

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

In the Matter of the Accusation Against:

AYN PHARMACY DBA THE
PRESCRIPTION CENTER; AFSHIN
YOUSSEF NASSIR, PRESIDENT; PAYAM
NASSIR, VICE PRESIDENT,

License No. PHY 41455

and

AFSHIN YOUSSEF NASSIR,

Pharmacist License No. RPH 46543

Respondents.

Case No. 5056

OAH No. 2015090262

DECISION AFTER REJECTION

This matter came on regularly for hearing on March 14, 2016, before Carla L. Garrett, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, in Los Angeles, California. Kevin J. Rigley, Deputy Attorney General, represented Complainant Virginia Herold, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Complainant). Herbert L. Weinberg, Attorney at Law, represented Respondent AYN Pharmacy dba The Prescription Center (Respondent Pharmacy) and Respondent Afshin Yousef Nassir (Respondent Nassir), who appeared at the hearing.

At the hearing, the Accusation was amended to reflect the withdrawal of paragraph 18(b) in its entirety, and to show the change from "through" to "and" in the last line of paragraph 19, such that it read, "paragraph 18, subparagraphs a and c, inclusive, as though set forth fully herein."

Oral and documentary evidence was received, the record was closed, and the matter was submitted for decision on March 14, 2016. On April 13, 2016, the ALJ issued a proposed decision in this matter.

On July 15, 2016, the California State Board of Pharmacy ("Board") issued an Order pursuant to Government Code section 11515 rejecting the April 13, 2016, Proposed Decision of the ALJ in the above-entitled matter. On August 18, 2016, the Board issued an Order reflecting that the transcript had been received and the deadline for submission of written argument was set

for September 19, 2016. Complainant submitted written argument, but the Board did not receive written argument from respondents.

The Board, having reviewed and considered the entire record, including the transcript, exhibits and written argument, now issues this decision.

FACTUAL FINDINGS

1. On July 21, 2015, Complainant executed Accusation 5056 against Respondents in her official capacity as Executive Officer of the Board of Pharmacy (the Board).¹ Respondents filed a request for a hearing.

2. On December 23, 1996, the Board issued License Number PHY 41455 to Respondent Pharmacy. The registration was in full force and effect at all relevant times and will expire on March 1, 2017, unless renewed.

3. On August 16, 1993, the Board issued Pharmacist License Number RPH 46543 to Respondent Nassir, which was in full force and effect at all relevant times. Respondent Nassir is and has been the president, 51 percent shareholder, and the pharmacist in charge of Respondent Pharmacy since March 18, 1996.

Inspection

4. After receiving multiple complaints concerning Respondent Pharmacy, the Board assigned Antony Ngondara, Inspector, to investigate. Inspector Ngondara, who is a pharmacist, testified at hearing. On July 16, 2013, Inspector Ngondara, along with Inspector Christine Acosta, conducted an unannounced on-site inspection of Respondent Pharmacy. The results of the inspection and investigation revealed nine purported violations identified by Inspector Ngondara. Specifically, the noted violations related to: (1) drug stock repackaging and labeling; (2) Controlled Substance Utilization Review and Evaluation System (CURES) reporting; (3) patient-centered labels; (4) the Board's email notification list; (5) compounding expiration date and labeling; (6) record keeping of compounded drug product; (7) labeling of compounded drugs; (8) training of compounding staff, and (9) operational standards and security. During the inspection, Inspector Ngondara took photographs depicting the purported violations. He prepared a written report on November 13, 2013.

5. With respect to the first violation (drug stock repackaging and labeling), Inspector Ngondara found that Respondent Pharmacy contained unlabeled bottles of prepackaged medications at the filling station, in violation of Business and Professions Code (B&P Code) section 4342 and California Code of Regulations, title 16, (CCR), section 1714, subdivision (b). Additionally, he found filled cream dispensers in the compounding area, but they were

¹ The Accusation alleges in Paragraph 18(a) that "Respondents submitted a Community Pharmacy Self-Assessment and a Compounding Self-Assessment to the Board, both signed under penalty of perjury by Respondent Pharmacist, wherein Respondents falsely represented that Respondent Pharmacy was in compliance with various state laws." However, no self-assessment completed by Respondents was proffered or received into evidence.

unlabeled. The unlabeled medications did not contain expiration dates or lot numbers. Also, he found that some stock medications and finished compound products had expired, had no expiration dates, or contained unclear labeling. Inspector Ngondara considered finished products with no expiration date as lacking quality of strength and, therefore, unfit for use in compounding or distributing to patients. Consequently, he ordered that the medication be destroyed.

6. Lusine Yeranosyan, who served as one of Respondent Pharmacy's pharmacy technicians, testified at hearing. She was present at the time of the inspection. Ms. Yeranosyan was working at the prescription counter and was in the process of labeling the unlabeled bottles on the shelf. Specifically, Respondent Pharmacy had received multiple orders for the same prescription, which she was in the process of filling or renewing. She continued labeling the bottles as Inspectors Ngondara and Acosta conducted their inspection. It took approximately 45 minutes to complete the labeling of the bottles. At hearing, Inspector Ngondara conceded that medications left unlabeled for a short period, while awaiting labels stemming from multiple prescriptions of the same medication, would not have been a violation.

7. Dr. Payim Nassir,² who served as Respondent Pharmacy's vice president, testified at hearing. He was present at the time of the inspection.³ With respect to some of the expired medication, Dr. Nassir explained that Respondent Pharmacy contained a cabinet designated for drugs that were to be destroyed, which included expired drugs. The general protocol for expired drugs was to quarantine the expired medication in a separate part of the pharmacy in the cabinet, where they awaited the individual from the distribution company to retrieve the expired drugs and destroy them, which generally occurred every six months.

8. In response to Inspector Ngondara's inspection, on July 26, 2013, Respondents emailed, through their attorney, a letter addressing the violations cited. With respect to the first violation concerning drug stock repackaging and labeling, in addition to unlabeled medication that Ms. Yeranosyan was addressing at the time of the inspection, and the expired drugs quarantined in a cabinet, Respondents advised that all recently repackaged drugs⁴ were packed for shipment via RxReverse Distributors. They were processed on July 26, 2013.

9. With respect to the second violation regarding CURES reporting, Inspector Ngondara found that Respondent Pharmacy failed to transmit dispensed controlled substance data on a weekly basis to the Department of Justice, in violation of Health and Safety Code (H&S Code), section 11165, subdivision (d). To confirm whether Respondent Pharmacy had committed this violation, Inspector Ngondara requested a compliance report from the Board's CURES analyst, who provided him with a compliance report with a date range of September 20, 2010 through September 20, 2013. By reference to the compliance report, Respondent Pharmacy

² Payam Nassir is the brother of Respondent Nassir, and is the vice-president and 49percent shareholder of Respondent Pharmacy.

³ Respondent Nassir was not present during the inspection.

⁴ At hearing, Dr. Nassir explained that repackaged drugs involved taking a container filled with a large volume of medication and repackaging the medication into smaller bottles.

had failed to submit controlled substance data from at least September 20, 2010 to September 3, 2013.

10. In response, Respondents advised that Respondent Pharmacy had been taking steps to transmit its CURES reports on a weekly basis, but subsequently learned its transmissions had not been received. Consequently, beginning on July 18, 2013, Respondents elected to use an outside company to submit CURES reports on behalf of Respondent Pharmacy.

11. With respect to the third violation regarding patient-centered labels, Inspector Ngondara found Respondent Pharmacy's prescription labels failed to conform to the requirements of CCR section 1707.5, in that, the order of the information on the labels should have first included the names of the patient, followed by the name of the drug, followed by the directions for use. Respondent Pharmacy's prescription labels first included the names of patients, followed by directions for use, followed by the name of the drug.

12. In response, Respondents indicated they had reformatted Respondent Pharmacy's patient-centered label to conform to the regulations by listing the name of the patient, followed by the name of the drug, followed by the directions for use.

13. With respect to the fourth violation regarding the Board's email notification list, Inspector Ngondara found Respondent Pharmacy failed to join the Board's email notification list, in violation of B&P Code section 4013.

14. In response, Respondents advised that they subscribed to the Board's email notification list on the day following the inspection, July 17, 2013.

15. With respect to the fifth violation five related to compounding expiration dating and labeling, Inspector Ngondara found Respondent Pharmacy contained completed compounded drug products that lacked expiration dating, in violation of CCR section 1735.2, subdivision (h), and CCR section 1735.2, subdivision (i). Specifically, Inspector Ngondara observed large buckets of compounded creams with no lot number or expiration date. He further found that the large buckets of medication were prepackaged into smaller cream dispensers which were not labeled either.

16. In response, Respondents stated that all identified items had been quarantined for reverse distribution.

17. With respect to the sixth violation regarding record keeping of compounded drug products, Inspector Ngondara found Respondent Pharmacy's compounding log did not include the equipment it used in compounding medications, in violation of CCR section 1735.3, subdivision (a).

