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

20 REGULATIONS

21 16. Section 1711 of the California Code of Regulations, Title 16, (CCR) states, in
22 pertinent part:

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

27 17. Section 1718 of the California Code of Regulations, Title 16, (CCR) states:

28 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.

18. Section 1769 of the California Code of Regulations, Title 16, (CCR) states, in
pertinent part:

(a) When considering the denial of a facility or personal license under
Section 480 of the Business and Professions Code, the board, in evaluating the
rehabilitation of the applicant and his present eligibility for licensing or registration,
will consider the following criteria:

1 (1) The nature and severity of the act(s) or offense(s) under consideration
as grounds for denial.

2 (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s)
3 under consideration as grounds for denial under Section 480 of the Business and
Professions Code.

4 (3) The time that has elapsed since commission of the act(s) or crime(s)
5 referred to in subdivision (1) or (2).

6 (4) Whether the applicant has complied with any terms of parole,
probation, restitution or any other sanctions lawfully imposed against the applicant.

7 (5) Evidence, if any, of rehabilitation submitted by the applicant.

8 19. Section 1304.04 of the Code of Federal Regulations, Title 21, (CFR) sets forth the
9 DEA requirements for the maintenance and inventories of controlled substances and states, in
10 pertinent part:

11 (a) Except as provided in paragraphs (a)(1) and (a)(2) of this section,
12 every inventory and other records required to be kept under this part must be kept by
13 the registrant and be available, for at least 2 years from the date of such inventory or
records, for inspection and copying by authorized employees of the Administration.

14 20. Section 1304.11 of the Code of Federal Regulations, Title 21, (CFR) sets forth the
DEA inventory requirements for controlled substances and states, in pertinent part:

15 (a) General requirements. Each inventory shall contain a complete and
16 accurate record of all controlled substances on hand on the date the inventory is
17 taken, and shall be maintained in written, typewritten, or printed form at the
18 registered location. An inventory taken by use of an oral recording device must be
19 promptly transcribed. Controlled substances shall be deemed to be "on hand" if they
20 are in the possession of or under the control of the registrant, including substances
21 returned by a customer, ordered by a customer but not yet invoiced, stored in a
22 warehouse on behalf of the registrant, and substances in the possession of employees
23 of the registrant and intended for distribution as complimentary samples. A separate
24 inventory shall be made for each registered location and each independent activity
registered, except as provided in paragraph (e)(4) of this section. In the event
25 controlled substances in the possession or under the control of the registrant are
26 stored at a location for which he/she is not registered, the substances shall be included
27 in the inventory of the registered location to which they are subject to control or to
28 which the person possessing the substance is responsible. 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.

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1 **COST RECOVERY**

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

6 **DRUGS**

7 22. Floxin is a dangerous drug pursuant to Business and Professions Code section 4022.

8 23. Levaquin is a dangerous drug pursuant to Business and Professions Code section
9 4022.

10 24. Naproxen is a dangerous drug pursuant to Business and Professions Code section
11 4022.

12 25. Viagra is a dangerous drug pursuant to Business and Professions Code section 4022.

13 26. Vicodin, a brand name for hydrocodone, is a Schedule III controlled substance as
14 designated by Health and Safety Code section 11056(e)(4), and is a dangerous drug pursuant to
15 Business and Professions Code section 4022.

16 27. Xanax, a brand name for alprazolam, is a Schedule IV controlled substance as
17 designated by Health and Safety Code section 11057(d)(1), and is a dangerous drug pursuant to
18 Business and Professions Code section 4022.

19 **FACTS**

20 28. The President of Respondent Cal-Mex, Olugbenga Solomon Oduyale, is a licensed
21 pharmacist. On or about August 8, 1989, the Board of Pharmacy issued original pharmacist
22 license number RPH 42719 to Olugbenga Solomon Oduyale. The license will expire on October
23 31, 2012, unless renewed.