18. In response, Respondents indicated that the compounding logs would now identify equipment used.

19. With respect to the seventh violation seven regarding the labeling of compounded drugs, Inspector Ngondara found Respondent Pharmacy contained prepackaged cream dispensers

that did not include a label which named each active ingredient, the lot number, or the expiration date, in violation of CCR section 1735.4, subdivisions (a) and (c). Additionally, large buckets of cream did not include lot numbers or expiration dates.

20. In response, Respondents advised that all compounded products were now labeled with expiration dates and lot numbers.

21. With respect to the eighth violation regarding the training of compounding staff, Inspector Ngondara found that while at the site, Payam Nassir could not locate written documentation evidencing training of compounding staff, in violation of CCR section 1735.7.

22. In response, Respondents submitted a copy of the Respondent Pharmacy's compounding policy and procedure manual, which they considered a training guide for all staff charged with compounding, as well as compounding training verification for one of its three pharmacy technicians.

23. With respect to the ninth violation regarding operational standards and security, Inspector Ngondara found Respondent Pharmacy contained buckets used to compound and store finished compounded cream, which were not clean, in violation of CCR section 1714. Additionally, the scale used to weigh medication was not clean.

24. In response, Respondents stated that stock intended for current use would be examined by a pharmacy technician every 60 days, that expired drugs would be removed for reverse distribution, and drugs scheduled to expire within 90 days would be identified.

Previous Inspection

25. At hearing, to offer further explanation about the alleged violations, Respondents proffered an inspection report from an inspection conducted less than a year prior to Inspector Ngondara's inspection. Specifically, on August 1, 2012, Sarah Bailey, Inspector of the Board, conducted an inspection of Respondent Pharmacy, prepared an inspection report, and provided a copy of it to Respondent Pharmacy. Respondent Nassir, who testified at hearing, explained Inspector Bailey found no deficiencies, but discussed new laws. Specifically, according to Respondent Nassir, she discussed patient centered labels for prescription drug containers and approved the manner in which Respondent Pharmacy prepared its patient centered labels. As such, he relied on this approval for his pharmacy (Respondent Pharmacy) when preparing patient centered labels.

26. Additionally, Respondent Nassir explained that Inspector Bailey discussed registering on the Board's email notification list, which he did on the spot, with her assistance. Finally, according to Respondent Nassir, Inspector Bailey discussed CURES with him, and determined that Respondent Pharmacy was compliant with his CURES submission. As such, Respondent Nassir had no idea why the Board believed he had not submitted his CURES through September 2013 or why the Board did not show that he had registered on its email notification list.

27. Inspector Bailey did not testify at hearing to authenticate or discuss the contents of her inspection report, or otherwise provide corroborating evidence of Respondent Nassir's testimony regarding her inspection report or her purported discussions with him.

Conviction

28. On October 21, 2014, Respondent Nassir was convicted in the Superior Court of California, County of Los Angeles, in Case No. SA076100, upon a plea of nolo contendere, of larceny, in violation of Penal Code section 496, a misdemeanor. The conviction was substantially related to the qualifications, functions, and duties of a licensee.

29. The purported facts and circumstances underlying the conviction were set forth in the investigation report of the Los Angeles County Sheriff's Department. The report indicated, among other things, that Respondent Pharmacy entered into a lease agreement on August 16, 2007 with Beverly Hills Triangle, LLC (lessor) for commercial property located in Beverly Hills. Respondents made improvements to the property, and in 2008, produced an addendum to the lease agreement that claimed the lessor would pay for the improvements, and would permit rent credit concessions, totaling more than \$400,000 in addendum provisions. However, the lessor alleged the addendum was a falsified document, resulting in the lessor filing and prevailing in a civil matter against Respondents, obtaining a \$700,000 judgment. The civil judgment, among other things, prompted the filing of criminal charges against Respondent Nassir in relation to the purported falsified addendum. Respondent Nassir entered into a plea agreement electing to plead nolo contendere to a larceny charge.

30. Respondent Nassir provided no relevant testimony concerning the criminal acts that led to his conviction. Rather, he attempted to contest the legitimacy of his conviction by attacking the character of others involved in the lease transaction, as well as in the prosecution of his criminal matter. Such action demonstrates a failure on his part to take responsibility for his conduct.

31. The court placed Respondent Nassir on summary probation for a period of 24 months, under certain terms and conditions, including spending one day in county jail, for which Respondent Nassir received a one day credit. The court also ordered Respondent to pay fines, fees, assessments, and restitution in the amount of \$160, and perform 30 days of Cal Trans service.

Costs of Prosecution

32. The Board incurred costs of investigation and prosecution in the amount of \$12,517.50. These costs are reasonable pursuant to Business and Professions Code section 125.3.

LEGAL CONCLUSIONS

1. a. In the part of this proceeding based on the accusation against a pharmacist, the burden of proof is on Complainant to establish alleged violations by "clear and convincing proof to a reasonable certainty." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135

Cal.App.3d 853.) This means the burden rests on Complainant to establish the charging allegations against a pharmacist by proof that is clear, explicit and unequivocal - so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.)

b. In the part of this proceeding based on the accusation against a pharmacy, the burden of proof remains on Complainant, but the standard of proof is preponderance of the evidence. The pharmacy's license is not a "professional" license in that there are not extensive education, training and testing requirements to obtain such licensure. Since it is a nonprofessional license, Complainant must establish cause for discipline against a pharmacy license by demonstrating cause for discipline by a preponderance of the evidence. (*Imports Performance v Dept. of Consumer Affairs, Bur. of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; *San Benito Foods v Veneman* (1996) 50 Cal.App.4th 1889.) Such distinction is unnecessary in this matter, however, because in this action, each violation found was proven by clear and convincing evidence.

2. Under Business and Professions Code section 4300, subdivision (a), the Board may suspend or revoke a license or registration.⁵

3. Code section 4301 states, in pertinent part, that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to:

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

"(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. ¶...¶

"(1) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty

⁵ All references to Code are to the Business and Professions Code except where noted.

or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision.

The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment." ¶...¶

"(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."

4. Code section 4302 provides:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

5. Health and Safety Code section 11165, subdivision (d), provides:

"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."

6. California Code of Regulations, title 16, section 1714, provides, in pertinent part:

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

"(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

7. California Code of Regulations, title 16, section 1707.5, subdivision (a), provides:

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

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

"(A) Name of the patient

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

"(C) The directions for the use of the drug.

"(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription."

8. Section 4013 provides, in pertinent part:

"(a) Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

"(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail notification list within 30 days of a change in the facility's e-mail address."

9. California Code of Regulations, title 16, section 1735.2, subdivisions (h) and (i), provides:

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

"(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product."

10. California Code of Regulations, title 16, section 1735.4, subdivision (c), provides:

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

11. California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), provides, "for each compounded drug product, the pharmacy records shall include ... the master formula record."

12. California Code of Regulations, title 16, section 1735.2, subdivision (d)(2), provides, "a drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes ... equipment to be used."

13. California Code of Regulations, title 16, section 1735.7, subdivisions (a) and (b), provides:

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

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

14. California Code of Regulations, title 16, section 1770, provides that a crime "shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

15. Cause exists to discipline the license of Respondent Nassir, pursuant to Code section 4301, subdivisions (f), (j), (l), and (o), in that he engaged in unprofessional conduct when he committed a criminal act of larceny that resulted in his misdemeanor conviction, as set forth in Factual Findings 28 through 31.

16. Cause does not exist to discipline the license of Respondent Pharmacy, pursuant to Code section 4301, in that Complainant failed to demonstrate that Respondent Pharmacy engaged in unprofessional conduct concerning alleged violations or misrepresentations in Respondent's Pharmacy's Community Pharmacy Self-Assessment and in its Compounding Self-Assessment, as Complainant proffered no self-assessment documents.

17. Cause exists to discipline the license of Respondent Nassir and Respondent Pharmacy, pursuant to Code section 4301, subdivisions (f), in conjunction with Code section 4302, in that Respondent Nassir, who was also owner of Respondent Pharmacy, committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption by committing a criminal act of larceny that resulted in his misdemeanor conviction, as set forth in Factual Findings 28 through 31.

18. Cause does not exist to discipline the license of Respondent Pharmacy, pursuant to Code section 4301, subdivision (f), in that Complainant failed to demonstrate that Respondent Pharmacy committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption in relation to alleged violations or misrepresentations in Respondent Pharmacy's Community Pharmacy Self-Assessment and in its Compounding Self-Assessment, as Complainant proffered no self-assessment documents.

19. Cause exists to discipline the licenses of Respondent Nassir and Respondent Pharmacy, pursuant to Code section 4301, subdivision (1), in conjunction with section 4302, in that Respondent Nassir, owner of Respondent Pharmacy, was convicted of a crime substantially related to the qualifications, functions, and duties of a licensee, evidenced by his conviction of larceny, as set forth in Factual Findings 28 through 31.

20. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1714. Specifically, evidenced by the results of a July 16, 2013 inspection, Respondents committed violations related to drug stock repackaging and labeling, compounding expiration date and labeling, labeling of compounded drugs, unclean buckets used to compound and store

finished compounded cream, and an unclean scale used to weigh medication, as set forth in Factual Findings 4 through 24.

21. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (j), in that they failed to comply with Health and Safety Code section 11165, subdivision (d), by failing to comply with weekly CURES reporting requirements, in that they failed to submit any CURES reports for nearly a three year period, as set forth in Factual Findings 4, 9, and 10. While Respondents contend that Inspector Baily had declared them in compliance with CURES during her August 1, 2012 inspection, Inspector Baily did not testify at hearing or otherwise substantiate Respondents' assertion. Additionally, Respondents offered no other credible, independent evidence suggesting their assertion is true. As such, Respondent's position is not persuasive.

22. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1707.5, subdivision (a), by failing to comply with labeling requirements in that patient-centered labels did not first list the name of the patient, then the name of the drug, followed by the directions for use, as set forth in Factual Findings 4 and 12.

23. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with Code section 4013, by failing to join the Board's email notification list, as set forth in Factual Findings 4 and 13. While Respondents contend they registered for the email notification list in the presence of Inspector Baily during her August 1, 2012 inspection, Inspector Baily did not testify at hearing or otherwise substantiate Respondents' assertion. Additionally, Respondents offered no other credible, independent evidence suggesting their assertion is true. As such, Respondents' contention is not persuasive.

24. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (h) and (i), by failing to comply with compounding requirements in that numerous prepackaged and compounded medications lacked expiration dates, as set forth in Factual Findings 4, 5, 15, and 19. While Respondents demonstrated through the testimony of Ms. Yeranosyan that some unlabeled medication in the prescription filling station were in the process of receiving labels, Respondents proffered no evidence to rebut Inspector Ngondara's testimony and report concerning labeling violations found in other areas of the pharmacy.

25. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.4, subdivision (c), by failing to comply with compounded drug labeling requirements, as set forth in Factual Findings 4, 5, 15, and 19.

26. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), in conjunction with section 1735.3, subdivision (d)(2), by failing to comply with compounded drug recordkeeping requirements, as set forth in Factual Findings 4 and 17.

27. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.7, by failing to comply with compounding staff training requirements, as Respondents failed to produce training verifications for all of their compounding staff, as set forth in Factual Findings 4 and 21.

28. A determination that cause exists to suspend or revoke Respondents' licenses does not end the inquiry. Such cause may be overcome with substantial, persuasive evidence of rehabilitation and good character. The Board has compiled a list of factors to evaluate whether a licensee has been rehabilitated from prior misconduct. That list, found in A Manual of Disciplinary Guidelines and Model Disciplinary Orders (Revised 10/2007), and which is incorporated by reference into the Board's regulations,⁶ includes the nature and severity of the act under consideration; the actual or potential harm to any consumer or to the public; a licensee's prior disciplinary record; aggravating evidence; rehabilitation evidence; the licensee's compliance with the terms of any sentence, probation, or parole; the time that has elapsed since commission of the act; and evidence of dismissal of any conviction under Penal Code section 1203.4.

29. Here, Respondent Nassir proffered no rehabilitation evidence in relation to his 2014 larceny conviction, and demonstrated no remorse. In fact, Respondent Nassir attempted to contest the legitimacy of his conviction by attacking the character of others involved in the lease transaction, as well as in the prosecution of his criminal matter, as opposed to accepting responsibility for his actions. The crime (i.e., larceny), by its nature, resulted in harm to a member of the public. Because the conviction was substantially related to the qualifications, functions or duties of a licensee, it demonstrates a potential for future harm to the public. Notwithstanding this, the evidence shows the crime itself occurred a significant time ago (i.e., approximately eight years), and Complainant has submitted no evidence demonstrating that Respondent Nassir has engaged in any criminal activity since then. As such, Respondent Nassir's crime appears to be aberrational.

30. Respondents presented credible evidence that they have made certain changes to prevent any further violations in Respondent Pharmacy. Specifically, after the last inspection, they elected to use an outside company to submit CURES reports on behalf of Respondent Pharmacy, reformatted patient-centered labels, began identifying equipment used on compounding logs, registered for the Board's email notification program, began labeling all compounded products with expiration dates and lot numbers, and committed to removing expired drugs for reverse distribution.

31. Pharmacy Law also requires that public protection must take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence. (Bus. & Prof. Code, § 4313.) This decision is made to protect consumers in accordance with the Board's statutory duty to prevent harm to consumers.

32. Given the above, outright revocation of Respondents' licenses is not necessary. Rather, a substantial period of probation with stringent, meaningful terms of probation should be

⁶ Cal. Code Regs., tit. 16, § 1760.

adequate to protect the public. As such, and because Respondent Nassir, as the president and 51 percent shareholder of Respondent Pharmacy, is thereby closely aligned with the overall management of Respondent Pharmacy, both Respondent Nassir and Respondent Pharmacy shall receive the same period of probation, to wit, five years, with specific terms and conditions. Given the severity of the misconduct, Respondent Nassir shall also be restricted from acting in any capacity as a mentor or supervisor to pharmacy staff, shall be restricted from preparing sterile products for the first part of probation, shall have supervised practice, shall not be allowed to obtain ownership of any new pharmacy, shall provide community service, and shall take an ethics course.

Costs

32. Under Code section 125.3, the Board may request the administrative law judge to direct a licensee found to have committed violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case. These reasonable costs are \$12,517.50, as set forth in Factual Finding 31.

33. Under *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.App.4th 32, 45, the Board must exercise its discretion to reduce or eliminate cost awards so as to prevent cost award statutes from deterring licensees with potentially meritorious claims or defenses from exercising their right to a hearing. "Thus the [Board] may not assess the full costs of investigation and prosecution when to do so will unfairly penalize a [licensee] who has committed some misconduct, but who has used the bearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed." (*Id.*) The Board, in imposing costs in such situations, must consider the licensee's subjective good faith belief in the merits of his or her position and the Board must consider whether or not the licensee has raised a colorable defense. The Board must also consider the licensee's ability to make payment.

34. Respondents did not challenge the costs, and presented no evidence indicating they were unable to pay them. As such, Respondent shall pay the Board its reasonable costs in the amount of \$12,517.50.

ORDER

Respondent Nassir

Pharmacist License Number RPH 46543 issued to Respondent Afshin Yousef Nassir is revoked; however, the order of revocation is stayed and Respondent Nassir is placed on probation for five (5) years upon the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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

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

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

2. Report to the Board

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

3. Interview with the Board

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

4. Cooperate with Board Staff

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

5. Continuing Education

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

6. Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in Board case number 5056 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in Board case number 5056, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in Board case number 5056 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in Board case number 5056 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

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

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

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

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$12,517.50. Respondent shall make said payments at the rate of \$1,251.75 or more each month until this obligation is satisfied.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation. Respondents Nassir and Pharmacy are jointly and severally liable for such costs.

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

9. Probation Monitoring Costs

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

10. Status of License

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

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

11. License Surrender While on Probation/Suspension

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

Upon acceptance of the surrender, Respondent shall relinquish his or her pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the License sought as of the date the application for that License is submitted to the Board, including any outstanding costs.

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

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

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

13. Tolling of Probation

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

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

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

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

14. Violation of Probation

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

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was

stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

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

16. Restricted Practice

Respondent Nassir shall not prepare, oversee or participate in the preparation of sterile drug products during the first three (3) years of probation.

17. Community Services Program

Within 60 days of the effective date of this decision, respondent shall submit to the board, for its prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 20 hours per year for each year of probation. Such service hours shall be separate and distinct hours from those provided by Respondent Pharmacy under its probationary terms below.

18. Supervised Practice

Respondent Nassir shall practice only under the supervision of a pharmacist not on probation with the board. Respondent shall not practice until the supervisor is approved by the board. The supervision shall be, as required by the board, either:

Continuous - 75% to 100% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

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

Within 30 days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating the supervisor has read the decision in case number 5056 and is familiar with the level of supervision as determined by the board.

If respondent changes employment, respondent shall have his or her new supervisor, within 15 days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 5056 and is familiar with the level of supervision as determined by the board.

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

19. No Supervision of Ancillary Personnel

Respondent Nassir shall not supervise any ancillary personnel, including, but not limited to, registered pharmacy technicians or exemptees, of any entity licensed by the board.