24 29. From approximately March of 1997 until approximately January of 2003, Olugbenga
25 Solomon Oduyale worked as the Pharmacist-in-Charge at Rite-Aid Pharmacy in Calexico,
26 California (Calexico Rite-Aid).

27 30. On or about December 31, 2002, just after midnight, Olugbenga Solomon Oduyale
28 was observed by a California Highway Patrol (CHP) Officer driving erratically, drifting across

1 lanes of traffic. The Officer pulled Olugbenga Solomon Oduyale over and observed a wooden
2 billyclub and two brown prescription bottles without prescription labels on them in his car.
3 Olugbenga Solomon Oduyale was in possession of the controlled substances Vicodin and Xanax
4 illegally without a valid prescription and the controlled substances were in containers without
5 proper labeling. Olugbenga Solomon Oduyale was arrested for possession of controlled
6 substances and a dangerous weapon.

7 31. Once Olugbenga Solomon Oduyale was arrested, the officer searched Olugbenga
8 Solomon Oduyale and found more prescription medicines which were identified as Viagra,
9 Floxin, Naproxen, and Levaquin. Olugbenga Solomon Oduyale also had \$968.00 in cash in his
10 pocket and \$3,734.00 in cash in the trunk of his car.

11 32. From approximately January of 2003 until approximately March of 2005, Olugbenga
12 Solomon Oduyale worked as the Pharmacist-in-Charge at Palo Verde Hospital Pharmacy (PVH
13 Pharmacy) in Blythe, California.

14 33. On or about March 11, 2004, the Board conducted an inspection of PVH Pharmacy.
15 The inspection revealed that Olugbenga Solomon Oduyale failed to keep accurate and complete
16 records of the acquisition and disposition of controlled substances at PVH Pharmacy. Olugbenga
17 Solomon Oduyale did not have a written quality assurance program at PVH Pharmacy.
18 Olugbenga Solomon Oduyale did not have a Drug Enforcement Agency (DEA) Inventory at the
19 PVH Pharmacy. Most drug deliveries at PVH Pharmacy were received and signed for by non-
20 pharmacists. As Pharmacist-in-Charge, Olugbenga Solomon Oduyale should not have permitted
21 non-pharmacists to accept drug deliveries.

22 34. On or about April 29, 2005, Accusation Case No. 2733 was filed before the Board
23 against Olugbenga Solomon Oduyale. A copy of Accusation Case No. 2733 is attached hereto as
24 Exhibit 1 and is incorporated by reference.

25 35. Following a hearing on February 6, 7, and 8, 2006, in Accusation Case No. 2733, a
26 decision was rendered against Olugbenga Solomon Oduyale revoking his pharmacist's license,
27 with the revocation stayed and probation imposed for three years on terms and conditions. The
28 decision was to become effective on August 31, 2006, but Olugbenga Solomon Oduyale filed a

1 Petition for Reconsideration. The Board granted reconsideration solely on a condition of
2 probation concerning supervision. The Board rendered a decision after reconsideration allowing
3 Olugbenga Solomon Oduyale to supervise ancillary personnel, including registered pharmacy
4 technicians. The decision became effective on December 21, 2006. The three year probationary
5 term was completed on December 20, 2009. The decision was rendered imposing discipline for
6 the following violations based upon the facts set forth in paragraphs 29 through 33 above:

- 7 a. Dispensing prescription drugs in containers not labeled as legally required;
- 8 b. Failure to provide records of filled prescriptions at PVH Pharmacy and all records
9 required for inspection by the Board's inspector;
- 10 c. Failure to have all records of sale, acquisition, or disposition of dangerous drugs open
11 to inspection by the Board inspector at all times during business hours;
- 12 d. Failure to have a quality assurance program in place at PVH Pharmacy when
13 inspected on March 11, 2004;
- 14 e. Failure to have an accurate and complete written DEA inventory at PVH when
15 inspected on March 11, 2004; and
- 16 f. As Pharmacist-in-Charge, regularly allowing non-pharmacists to receive and sign for
17 drug delivers made to PVH Pharmacy.

18 **FIRST CAUSE FOR DENIAL OF APPLICATION**

19 **(Unprofessional Conduct – Dispensing Dangerous Drugs Without Labeling)**

20 36. Respondent's application is subject to denial under Code sections 4300 (c) and 4301
21 (o) for violation of section 4076 (a) in that Olugbenga Solomon Oduyale dispensed prescription
22 drugs (dangerous drugs) in containers not labeled as legally required, as set forth above in
23 paragraphs 28 to 35.

24 **SECOND CAUSE FOR DENIAL OF APPLICATION**

25 **(Unprofessional Conduct – Failure to Provide Records)**

26 37. Respondent's application is subject to denial under Code sections 4300 (c) and 4301
27 (o) for violation of sections 4081 and 4332 in that Olugbenga Solomon Oduyale failed to provide
28 to the Board's inspector records of all filled prescriptions at the PVH Pharmacy and all required

1 records during the inspection on or about March 11, 2004 and for a reasonable time thereafter
2 when requested by the Board inspector, as set forth above in paragraphs 28 to 35.

3 **THIRD CAUSE FOR DENIAL OF APPLICATION**

4 **(Unprofessional Conduct – Failure to Maintain Accurate Records and**
5 **Complete Accountability of Inventory)**

6 38. Respondent's application is subject to denial under Code sections 4300 (c) and 4301
7 (o) for violation of section 4081 as well as CCR section 1718 in that Olugbenga Solomon
8 Oduyale failed to have all records of sale, acquisition, or disposition of dangerous drugs open to
9 inspection by the Board inspector at all times during business hours at PVH Pharmacy, including
10 complete accountability for all inventory, as set forth above in paragraphs 28 to 35.

11 **FOURTH CAUSE FOR DENIAL OF APPLICATION**

12 **(Unprofessional Conduct – Failure to Implement Quality Assurance Program)**

13 39. Respondent's application is subject to denial under Code sections 4300 (c) and 4301
14 (o) for violation of section 4125 as well as CCR section 1711 in that Olugbenga Solomon
15 Oduyale failed to have a quality assurance program in place at PVH Pharmacy when inspected on
16 or about March 11, 2004, as set forth above in paragraphs 28 to 35.

17 **FIFTH CAUSE FOR DENIAL OF APPLICATION**

18 **(Unprofessional Conduct – Failure to Maintain DEA Inventory)**

19 40. Respondent's application is subject to denial under Code sections 4300 (c) and 4301
20 (o) for violation of CCR section 1718 and CFR sections 1304.04 and 1304.11 in that Olugbenga
21 Solomon Oduyale failed to have an accurate and complete written or printed DEA Inventory at
22 PVH Pharmacy when inspected on or about March 11, 2004, as set forth above in paragraphs 28
23 to 35.

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SIXTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct – Allowing Non-Pharmacists to Receive Drug Purchases)

41. Respondent's application is subject to denial under Code sections 4300 (c) and 4301 (o) for violation of section 4059.5(a) in that as Pharmacist-in-Charge at PVH Pharmacy, Olugbenga Solomon Oduyale regularly allowed non-pharmacists to receive and sign for drug deliveries made to PVH Pharmacy, as set forth above in paragraphs 28 to 35.