20. No New Ownership of Licensed Premises

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

21. Ethics Course

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

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

Respondent Pharmacy

License Number PHY 41455 issued to Respondent Pharmacy AYN Pharmacy dba The Prescription Center is revoked; however, the order of revocation is stayed and Respondent Pharmacy is placed on probation for five (5) years upon the following terms and conditions:

1. Obey All Laws

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

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or

the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. Report to the Board

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

3. Interview with the Board

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

4. Cooperate with Board Staff

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

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent owner shall pay to the Board its costs of investigation and prosecution in the amount of \$12,517.50, unless already satisfied pursuant to Probation Condition 8 listed above pertaining to Respondent Nassir. Respondent owner shall make said payments at the rate of \$1,251.75 or more each month until this obligation is satisfied. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation. Respondents Nassir and Pharmacy are jointly and severally liable for such costs.

The filing of bankruptcy by Respondent owner shall not relieve Respondent of its responsibility to reimburse the Board its costs of investigation and prosecution.

6. Probation Monitoring Costs

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

7. Status of License

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

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

8. License Surrender While on Probation/Suspension

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

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

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

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

Respondent owner further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

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

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

10. Owners and Officers: Knowledge of the Law

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

11. Posted Notice of Probation

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

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

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

12. Violation of Probation

If a Respondent owner has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent license, and probation shall be automatically

extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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

13. Completion of Probation

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

14. Community Services Program

Within sixty (60) days of the effective date of this decision, Respondent Pharmacy shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least 20 hours per year for each year of probation. Such service hours shall be separate and distinct hours from those provided by Respondent Nassir under his probationary terms above.

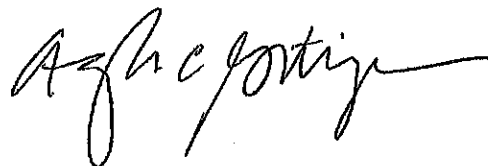
Within thirty (30) days of board approval thereof, respondent owner shall submit documentation to the board demonstrating commencement of the community service program. Respondent owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

This Decision shall become effective at 5:00 p.m. on November 28, 2016.

It is so ORDERED on October 25, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:

AYN PHARMACY DBA THE
PRESCRIPTION CENTER; AFSHIN
YOUSSEF NASSIR, PRESIDENT; PAYAM
NASSIR, VICE PRESIDENT,
Permit No. PHY 41544

and

AFSHIN YOUSSEF NASSIR
Pharmacist License No. RPH 46543

Respondents.

Case No. 5056

OAH No. 2015090262

TO ALL PARTIES AND THEIR ATTORNEY OF RECORD:

ORDER SETTING DATE FOR SUBMISSION OF WRITTEN ARGUMENT

The administrative record of the hearing in the above-entitled matter having now become available, the parties are hereby notified of the opportunity to submit written argument in accordance with the Order Rejecting the Proposed Decision dated July 15, 2016.

Written argument shall be filed with the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, California, 95834 on or before September 19, 2016. **No new evidence may be submitted.**

IT IS SO ORDERED this 18th day of August 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:

AYN PHARMACY DBA THE
PRESCRIPTION CENTER; AFSHIN
YOUSSEF NASSIR, PRESIDENT; PAYAM
NASSIR, VICE PRESIDENT,
Permit No. PHY 41455

and

AFSHIN YOUSSEF NASSIR,
Pharmacist License No. RPH 46543

Respondents.

Case No. 5056

OAH No. 2015090262

ORDER REJECTING PROPOSED DECISION

Pursuant to section 11517 of the Government Code, the Proposed Decision of the administrative law judge in the above-entitled matter is rejected. The California State Board of Pharmacy (hereinafter "board") will decide the case upon the record, including the transcript(s) of the hearing, and upon such written argument as the parties may wish to submit. No new evidence will be permitted.

The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

It is so ORDERED on July 15, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:

AYN PHARMACY DBA THE
PRESCRIPTION CENTER; AFSHIN
YOUSEF NASSIR, PRESIDENT; PAYAM
NASSIR, VICE PRESIDENT,

Permit No. PHY 41455

and

AFSHIN YOUSEF NASSIR,

Pharmacist License No. RPH 46543

Respondents.

Case No. 5056

OAH No. 2015090262

PROPOSED DECISION

This matter came on regularly for hearing on March 14, 2016, before Carla L. Garrett, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, in Los Angeles, California.

Kevin J. Rigley, Deputy Attorney General, represented Complainant Virginia Herold, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Complainant). Herbert L. Weinberg, Attorney at Law, represented Respondent AYN Pharmacy dba The Prescription Center (Respondent Pharmacy) and Respondent Afshin Yousef Nassir (Respondent Nassir), who appeared at the hearing.

At the hearing, the Accusation was amended to reflect the withdrawal of paragraph 18(b) in its entirety, and to show the change from "through" to "and" in the last line of paragraph 19, such that it read, "paragraph 18, subparagraphs a and c, inclusive, as though set forth fully herein."

Oral and documentary evidence was received, the record was closed, and the matter was submitted for decision on March 14, 2016.

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FACTUAL FINDINGS

1. On July 21, 2015, Complainant executed Accusation 5056 against Respondents in her official capacity as Executive Officer of the Board of Pharmacy (the Board).¹ Respondents filed a request for a hearing.
2. On December 23, 1996, the Board issued Permit Number PHY 41455 to Respondent Pharmacy. The registration was in full force and effect at all relevant times and will expire on March 1, 2017, unless renewed.
3. On August 16, 1993, the Board issued Pharmacist License Number RPH 46543 to Respondent Nassir, which was in full force and effect at all relevant times. Respondent Nassir is and has been the president, 51 percent shareholder, and the pharmacist in charge of Respondent Pharmacy since March 18, 1996.

Inspection

4. After receiving multiple complaints concerning Respondent Pharmacy, the Board assigned Antony Ngondara, Inspector, to investigate. Inspector Ngondara, who is a pharmacist, testified at hearing. On July 16, 2013, Inspector Ngondara, along with Inspector Christine Acosta, conducted an unannounced on-site inspection of Respondent Pharmacy. The results of the inspection and investigation revealed nine purported violations identified by Inspector Ngondara. Specifically, the noted violations related to: (1) drug stock repackaging and labeling; (2) Controlled Substance Utilization Review and Evaluation System (CURES) reporting; (3) patient-centered labels; (4) the Board's email notification list; (5) compounding expiration date and labeling; (6) record keeping of compounded drug product; (7) labeling of compounded drugs; (8) training of compounding staff, and (9) operational standards and security. During the inspection, Inspector Ngondara took photographs depicting the purported violations. He prepared a written report on November 13, 2013.

5. With respect to the first violation (drug stock repackaging and labeling), Inspector Ngondara found that Respondent Pharmacy contained unlabeled bottles of prepackaged medications at the filling station, in violation of Business and Professions Code (B&P Code) section 4342 and California Code of Regulations, title 16, (CCR), section 1714, subdivision (b). Additionally, he found filled cream dispensers in the compounding area, but they were unlabeled. The unlabeled medications did not contain expiration dates or lot numbers. Also, he found that some stock medications and finished compound products had expired, had no expiration dates, or contained unclear labeling. Inspector Ngondara

¹ The Accusation alleges in Paragraph 18(a) that "Respondents submitted a Community Pharmacy Self-Assessment and a Compounding Self-Assessment to the Board, both signed under penalty of perjury by Respondent Pharmacist, wherein Respondents falsely represented that Respondent Pharmacy was in compliance with various state laws." However, no self-assessment completed by Respondents was proffered or received into evidence.

considered finished products with no expiration date as lacking quality of strength and, therefore, unfit for use in compounding or distributing to patients. Consequently, he ordered that the medication be destroyed.

6. Lusine Yeranosyan, who served as one of Respondent Pharmacy's pharmacy technicians, testified at hearing. She was present at the time of the inspection. Ms. Yeranosyan was working at the prescription counter and was in the process of labeling the unlabeled bottles on the shelf. Specifically, Respondent Pharmacy had received multiple orders for the same prescription, which she was in the process of filling or renewing. She continued labeling the bottles as Inspectors Ngondara and Acosta conducted their inspection. It took approximately 45 minutes to complete the labeling of the bottles. At hearing, Inspector Ngondara conceded that medications left unlabeled for a short period, while awaiting labels stemming from multiple prescriptions of the same medication, would not have been a violation.

7. Dr. Payim Nassir,² who served as Respondent Pharmacy's vice president, testified at hearing. He was present at the time of the inspection.³ With respect to some of the expired medication, Dr. Nassir explained that Respondent Pharmacy contained a cabinet designated for drugs that were to be destroyed, which included expired drugs. The general protocol for expired drugs was to quarantine the expired medication in a separate part of the pharmacy in the cabinet, where they awaited the individual from the distribution company to retrieve the expired drugs and destroy them, which generally occurred every six months.

8. In response to Inspector Ngondara's inspection, on July 26, 2013, Respondents emailed, through their attorney, a letter addressing the violations cited. With respect to the first violation concerning drug stock repackaging and labeling, in addition to unlabeled medication that Ms. Yeranosyan was addressing at the time of the inspection, and the expired drugs quarantined in a cabinet, Respondents advised that all recently repackaged drugs⁴ were packed for shipment via RxReverse Distributors. They were processed on July 26, 2013.