SEVENTH CAUSE FOR DENIAL OF APPLICATION

(Acts if Done by Licentiate are Grounds for Discipline)

42. Respondent's application is subject to denial under Code sections 480(a)(3)(A) in that Olugbenga Solomon Oduyale has done acts that if done by a licentiate would be grounds for suspension or revocation of his license, when Olugbenga Solomon Oduyale dispensed prescription drugs (dangerous drugs) in containers not labeled as legally required in violation of section 4076(a); failed to provide to the Board's inspector records of all filled prescriptions at the PVH Pharmacy and all required records during the inspection on or about March 11, 2004 and for a reasonable time thereafter when requested by the Board inspector in violation of sections 4081 and 4332; failed to have all records of sale, acquisition, or disposition of dangerous drugs open to inspection by the Board inspector at all times during business hours at PVH Pharmacy, including complete accountability for all inventory, in violation of section 4081 as well as CCR section 1718; failed to have a quality assurance program in place at PVH Pharmacy when inspected on or about March 11, 2004 in violation of section 4125 as well as CCR section 1711; failed to have an accurate and complete written or printed DEA Inventory at PVH Pharmacy when inspected on or about March 11, 2004 in violation of CCR section 1718 and CRF sections 1304.04 and 1304.11; and regularly allowed non-pharmacists to receive and sign for drug deliveries made to PVH Pharmacy in violation of Code section 4059.5(a), as set forth above in paragraphs 28 to 35.

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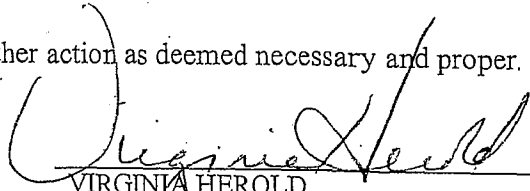
PRAYER

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. Denying the application of Calmex Special Services, Inc. dba Cal-Mex Pharmacy for a pharmacy permit.

2. Taking such other and further action as deemed necessary and proper.

DATED: 5/10/11



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

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EXHIBIT 1
ACCUSATION CASE NO. 2733

1 BILL LOCKYER, Attorney General
of the State of California
2 SUSAN FITZGERALD, State Bar No. 112278
Deputy Attorney General
3 California Department of Justice
110 West "A" Street, Suite 1100
4 San Diego, CA 92101

5 P.O. Box 85266
San Diego, CA 92186-5266
6 Telephone: (619) 645-2066
Facsimile: (619) 645-2061

7 Attorneys for Complainant
8

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

12 In the Matter of the Accusation Against:

Case No. 2733

13 OLUGBENGA SOLOMON ODUYALE, RPH
2209 E 27th St
14 Yuma, AZ 85365

ACCUSATION

15 Original Pharmacist License No. RPH 42719

16 Respondent.
17

18 Complainant alleges:

19 PARTIES

20 1. Patricia F. Harris (Complainant) brings this Accusation solely in her official
21 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

22 2. On or about August 8, 1989, the Board of Pharmacy issued Original Pharmacist
23 License Number RPH 42719 to Olugbenga Solomon Oduyale, RPH (Respondent). The Original
24 Pharmacist License was in full force and effect at all times relevant to the charges brought herein
25 and will expire on October 31, 2006, unless renewed.

26 JURISDICTION

27 3. This Accusation is brought before the Board of Pharmacy (Board), Department of
28 Consumer Affairs, under the authority of the following sections of the California Business &

1 Professions Code:

2 A. Section 4301 of the Code states:

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

7 "...

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

11 "...

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

14 "...

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

19 "(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the
20 Board.

21 "..."

22 B. Section 4059 of the Code states, in pertinent part, that a person may not furnish
23 any dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist,
24 or veterinarian.

25 C. Section 4059.5 states in pertinent part:

26 "(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices
27 may only be ordered by an entity licensed by the board and must be delivered to the licensed
28 premises and signed for and received by the pharmacist-in-charge or, in his or her absence,

1 another pharmacist designed by the pharmacist-in-charge. Where a licensee is permitted to
2 operate through an exemptee, the exemptee may sign for and receive the delivery.

3 " "

4 D. Section 4060 of the Code states:

5 "No person shall possess any controlled substance, except that furnished to a
6 person upon the prescription of a physician, dentist, podiatrist, or veterinarian,
7 or furnished pursuant to a drug order issued by a certified nurse-midwife
8 pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1,
9 or a physician assistant pursuant to Section 3502.1. This section shall not
10 apply to the possession of any controlled substance by a manufacturer,
11 wholesaler, pharmacy, physician, podiatrist, dentist, veterinarian, certified
12 nurse-midwife, nurse practitioner, or physician assistant, when in stock in
13 containers correctly labeled with the name and address of the supplier or
14 producer.

15 "Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner,
16 or a physician assistant to order his or her own stock of dangerous drugs and devices."

17 E. Section 4076 of the Code states in pertinent part:

18 "(a) A pharmacist shall not dispense any prescription except in a container that
19 meets the requirements of state and federal law and is correctly labeled with all of the
20 following. . .

21 " "

22 F. Section 4332 states:

23 "Any person who fails, neglects, or refuses to maintain the records required by Section
24 4081 or who, when called upon by an authorized officer or member of the board, fails, neglects,
25 or refused to produce the records within a reasonable time, or who willfully produces or furnishes
26 records that are false, is guilty of a misdemeanor."

27 G. Section 4125 states in pertinent part:

28 "(a) Every pharmacy shall establish a quality assurance program that shall, at a

1 minimum. document medication errors attributable, in whole or in part, to the pharmacy or its
2 personnel. The purpose of the quality assurance program shall be to assess errors that occur in
3 the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take
4 appropriate action to prevent a recurrence.

5 "...."

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

10 4. This Accusation is also brought under the authority of the following sections of
11 the California Health & Safety Code (H&S Code):

12 A. H&S Code section 11171 states that "[n]o person shall prescribe, administer,
13 or furnish a controlled substance except under the conditions and in the manner
14 provided in this division."

15 B. H&S Code section 11173 states in pertinent part:

16 "(a) No person shall obtain or attempt to obtain controlled substances, or
17 procure or attempt to procure the administration of or prescription for controlled
18 substances, (1) by fraud, deceit, misrepresentation, or subterfuge. . .

19 "...."

20 C. H&S Code section 11350(a) states that it is illegal to possess narcotic Schedule I
21 controlled substances or any narcotic drugs in Schedules II, III, IV, or V without a legitimate
22 prescription.

23 D. H&S Code section 11352(a) states in pertinent part that it is illegal to transport,
24 sell, furnish, administer, give away or attempt to do any of those things with respect to any
25 narcotic controlled substances unless upon a legitimate written prescription.

26 E. H&S Code section 11377(a) states in pertinent part that it is illegal to possess any
27 non-narcotic controlled substance without a legitimate prescription.

28 //

1 F. H&S Code section 11379(a) states in pertinent part that it is illegal to transport,
2 sell, furnish, administer, give away or attempt to do any of those things with respect to any non-
3 narcotic controlled substances unless upon a legitimate prescription.

4 5. This Accusation is also brought under the authority of the following sections of
5 Title 16, California Code of Regulations (CCR):

6 A. Section 1711 establishes the requirements for a pharmacy's quality assurance
7 program.

8 B. Section 1718 states:

9 "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
10 Code shall be considered to include complete accountability for all dangerous drugs
11 handled by every licensee enumerated in Sections 4081 and 4332. The controlled
12 substances inventories required by Title 21, CFR, Section 1304 shall be available for
13 inspection upon request for at least 3 years after the date of the inventory."

14 6. This Accusation also refers to Title 21, Code of Federal Regulation, section 1304
15 et seq. which provides the DEA requirements concerning controlled substance record
16 keeping/inventories.