9. With respect to the second violation regarding CURES reporting, Inspector Ngondara found that Respondent Pharmacy failed to transmit dispensed controlled substance data on a weekly basis to the Department of Justice, in violation of Health and Safety Code (H&S Code), section 11165, subdivision (d). To confirm whether Respondent Pharmacy had committed this violation, Inspector Ngondara requested a compliance report from the Board's CURES analyst, who provided him with a compliance report with a date range of September 20, 2010 through September 20, 2013. By reference to the compliance report,

² Payam Nassir is the brother of Respondent Nassir, and is the vice-president and 49 percent shareholder of Respondent Pharmacy.

³ Respondent Nassir was not present during the inspection.

⁴ At hearing, Dr. Nassir explained that repackaged drugs involved taking a container filled with a large volume of medication and repackaging the medication into smaller bottles.

Respondent Pharmacy had failed to submit controlled substance data from at least September 20, 2010 to September 3, 2013.

10. In response, Respondents advised that Respondent Pharmacy had been taking steps to transmit its CURES reports on a weekly basis, but subsequently learned its transmissions had not been received. Consequently, beginning on July 18, 2013, Respondents elected to use an outside company to submit CURES reports on behalf of Respondent Pharmacy.

11. With respect to the third violation regarding patient-centered labels, Inspector Ngondara found Respondent Pharmacy's prescription labels failed to conform to the requirements of CCR section 1707.5, in that, the order of the information on the labels should have first included the names of the patient, followed by the name of the drug, followed by the directions for use. Respondent Pharmacy's prescription labels first included the names of patients, followed by directions for use, followed by the name of the drug.

12. In response, Respondents indicated they had reformatted Respondent Pharmacy's patient-centered label to conform to the regulations by listing the name of the patient, followed by the name of the drug, followed by the directions for use.

13. With respect to the fourth violation regarding the Board's email notification list, Inspector Ngondara found Respondent Pharmacy failed to join the Board's email notification list, in violation of B&P Code section 4013.

14. In response, Respondents advised that they subscribed to the Board's email notification list on the day following the inspection, July 17, 2013.

15. With respect to the fifth violation five related to compounding expiration dating and labeling, Inspector Ngondara found Respondent Pharmacy contained completed compounded drug products that lacked expiration dating, in violation of CCR section 1735.2, subdivision (h), and CCR section 1735.2, subdivision (i). Specifically, Inspector Ngondara observed large buckets of compounded creams with no lot number or expiration date. He further found that the large buckets of medication were prepackaged into smaller cream dispensers which were not labeled either.

16. In response, Respondents stated that all identified items had been quarantined for reverse distribution.

17. With respect to the sixth violation regarding record keeping of compounded drug products, Inspector Ngondara found Respondent Pharmacy's compounding log did not include the equipment it used in compounding medications, in violation of CCR section 1735.3, subdivision (a).

18. In response, Respondents indicated that the compounding logs would now identify equipment used.

19. With respect to the seventh violation seven regarding the labeling of compounded drugs, Inspector Ngondara found Respondent Pharmacy contained prepackaged cream dispensers that did not include a label which named each active ingredient, the lot number, or the expiration date, in violation of CCR section 1735.4, subdivisions (a) and (c). Additionally, large buckets of cream did not include lot numbers or expiration dates.

20. In response, Respondents advised that all compounded products were now labeled with expiration dates and lot numbers.

21. With respect to the eighth violation regarding the training of compounding staff, Inspector Ngondara found that while at the site, Payam Nassir could not locate written documentation evidencing training of compounding staff, in violation of CCR section 1735.7.

22. In response, Respondents submitted a copy of the Respondent Pharmacy's compounding policy and procedure manual, which they considered a training guide for all staff charged with compounding, as well as compounding training verification for one of its three pharmacy technicians.

23. With respect to the ninth violation regarding operational standards and security, Inspector Ngondara found Respondent Pharmacy contained buckets used to compound and store finished compounded cream, which were not clean, in violation of CCR section 1714. Additionally, the scale used to weigh medication was not clean.

24. In response, Respondents stated that stock intended for current use would be examined by a pharmacy technician every 60 days, that expired drugs would be removed for reverse distribution, and drugs scheduled to expire within 90 days would be identified.

Previous Inspection

25. At hearing, to offer further explanation about the alleged violations, Respondents proffered an inspection report from an inspection conducted less than a year prior to Inspector Ngondara's inspection. Specifically, on August 1, 2012, Sarah Bayley, Inspector of the Board, conducted an inspection of Respondent Pharmacy, prepared an inspection report, and provided a copy of it to Respondent Pharmacy. Respondent Nassir, who testified at hearing, explained Inspector Bailey found no deficiencies, but discussed new laws. Specifically, according to Respondent Nassir, she discussed patient centered labels for prescription drug containers and approved the manner in which Respondent Pharmacy prepared its patient centered labels. As such, he relied on this approval for his pharmacy (Respondent Pharmacy) when preparing patient centered labels.

26. Additionally, Respondent Nassir explained that Inspector Bailey discussed registering on the Board's email notification list, which he did on the spot, with her assistance. Finally, according to Respondent Nassir, Inspector Bailey discussed CURES with him, and determined that Respondent Pharmacy was compliant with his CURES submission. As such, Respondent Nassir had no idea why the Board believed he had not

submitted his CURES through September 2013 or why the Board did not show that he had registered on its email notification list.

27. Inspector Bailey did not testify at hearing to authenticate or discuss the contents of her inspection report, or otherwise provide corroborating evidence of Respondent Nassir's testimony regarding her inspection report or her purported discussions with him.

Conviction

28. On October 21, 2014, Respondent Nassir was convicted in the Superior Court of California, County of Los Angeles, in Case No. SA076100, upon a plea of nolo contendere, of larceny, in violation of Penal Code section 496, a misdemeanor. The conviction was substantially related to the qualifications, functions, and duties of a licensee.

29. The purported facts and circumstances underlying the conviction were set forth in the investigation report of the Los Angeles County Sheriff's Department. The report indicated, among other things, that Respondent Pharmacy entered into a lease agreement on August 16, 2007 with Beverly Hills Triangle, LLC (lessor) for commercial property located in Beverly Hills. Respondents made improvements to the property, and in 2008, produced an addendum to the lease agreement that claimed the lessor would pay for the improvements, and would permit rent credit concessions, totaling more than \$400,000 in addendum provisions. However, the lessor alleged the addendum was a falsified document, resulting in the lessor filing and prevailing in a civil matter against Respondents, obtaining a \$700,000 judgment. The civil judgment, among other things, prompted the filing of criminal charges against Respondent Nassir in relation to the purported falsified addendum. Respondent Nassir entered into a plea agreement electing to plead nolo contendere to a larceny charge.

30. Respondent Nassir provided no relevant testimony concerning the criminal acts that led to his conviction. Rather, he attempted to contest the legitimacy of his conviction by attacking the character of others involved in the lease transaction, as well as in the prosecution of his criminal matter. Such action demonstrates a failure on his part to take responsibility for his conduct.

31. The court placed Respondent Nassir on summary probation for a period of 24 months, under certain terms and conditions, including spending one day in county jail, for which Respondent Nassir received a one day credit. The court also ordered Respondent to pay fines, fees, assessments, and restitution in the amount of \$160, and perform 30 days of Cal Trans service.

Costs of Prosecution

32. The Board incurred costs of investigation and prosecution in the amount of \$12,517.50. These costs are reasonable pursuant to Business and Professions Code section 125.3.

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LEGAL CONCLUSIONS

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

2. Under Business and Professions Code section 4300, subdivision (a), the Board may suspend or revoke a license or registration.⁵

3. Code section 4301 states, in pertinent part, that the Board shall take action against any holder of a license who is guilty of unprofessional conduct, which includes, but is not limited to:

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

“(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. ¶ . . . ¶

“(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision.

⁵ All statutory references are to the Business and Professions Code except where noted.

The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.” ¶ . . . ¶

“(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.”

4. Code section 4302 provides:

“The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.”

5. Health and Safety Code section 11165, subdivision (d), provides:

“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.”

6. California Code of Regulations, title 16, section 1714, provides, in pertinent part:

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

“(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.”

7. California Code of Regulations, title 16, section 1707.5, subdivision (a), provides:

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

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

“(A) Name of the patient

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

“(C) The directions for the use of the drug.

“(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.”

8. Section 4013 provides, in pertinent part:

“(a) Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

“(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail notification list within 30 days of a change in the facility's e-mail address.”

9. California Code of Regulations, title 16, section 1735.2, subdivisions (h) and (i), provides:

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

“(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.”

10. California Code of Regulations, title 16, section 1735.4, subdivision (c), provides:

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

11. California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), provides, “for each compounded drug product, the pharmacy records shall include . . . the master formula record.”

12. California Code of Regulations, title 16, section 1735.2, subdivision (d)(2), provides, “a drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes . . . equipment to be used.”