17 DRUGS

18 7. The following are all dangerous drugs, pursuant to Business & Professions
19 Code section 4022 and are also controlled substances, if so identified below:

20 A. "Oxycontin," a brand name for oxycodone, is a Schedule II controlled substance
21 under H&S Code section 11055(b)(1)(N);

22 B. Hydrocodone, a narcotic drug, with acetaminophen 5/500 mg, a brand name for
23 which is "Vicodin," is a Schedule III controlled substance under H&S Code
24 section 11056(e)(4);

25 C. Depo-testosterone is a male hormone and is a Schedule III controlled substance
26 under H&S Code section 11056(f)(30);

27 D. "Ketalar," a brand name for ketamine, is a Schedule III controlled substance under
28 H&S Code section 11056(g);

- 1 E. "Vicodin ES," a brand name for hydrocodone 7.5 mg with APAP, is a Schedule
2 III controlled substance under H&S Code section 11056(e)(4);
- 3 F. "Tylenol w/Codeine," a brand name for APAP with codeine, is a Schedule III
4 controlled substance under H&S Code section 11056(e)(2);
- 5 G. "Xanax," a brand name for alprazolam, is a Schedule IV controlled substance
6 under H&S Code section 11057(d)(1);
- 7 H. "Ativan," a brand name for lorazepam, is a Schedule IV controlled substance
8 under H&S Code section 11057(d)(16);
- 9 I. "Luminal," a brand name for phenobarbital, is a Schedule IV controlled substance
10 under H&S Code section 11057(d)(26);
- 11 J. "Phenergan w/Codeine," a brand name for promethazine with codeine, is a
12 Schedule V controlled substance under H&S Code section 11058(c)(1);
- 13 K. "Soma" is a dangerous drug under Business & Professions Code section 4022;
- 14 L. "Lupron" is a dangerous drug under Business & Professions Code section 4022;
- 15 M. "Epogen" is a dangerous drug under Business & Professions Code section 4022;
- 16 N. "Viagra" is a dangerous drug under Business & Professions Code section 4022;
- 17 O. "Naprosyn" is a dangerous drug under Business & Professions Code section 4022;
- 18 P. "Levaquin" is a dangerous drug under Business & Professions Code section 4022;
- 19 Q. "Floxin" is a dangerous drug under Business & Professions Code section 4022;

20 CHARGES AND ALLEGATIONS RE 2002 INCIDENT

21 8. On or about December 31, 2002, Respondent was stopped by the California
22 Highway Patrol while driving on Interstate 8. He was found to have in his possession and control
23 two amber, unlabeled drug prescription bottles, one of which he indicated contained "Vicodin"
24 and the other "Xanax," both for a "Mrs. Robinson." When the highway patrolman noted a variety
25 of different pills in the container Respondent identified as having Xanax in it. Respondent then
26 also said that it contained, additionally, Viagra, an antibiotic, and Claritin. In fact, the bottles
27 contained Vicodin in one bottle and Xanax mixed with Viagra, Floxin, Naproxin and 35
28 unidentified pills in the other.

- 1 9. A further search uncovered the following:
- 2 * an amber unlabeled prescription container with 16 1/2 Viagra tablets;
- 3 * a sealed bottle of Viagra;
- 4 * 2 white bottles containing 94 and 100 Naproxen tablets;
- 5 * an amber prescription container labeled only "Levaquin" with 5 pills;
- 6 * a silver-foil wrapped card containing 8 unidentified pills;
- 7 * a gold-foil wrapped card containing 4 unidentified white pills;
- 8 * miscellaneous pills in Respondent's pocket: 4 Viagra, 2 Naproxen, 1 Floxin, and
- 9 one unidentified pill;
- 10 * \$4,702.00 in cash. \$968.00 in Respondent's pocket.

11 10. Respondent could not produce any prescriptions for any drugs for "Mrs
12 Robinson."

13 11. Respondent was arrested and "Mirandized," after which he told the highway
14 patrolman that the Vicodin was for a "Don Brenizer" and the Xanax for "Mrs. Robinson."

15 12. Respondent's then-employer, Rite-Aid Pharmacy #5675 in Calexico, California,
16 did not know Respondent had taken any of the above drugs.

17 13. Respondent admitted that he was taking the Levaquin himself and did not have a
18 prescription for it.