13. California Code of Regulations, title 16, section 1735.7, subdivisions (a) and (b), provides:

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

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

14. California Code of Regulations, title 16, section 1770, provides that a crime “shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.”

15. Cause exists to discipline the license of Respondent Nassir, pursuant to Code section 4301, subdivisions (f), (j), (l), and (o), in that he engaged in unprofessional conduct when he committed a criminal act of larceny that resulted in his misdemeanor conviction, as set forth in Factual Findings 28 through 31.

16. Cause does not exist to discipline the license of Respondent Pharmacy, pursuant to Code section 4301, in that Complainant failed to demonstrate that Respondent Pharmacy engaged in unprofessional conduct concerning alleged violations or misrepresentations in Respondent’s Pharmacy’s Community Pharmacy Self-Assessment and in its Compounding Self-Assessment, as Complainant proffered no self-assessment documents.

17. Cause exists to discipline the license of Respondent Nassir, pursuant to Code section 4301, subdivisions (f), in that he committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption by committing a criminal act of larceny that resulted in his misdemeanor conviction, as set forth in Factual Findings 28 through 31.

18. Cause does not exist to discipline the license of Respondent Pharmacy, pursuant to Code section 4301, subdivision (f), in that Complainant failed to demonstrate that Respondent Pharmacy committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption in relation to alleged violations or misrepresentations in Respondent Pharmacy’s Community Pharmacy Self-Assessment and in its Compounding Self-Assessment, as Complainant proffered no self-assessment documents.

19. Cause exists to discipline the license of Respondent Nassir, pursuant to Code section 4301, subdivision (l), in conjunction with section 4302, in that he was convicted of a crime substantially related to the qualifications, functions, and duties of a licensee, evidenced by his conviction of larceny, as set forth in Factual Findings 28 through 31.

20. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1714. Specifically, evidenced by the results of a July 16, 2013 inspection, Respondents committed violations related to drug stock repackaging and labeling, compounding expiration date and labeling, labeling of compounded drugs, unclean buckets used to compound and store finished compounded cream, and an unclean scale used to weigh medication, as set forth in Factual Findings 4 through 24.

21. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (j), in that they failed to comply with Health and Safety Code section 11165, subdivision (d), by failing to comply with weekly CURES reporting requirements, in that they failed to submit any CURES reports for nearly a three year period, as set forth in Factual Findings 4, 9, and 10. While Respondents contend that Inspector Baily had declared them in compliance with CURES during her August 1, 2012 inspection, Inspector Baily did not testify at hearing or otherwise substantiate Respondents' assertion. Additionally, Respondents offered no other credible, independent evidence suggesting their assertion is true. As such, Respondent's position is not persuasive.

22. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1707.5, subdivision (a), by failing to comply with labeling requirements in that patient-centered labels did not first list the name of the patient, then the name of the drug, followed by the directions for use, as set forth in Factual Findings 4 and 12.

23. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with Code section 4013, by failing to join the Board's email notification list, as set forth in Factual Findings 4 and 13. While Respondents contend they registered for the email notification list in the presence of Inspector Baily during her August 1, 2012 inspection, Inspector Baily did not testify at hearing or otherwise substantiate Respondents' assertion. Additionally, Respondents offered no other credible, independent evidence suggesting their assertion is true. As such, Respondents' contention is not persuasive.

24. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (h) and (i), by failing to comply with compounding requirements in that numerous prepackaged and compounded medications lacked expiration dates, as set forth in Factual Findings 4, 5, 15, and 19. While Respondents demonstrated through the testimony of Ms. Yeranosyan that some unlabeled medication in the prescription filling station were in the process of receiving labels, Respondents proffered no evidence to rebut Inspector Ngondara's testimony and report concerning labeling violations found in other areas of the pharmacy.

25. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of

Regulations, title 16, section 1735.4, subdivision (c), by failing to comply with compounded drug labeling requirements, as set forth in Factual Findings 4, 5, 15, and 19.

26. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), in conjunction with section 1735.3, subdivision (d)(2), by failing to comply with compounded drug recordkeeping requirements, as set forth in Factual Findings 4 and 17.

27. Cause exists to discipline the licenses of Respondents, pursuant to Code section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.7, by failing to comply with compounding staff training requirements, as Respondents failed to produce training verifications for all of their compounding staff, as set forth in Factual Findings 4 and 21.

28. A determination that cause exists to suspend or revoke Respondents' licenses does not end the inquiry. Such cause may be overcome with substantial, persuasive evidence of rehabilitation and good character. The Board has compiled a list of factors to evaluate whether a licensee has been rehabilitated from prior misconduct. That list, found in *A Manual of Disciplinary Guidelines and Model Disciplinary Orders* (Revised 10/2007), and which is incorporated by reference into the Board's regulations,⁶ includes the nature and severity of the act under consideration; the actual or potential harm to any consumer or to the public; a licensee's prior disciplinary record; aggravating evidence; rehabilitation evidence; the licensee's compliance with the terms of any sentence, probation, or parole; the time that has elapsed since commission of the act; and evidence of dismissal of any conviction under Penal Code section 1203.4.

29. Here, Respondent Nassir proffered no rehabilitation evidence in relation to his 2014 larceny conviction, and demonstrated no remorse. In fact, Respondent Nassir attempted to contest the legitimacy of his conviction by attacking the character of others involved in the lease transaction, as well as in the prosecution of his criminal matter, as opposed to accepting responsibility for his actions. The crime (i.e., larceny), by its nature, resulted in harm to a member of the public. Because the conviction was substantially related to the qualifications, functions or duties of a licensee, it demonstrates a potential for future harm to the public. Notwithstanding this, the evidence shows the crime itself occurred a significant time ago (i.e., approximately eight years), and Complainant has submitted no evidence demonstrating that Respondent Nassir has engaged in any criminal activity since then. As such, Respondent Nassir's crime appears to be aberrational.

30. Respondents presented credible evidence that they have made certain changes to prevent any further violations in Respondent Pharmacy. Specifically, after the last inspection, they elected to use an outside company to submit CURES reports on behalf of Respondent Pharmacy, reformatted patient-centered labels, began identifying equipment used on compounding logs, registered for the Board's email

⁶ Cal. Code Regs., tit. 16, § 1760.

notification program, began labeling all compounded products with expiration dates and lot numbers, and committed to removing expired drugs for reverse distribution.

31. Given the above, revocation of Respondents' licenses is not necessary. Rather, a substantial period of probation should be adequate to protect the public. As such, and because Respondent Nassir, as the president and 51 percent shareholder of Respondent Pharmacy, is thereby closely aligned with the overall management of Respondent Pharmacy, both Respondent Nassir and Respondent Pharmacy shall receive the same period of probation, to wit, three years, with specific terms and conditions.

Costs

32. Under Code section 125.3, the Board may request the administrative law judge to direct a licensee found to have committed violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case. These reasonable costs are \$12,517.50, as set forth in Factual Finding 31.

33. Under *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.App.4th 32, 45, the Board must exercise its discretion to reduce or eliminate cost awards so as to prevent cost award statutes from deterring licensees with potentially meritorious claims or defenses from exercising their right to a hearing. "Thus the [Board] may not assess the full costs of investigation and prosecution when to do so will unfairly penalize a [licensee] who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed." (*Id.*) The Board, in imposing costs in such situations, must consider the licensee's subjective good faith belief in the merits of his or her position and the Board must consider whether or not the licensee has raised a colorable defense. The Board must also consider the licensee's ability to make payment.

34. Respondents did not challenge the costs, and presented no evidence indicating they were unable to pay them. As such, Respondent shall pay the Board its reasonable costs in the amount of \$12,517.50.

ORDER

Respondent Nassir

Pharmacist License Number RPH 46543 issued to Respondent Afshin Yousef Nassir is revoked; however, the order of revocation is stayed and Respondent Nassir is placed on probation for three (3) years upon the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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

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

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

2. Report to the Board

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

3. Interview with the Board

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

4. Cooperate with Board Staff

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

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5. Continuing Education

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

6. Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 2015090262 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 2015090262, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 2015090262 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 2015090262 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

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

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

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

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$12,517.50. Respondent shall make said payments at the rate of \$1,251.75 or more each month until this obligation is satisfied.

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

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

9. Probation Monitoring Costs

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

10. Status of License

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

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

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may tender his or her license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other

action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish his or her pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

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

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

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

13. Tolling of Probation

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the Board or its designee may consider a modification of this requirement. If Respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

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

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

probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

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

Respondent Pharmacy

Permit Number PHY 41455 issued to Respondent Pharmacy AYN Pharmacy dba The Prescription Center is revoked; however, the order of revocation is stayed and Respondent Pharmacy is placed on probation for three (3) years upon the following terms and conditions:

1. Obey All Laws

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

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's 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.