19 14. On or about December 30, 2002, Respondent fraudulently created a prescription
20 for Donald Brenizer for 30 tablets of hydrocodone with APAP 5/500 mg. using the name of a
21 doctor in the area. That doctor knew nothing of the prescription and had never treated Donald
22 Brenizer.

23 FIRST CAUSE FOR DISCIPLINE

24 (Unprofessional Conduct: Illegal Possession of Vicodin)

25 15. Respondent is subject to disciplinary action under section 4301(o) in conjunction
26 with section 4060 and, separately, under section 4301(j) in conjunction with H&S Code section
27 11350(a), in that he illegally possessed hydrocodone with APAP, as more particularly alleged in
28 paragraphs 8-14 above and incorporated herein by reference.

1 SECOND CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct: Illegal Possession of Xanax)

3 16. Respondent is subject to disciplinary action under section 4301(o) in conjunction
4 with section 4060 and, separately, under section 4301(j) in conjunction with H&S Code section
5 11377(a) in that he illegally possessed Xanax, as more particularly alleged in paragraphs 8-14
6 above and incorporated herein by reference.

7 THIRD CAUSE FOR DISCIPLINE

8 (Unprofessional Conduct: Illegal Prescribing or Furnishing of Controlled Substances)

9 17. Respondent is subject to disciplinary action under section 4301(j) in conjunction
10 with H&S Code section 11171 in that he illegally prescribed and/or furnished hydrocodone with
11 APAP and Xanax in violation of the California Health & Safety Code, as more particularly
12 alleged in paragraphs 8-14 above and incorporated herein by reference.

13 FOURTH CAUSE FOR DISCIPLINE

14 (Unprofessional Conduct: Act of Moral Turpitude, Dishonesty,
15 Fraud, Deceit, or Corruption)

16 18. Respondent is subject to disciplinary action under section 4301(f) for acts of
17 moral turpitude, dishonesty, fraud, deceit, or corruption, as more particularly alleged in
18 paragraphs 8-14 above and incorporated herein by reference.

19 FIFTH CAUSE FOR DISCIPLINE

20 (Unprofessional Conduct: Obtaining Controlled Substances by
21 Fraud, Deceit, Misrepresentation or Subterfuge)

22 19. Respondent is subject to disciplinary action under section 4301(j) in conjunction
23 with H&S Code section 11173(a) in that he obtained hydrocodone with APAP and Xanax by
24 fraud, deceit, misrepresentation or subterfuge, as more particularly alleged in paragraphs 8-14
25 above and incorporated herein by reference.

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SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Illegal Transporting of Generic Vicodin)

20. Respondent is subject to disciplinary action under section 4301(j) in conjunction with H&S Code section 11352(a) in that he transported generic Vicodin without a legitimate prescription, as more particularly alleged in paragraphs 8-14 above and incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Illegal Transporting of Xanax)

21. Respondent is subject to disciplinary action under section 4301(j) in conjunction with H&S Code section 11379(a) in that he transported Xanax without a legitimate prescription, as more particularly alleged in paragraphs 8-14 above and incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Furnishing Dangerous Drugs to Oneself W/O Prescription)

22. Respondent is subject to disciplinary action under section 4301(o) in conjunction with section 4059 in that he furnished himself Levaquin, Viagra, Naproxen, and Floxin without a prescription, as more particularly alleged in paragraphs 8-14 above and incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Dispensing Dangerous Drugs Without Labeling)

23. Respondent is subject to disciplinary action under section 4301(o) in conjunction with section 4076 in that he dispensed prescription drugs in containers not labeled at all or not labeled as legally required, as more particularly alleged in paragraphs 8-14 above and incorporated herein by reference.

CHARGES AND ALLEGATIONS RE 2004 PHARMACY INSPECTION/AUDIT

24. At all times relevant to the charges and allegations below and since January 13, 2003, Respondent has been the pharmacist-in-charge (PIC) of the hospital pharmacy at Palo Verde Hospital in Blythe, California.