2. Report to the Board

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

3. Interview with the Board

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

4. Cooperate with Board Staff

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

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent owner shall pay to the Board its costs of investigation and prosecution in the amount of \$12,517.50, unless already satisfied pursuant to Probation Condition 8 listed above pertaining to Respondent Nassir. Respondent owner shall make said payments at the rate of \$1,251.75 or more each month until this obligation is satisfied. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent owner shall not relieve Respondent of its responsibility to reimburse the Board its costs of investigation and prosecution.

6. Probation Monitoring Costs

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

7. Status of License

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

If Respondent license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal

or reapplication Respondent's permit shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

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

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

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

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

Respondent owner further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

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

(15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

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

10. Owners and Officers: Knowledge of the Law

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

11. Posted Notice of Probation

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

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

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

12. Violation of Probation

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

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

13. Completion of Probation

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

DATED: April 13, 2016

DocuSigned by:
Carla Garrett
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CARLA L. GARRETT
Administrative Law Judge
Office of Administrative Hearings

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7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 5056

11 **AYN PHARMACY DBA THE**
12 **PRESCRIPTION CENTER; AFSHIN**
13 **YOUSEF NASSIR, PRESIDENT; PAYAM**
14 **NASSIR, VICE PRES.**
9730 Wilshire Blvd., Suite 103 & 114
Beverly Hills, CA 90212

A C C U S A T I O N

15 Permit No. PHY 41455,

16 and

17 **AFSHIN YOUSEF NASSIR**
18 **9730 Wilshire Blvd # 103**
Beverly Hills, CA 90210

19 **Pharmacist License No. RPH 46543**

20 Respondents.

21
22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about December 23, 1996, the Board of Pharmacy issued Permit Number PHY
27 41455 to Ayn Pharmacy dba The Prescription Center; Afshin Yousef Nassir, President; Payam

28 ///

1 Nassir, Vice Pres. (Respondent Pharmacy). The Permit was in full force and effect at all times
2 relevant to the charges brought herein and will expire on March 1, 2016, unless renewed.

3 3. On or about August 16, 1993, the Board of Pharmacy issued Pharmacist License
4 Number RPH 46543 to Afshin Yousef Nassir (Respondent Pharmacist). The Pharmacist License
5 was in full force and effect at all times relevant to the charges brought herein and will expire on
6 July 31, 2015, unless renewed.

7 JURISDICTION

8 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
9 Consumer Affairs, under the authority of the following laws. All section references are to the
10 Business and Professions Code unless otherwise indicated.

11 5. Section 4300.1 states:

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

17 STATUTES

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

21 7. Section 4301 states:

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

25 ...

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

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

3

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

6 . . .

7 “(l) The conviction of a crime substantially related to the qualifications, functions, and duties
8 of a licensee under this chapter. The record of conviction of a violation of Chapter 13
9 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
10 substances or of a violation of the statutes of this state regulating controlled substances or
11 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the
12 record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The
13 board may inquire into the circumstances surrounding the commission of the crime, in order to fix
14 the degree of discipline or, in the case of a conviction not involving controlled substances or
15 dangerous drugs, to determine if the conviction is of an offense substantially related to the
16 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a
17 conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of
18 this provision. The board may take action when the time for appeal has elapsed, or the judgment of
19 conviction has been affirmed on appeal or when an order granting probation is made suspending
20 the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal
21 Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or
22 setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

23 . . .

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

28 8. Section 4302 provides:

1 “The board may deny, suspend, or revoke any license of a corporation where conditions
2 exist in relation to any person holding 10 percent or more of the corporate stock of the
3 corporation, or where conditions exist in relation to any officer or director of the corporation that
4 would constitute grounds for disciplinary action against a licensee.”

5 9. Section 4013 provides, in pertinent part:

6 “(a) Any facility licensed by the board shall join the board's e-mail notification list within 60
7 days of obtaining a license or at the time of license renewal.

8 “(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail
9 notification list within 30 days of a change in the facility's e-mail address.

10

11 10. Health and Safety Code section 11165, subdivision (d), provides:

12 “For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance,
13 as defined in the controlled substances schedules in federal law and regulations, specifically
14 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal
15 Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
16 information to the Department of Justice as soon as reasonably possible, but not more than seven
17 days after the date a controlled substance is dispensed, in a format specified by the Department of
18 Justice:

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

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

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

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

- 1 (5) Quantity of the controlled substance dispensed.
- 2 (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision
- 3 (ICD-10) Code, if available.
- 4 (7) Number of refills ordered.
- 5 (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- 6 (9) Date of origin of the prescription.
- 7 (10) Date of dispensing of the prescription.

8 **REGULATIONS**

9 11. California Code of Regulations, title 16, section 1707.5, subdivision (a), provides in
10 pertinent part:

11 "Labels on drug containers dispensed to patients in California shall conform to the following
12 format:

13 (1) Each of the following items shall be clustered into one area of the label that comprises at
14 least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or,
15 if requested by the consumer, at least a 12-point typeface, and listed in the following order:

16 (A) Name of the patient

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

20 (C) The directions for the use of the drug.

21 (D) The condition or purpose for which the drug was prescribed if the condition or purpose
22 is indicated on the prescription.

23

24 12. California Code of Regulations, title 16, section 1714, provides in pertinent part:

25 . . .

26 (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
27 equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The

28

1 pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of
2 pharmacy.

3 (c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly
4 condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly
5 lighted. The pharmacy shall be equipped with a sink with hot and cold running water for
6 pharmaceutical purposes.

7

8 13. California Code of Regulations, title 16, section 1735.2, provides in pertinent part:

9 . . .

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

12 . . .

13 (2) Equipment to be used.

14 . . .

15 "(h) Every compounded drug product shall be given an expiration date representing the date
16 beyond which, in the professional judgment of the pharmacist performing or supervising the
17 compounding, it should not be used. This "beyond use date" of the compounded drug product
18 shall not exceed 180 days from preparation or the shortest expiration date of any component in the
19 compounded drug product, unless a longer date is supported by stability studies of finished drugs
20 or compounded drug products using the same components and packaging. Shorter dating than set
21 forth in this subsection may be used if it is deemed appropriate in the professional judgment of the
22 responsible pharmacist.

23 "(i) The pharmacist performing or supervising compounding is responsible for the proper
24 preparation, labeling, storage, and delivery of the compounded drug product.

25

26 14. California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), provides
27 that pharmacy records shall include the "master formula record" for each compounded drug
28 product.

1 15. California Code of Regulations, title 16, section 1735.4 provides:

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

5 "(b) A statement that the drug has been compounded by the pharmacy shall be included on
6 the container or on the receipt provided to the patient.

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

11 16. California Code of Regulations, title 16, section 1735.7, provides in pertinent part:

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

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

18

19 **COST RECOVERY**

20 17. Section 125.3 of the Code states, in pertinent part, that the Board may request the
21 administrative law judge to direct a licentiate found to have committed a violation or violations of
22 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
23 enforcement of the case.

24 **FIRST CAUSE FOR DISCIPLINE**

25 **(Unprofessional Conduct)**

26 18. Respondents are subject to disciplinary action under section 4301 in that Respondents
27 engaged in unprofessional conduct. The circumstances are as follows:

28 ///

1 a. Respondents submitted a Community Pharmacy Self-Assessment and a Compounding
2 Self Assessment to the Board, both signed under penalty of perjury by Respondent Pharmacist,
3 wherein Respondents falsely represented that Respondent Pharmacy was in compliance with
4 various state laws. Said misrepresentations include falsely stating that Respondent Pharmacy's
5 prescription labels were in compliance with state law, falsely stating that repackaged drugs were
6 labeled in compliance with state and federal law, falsely stating that records of each compounded
7 drug product included information about the equipment used in compounding the drug, falsely
8 stating labels on compounded drug products complied with state law regulating compounding
9 drugs, falsely stating that Respondent Pharmacy maintained written documentation demonstrating
10 that its compounding staff was properly skilled and trained in the compounding of drugs, and
11 falsely stating that Respondent maintained documentation of all compounding training provided to
12 pharmacy personnel.

13 b. Respondents have engaged in unprofessional and abusive business practices which
14 exploit and harm the California workers' compensation system. Specifically, for years
15 Respondents have charged exorbitant rates to workers' compensation insurance carriers for costs
16 and fees related to prescription medications. For example, with respect to Prescription No.
17 07941445, filled for Patient R.E. on or about July 15, 2013, Respondent Pharmacy charged the
18 carrier a total of \$6,611.95 for a 15-day supply (i.e., 120 grams) of ketoprofen 20%/lidocaine
19 5%/cyclobenzaprine 1% cream. The \$6,611.05 charge included \$1,318.20 for ingredient costs
20 plus a "dispensing fee" of \$5,293.73. Pursuant to the Workers' Compensation Pharmacy Fee
21 Schedule, the highest payment price for 120 grams of said cream, including a dispensing fee and
22 compounding fee, was \$373.66. Respondents' unprofessional and abusive business tactics also
23 include the sending of demand letters to carriers requiring payment of the exorbitant charges
24 within 30 days, and the filing of workers' compensation liens against the patient recoveries in cases
25 where full payment has not been received from the carrier. For example, in correspondence sent to
26 CNA Claims Plus Brea, dated December 5, 2012, Respondents cited charges totaling \$99,179.25
27 for filling fifteen 120-gram prescriptions of ketoprofen 20%/lidocaine 5%/cyclobenzaprine 1%
28 cream for Patient A.R. over an eight-month period (i.e., \$6611.95 per fill/refill). The demand

1 letter stated that although the charges totaled \$99,179.25, Respondents would accept \$83,000.00
2 in satisfaction of the bill as long as payment was received within 30 days. Respondents have
3 routinely engaged in such unprofessional business practices for years.

4 c. On or about August 16, 2007, Respondent Pharmacy entered into a lease agreement,
5 dated August 9, 2013, with Beverly Hills Triangle, LLC ("Lessor") wherein it agreed to lease
6 certain property located at 9735 Wilshire Boulevard in Beverly Hills, California, pursuant to
7 certain terms and conditions, for a period of four (4) years. The lease agreement was signed on
8 behalf of the lessee by Respondent Pharmacist in his capacity as president of Ayn Pharmacy
9 Corporation and on behalf of the Lessor by E.D. At the time that the lease agreement was
10 executed, E.D. had been diagnosed with terminal cancer and was not expected to survive the
11 duration of the lease agreement. Thereafter, Respondents made certain improvements to the
12 subject property, and in 2008 Respondents produced a purported addendum to the lease
13 agreement which they claimed required the Lessor to pay for said improvements. The claimed
14 addendum to the lease agreement also contained provisions related to purported rent credit
15 concessions, parking issues and lessee options for lease extensions. The claimed addendum to the
16 lease agreement was signed by Respondent Pharmacist on behalf of Ayn Pharmacy Corporation on
17 August 16, 2007, and was also purportedly signed by E.D. on behalf of the Lessor. If valid and
18 enforceable, the addendum to the lease agreement would have cost the Lessor more than
19 \$400,000.00 in property improvements and rent credits. The purported addendum to the lease
20 agreement was not genuine, however. Instead, it was a falsified document containing the forged
21 signature of E.D., which Respondents had prepared and produced as part of a scheme to defraud
22 the Lessor. The Lessor and E.D., filed a civil lawsuit against Respondents alleging that the
23 addendum had been forged and that Respondents had hoped to dupe the Lessor into believing it
24 has genuine after E.D. passed away from cancer. In the civil matter entitled *Beverly Hills*
25 *Triangle, LLC. V. Ayn Pharmacy Corp., et al.* (Super Ct. Los Angeles County, 2010, No.
26 BC399678), the Lessor and E.D. obtained a judgment against Respondents for more than
27 \$700,000.00 after a jury found that the signature of E.D. was a forgery. In the criminal matter
28 entitled *The People of the State of California v. Afshin Yousef Nassir* (Super. Ct. Los Angeles

1 County, 2010, No. SA076100), Respondent Nassir was charged with one felony count of forgery
2 and one count of larceny related to the falsified addendum. On or about October 21, 2014,
3 Respondent Nassir entered a plea of nolo contendere and was convicted of one count of violating
4 Penal Code section 496 (larceny). Pursuant to a plea agreement, the forgery charge was
5 dismissed.

6 **SECOND CAUSE FOR DISCIPLINE**

7 **(Act Involving Moral Turpitude/Dishonesty/Fraud/Deceit/Corruption)**

8 19. Respondents are subject to disciplinary action under section 4301, subdivision (f), in
9 that they engaged in an act involving moral turpitude, dishonesty, fraud, deceit and/or corruption.
10 Complainant refers to, and by this reference incorporates, the allegations set forth above in
11 paragraph 18, subparagraphs a through c, inclusive, as though set forth fully herein.

12 **THIRD CAUSE FOR DISCIPLINE**

13 **(Substantially-Related Criminal Conviction)**

14 20. Respondents are subject to disciplinary action under section 4301, subdivision (l), in
15 conjunction with section 4302, in that Respondent Nassir was convicted of a crime substantially
16 related to the qualifications, functions, and duties of a licensee. Complainant refers to, and by this
17 reference incorporates, the allegations set forth above in paragraph 18, subparagraph c, inclusive,
18 as though set forth fully herein.

19 **FOURTH CAUSE FOR DISCIPLINE**

20 **(Operational Standards Violation)**

21 21. Respondents are subject to disciplinary action under section 4301, subdivision (o), in
22 that they failed to comply with California Code of Regulations, title 16, section 1714. The
23 circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013,
24 Board inspectors observed the following violations: (1) Respondents' prescription filling station
25 contained numerous unlabeled bottles of prepackaged medications; (2) the medication
26 compounding area contained filled but unlabeled cream dispensers; (3) containers of both
27 tablet/capsule medication and compounded medication failed to identify expiration dates or lot
28 numbers; (4) many medication containers bore unclear labeling; (5) stock medications were

1 expired; (6) finished compound products had no expiration date; (7) the buckets used to
2 compound and store finish compounded cream were not clean; and (8) the scale used by
3 Respondents was not clean.

4 **FIFTH CAUSE FOR DISCIPLINE**

5 **(CURES Reporting Violations)**

6 22. Respondents are subject to disciplinary action under section 4301, subdivision (j), in
7 that they failed to comply with Health and Safety Code section 11165, subdivision (d). The
8 circumstances are that from September 20, 2010, to September 3, 2013, Respondents failed to
9 transmit required data to the California Department of Justice concerning their dispensing of
10 Schedule II, Schedule III and Schedule IV controlled substances.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Labeling Violations)**

13 23. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and
14 (o), in that they failed to comply with California Code of Regulations, title 16, section 1707.5,
15 subdivision (a). The circumstances are that during an inspection of Respondent pharmacy on or
16 about July 16, 2013, Board inspectors observed that finished prescription labels used by
17 Respondents failed to set forth drug and patient information in compliance with state law.

18 **SEVENTH CAUSE FOR DISCIPLINE**

19 **(Email Notification Violation)**

20 24. Respondents are subject to disciplinary action under section 4301, subdivision (o), in
21 that they failed to comply with section 4013. The circumstances are that Respondents failed to
22 join the Board's email notification list as required by state law.

23 **EIGHTH CAUSE FOR DISCIPLINE**

24 **(Violation of Compounding Requirements)**

25 25. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and
26 (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.2,
27 subdivisions (h) and (i). The circumstances are that during an inspection of Respondent

28 ///

1 pharmacy on or about July 16, 2013, Board inspectors observed that numerous prepackaged
2 compounded medications lacked expiration dates in violation of state law.

3 **NINTH CAUSE FOR DISCIPLINE**

4 **(Violation of Compounded Drug Labeling Requirements)**

5 26. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and
6 (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.4,
7 subdivision (c). The circumstances are that during an inspection of Respondent pharmacy on or
8 about July 16, 2013, Board inspectors observed that numerous prepackaged compounded
9 medications lacked proper labeling in that they did not provide medication strength, dosage form,
10 quantity, lot number and/or expiration information.

11 **TENTH CAUSE FOR DISCIPLINE**

12 **(Violation of Compounded Drug Recordkeeping Requirements)**

13 27. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and
14 (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3,
15 subdivision (a)(1), in conjunction with section 1735.2, subdivision (d)(2). The circumstances are
16 that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors
17 determined that Respondents' compounding logs failed to identify the equipment used in
18 compounding as required by state law.

19 **ELEVENTH CAUSE FOR DISCIPLINE**

20 **(Violation of Compounding Staff Training Requirements)**

21 28. Respondents are subject to disciplinary action under section 4301, subdivision (o), in
22 that they failed to comply with California Code of Regulations, title 16, section 1735.7. The
23 circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013,
24 Board inspectors determined that Respondents: (1) failed to maintain written documentation
25 sufficient to demonstrate that pharmacy personnel have the skills and training required to properly
26 and accurately perform their assigned responsibilities relating to compounding; (2) failed to
27 develop and maintain an on-going competency evaluation process for pharmacy personnel involved
28 in compounding and/or to maintain documentation of any and all such training.

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PRAYER

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

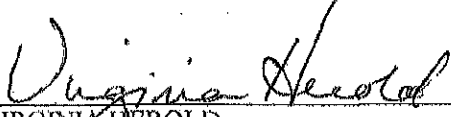
1. Revoking or suspending Permit Number PHY 41455, issued to Ayn Pharmacy dba The Prescription Center; Afshin Yousef Nassir, President; Payam Nassir, Vice Pres.;

2. Revoking or suspending Pharmacist License Number RPH 46543, issued to Afshin Yousef Nassir;

3. Ordering The Prescription Center and Afshin Yousef Nassir 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;

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

DATED: 7/21/15


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

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