///

1 25. In March 11, 2004, a Board inspector performed an inspection of Palo Verde
2 Hospital pharmacy. Numerous violations were uncovered.

3 TENTH CAUSE FOR DISCIPLINE

4 (Unprofessional Conduct: Failure to Provide Records)

5 26. Respondent is subject to disciplinary action under section 4301(o) in conjunction
6 with 4332 for failure to provide, or timely provide records to the Board's inspector, as more
7 particular alleged below:

8 A. During the inspection and for a reasonable time thereafter, Respondent PIC failed
9 to provide certain invoices for APAP/codeine, carisoprodol, lorazepam, promethazine/codeine,
10 and Vicodin ES when requested by the inspector.

11 B. During the inspection and for a reasonable time thereafter, Respondent PIC failed
12 to provide accurate and complete dispensing records of dangerous drugs when requested by the
13 inspector.

14 ELEVENTH CAUSE FOR DISCIPLINE

15 (Unprofessional Conduct: Failure to Maintain Accurate Records
16 and Complete Accountability of Inventory)

17 27. Respondent is subject to disciplinary action under section 4301(o) in conjunction
18 with 4081(a) and (b) as well as CCR §1718 for failure to maintain accurate records and complete
19 accountability of inventory, as more particular alleged below:

20 Respondent failed to maintain accurate records of acquisition and disposition of
21 controlled substances at Palo Verde hospital, including complete accountability for all inventory
22 during a specific audit period for carisoprodol, lorazepam and phenobarbital.

23 TWELFTH CAUSE FOR DISCIPLINE

24 (Unprofessional Conduct: Failure to Implement Quality Assurance Program)

25 28. Respondent is subject to disciplinary action under section 4301(o) in conjunction
26 with 4125 and CCR §1711 in that on March 11, 2004, Respondent did not have a quality
27 assurance program in place at Palo Verde hospital, as required by law.

28 //'

1 THIRTEENTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct: Failure to Maintain DEA Inventory)

3 29. Respondent is subject to disciplinary action under section 4301(o) in conjunction
4 with CCR §1718 and CFR §1304 et seq. in that on March 11, 2004, Respondent did not have a
5 DEA Inventory at Palo Verde hospital. A perpetual inventory maintained by the hospital did not
6 meet the requirements of a DEA inventory and was inaccurate.

7 FOURTEENTH CAUSE FOR DISCIPLINE

8 (Unprofessional Conduct: Allowing Non-Pharmacists to Receive Drug Purchases)

9 30. Respondent is subject to disciplinary action under section 4301(o) in conjunction
10 with section 4059.5(a) in that while PIC of Palo Verde hospital pharmacy he repeatedly allowed
11 non-pharmacists to receive drug purchases.

12 FIFTEENTH CAUSE FOR DISCIPLINE

13 (Unprofessional Conduct: Act of Moral Turpitude, Dishonesty,
14 Fraud, Deceit, or Corruption)

15 31. Respondent is subject to disciplinary action under section 4301(f) for dishonesty
16 in that on or about March 11, 2004 Respondent knowingly falsely stated to the Board's inspector
17 that only pharmacists received drug deliveries at Palo Verde hospital. In fact, only about 15% of
18 the deliveries between January 13, 2003 and March 11, 2004 were received by Respondent or
19 another pharmacist.

20 SIXTEENTH CAUSE FOR DISCIPLINE

21 (Unprofessional Conduct: Attempting to Subvert a Board Investigation)

22 32. Respondent is subject to disciplinary action under section 4301(q) for attempting
23 to subvert a Board investigation. as more particularly alleged above in paragraph 31, which is
24 incorporated here by reference.

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PRAAYER

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 Original Pharmacist License Number RPH 42719, issued to Olughenga Solomon Oduyale, RPH;

2. Ordering Olughenga Solomon Oduyale, RPH to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

3. Taking such other and further action as deemed necessary and proper.

DATED: 4/29/05

P. J. Harris
PATRICIA F. HARRIS
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant