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

In the Matter of the Accusation Against: **DR. N. VAHEDI PHARMACY INC. dba FUSION RX COMPOUNDING PHARMACY;** NAVID VAHEDI, President Pharmacy Permit No. PHY 49937, and **NAVID VAHEDI**, Pharmacist License No. RPH 59537 Respondents.	Case No. 5899 OAH No. 2017040451 ORDER GRANTING PETITION FOR RECONSIDERATION WITH RESPECT TO RESPONDENT FUSION RX COMPOUNDING ONLY

ORDER GRANTING RECONSIDERATION, IN PART,
AND
SETTING DATE FOR SUBMISSION OF WRITTEN ARGUMENT

On January 2, 2018, the California State Board of Pharmacy (Board) issued a Decision and Order adopting the administrative law judge's October 26, 2017, Proposed Decision as its decision in this matter[1]. Pursuant to section 11521 of the Government Code, on January 19, 2018, respondent Dr. N. Vahedi Pharmacy Inc., dba Fusion Rx Compounding Pharmacy (Fusion Rx Compounding Pharmacy), and its president, Navid Vahedi, timely requested reconsideration of a specific portion of the January 2, 2018, Decision and Order pertaining to pharmacy permit number PHY 49937. To allow it time to consider the petition, the Board issued a 10-day stay of the effective date of the entire decision.

Having now considered the petition, good cause appearing, IT IS HEREBY ORDERED:

(1) That reconsideration of the January 2, 2018, Decision and Order be, and hereby is, granted, as to respondent Fusion Rx Compounding Pharmacy (PHY 49937), only;

(2) The portion of the decision regarding respondent Fusion Rx Compounding Pharmacy (PHY 49937), is hereby further stayed until the Board renders its decision on reconsideration; and,

(3) That reconsideration will be based on the pertinent parts of the record in light of the petition for reconsideration. No new evidence will be allowed. Given the specificity of

[1] Minor technical changes were made to the Proposed Decision pursuant to Government Code section 11517, subdivision (c)(2)(C).

the request in the petition for reconsideration, the Board will not order a copy of the transcript of the hearing. The record will, however, include any written argument the parties may wish to submit. The Board is particularly interested in arguments addressing whether it is appropriate to suspend Fusion Rx Compounding Pharmacy's permit for 30 days, as described in page 27 of the Proposed Decision.

The parties shall have until **March 12, 2018**, to submit written argument. Any argument shall be served on the board at **1625 N. Market Blvd, N219, Sacramento, CA 95834, Attention Susan Cappello, Enforcement Manager.** Each party shall provide the other party with a copy of any written argument filed with the board.

The portion of the January 2, 2018, Decision and Order related to Respondent Navid Vahedi's pharmacist license (RPH 59537), initially effective February 1, 2018, and thereafter stayed until 5:00 p.m. February 11, 2018, shall become effective at 5:00 p.m. on February 11, 2018, as previously ordered.

IT IS SO ORDERED this 9th day of February, 2018.

By _____

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

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

In the Matter of the Accusation Against: **DR. N. VAHEDI PHARMACY INC. dba FUSION RX COMPOUNDING PHARMACY;** NAVID VAHEDI, president Pharmacy Permit No. PHY 49937, and **NAVID VAHEDI**, Pharmacist License No. RPH 59537 Respondents.	Case No. 5899 OAH No. 2017040451

ORDER STAYING EFFECTIVE DATE

Respondents Dr. N. Vahedi Pharmacy, Inc. dba Fusion Rx Compounding Pharmacy and Navid Vahedi timely requested reconsideration of the decision in the above-entitled matter pursuant to section 11521 of the Government Code. In order to allow the board additional time to consider the petition, in accordance with the provisions of section 11521 of the Government Code,

IT IS HEREBY ORDERED that the effective date of the Decision and Order, in the above-entitled matter is stayed until 5 p.m. on February 11, 2018.

IT IS SO ORDERED this 31st day of January 2018.

By _____

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

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

In the Matter of the Accusation Against: **DR. N VAHEDI PHARMACY INC. dba FUSION RX COMPOUNDING PHARMACY;** NAVID VAHEDI, president Pharmacy Permit No. PHY 49937, and **NAVID VAHEDI**, Pharmacist License No. RPH 59537 Respondents.	Case No. 5899 OAH No. 2017040451

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as the decision in the above-entitled matter, except that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical change is made to page 27 wherein the two paragraphs begin with "License number PHY 49537":

The license number should read as "PHY 49937".

The technical change made above does not affect the factual or legal basis of the Proposed Decision, which shall become effective at 5:00 p.m. on February 1, 2018.

IT IS SO ORDERED this 2nd day of January 2018.

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: DR. N. VAHEDI PHARMACY INC. dba FUSION RX COMPOUNDING PHARMACY; NAVID VAHEDI, president Pharmacy Permit No. PHY 49937, and NAVID VAHEDI, Pharmacist License No. RPH 59537, Respondents.	Case No. 5899 OAH No. 2017040451

PROPOSED DECISION

This matter came on regularly for hearing on September 25 and 26, 2017, at Los Angeles, California, before David B. Rosenman, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California. Complainant Virginia Herold was represented by Deputy Attorney General Gillian E. Friedman. Respondent Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX Compounding Pharmacy was present by its president, Navid Vahedi, who also was present in his individual capacity as a named respondent. Respondents were represented by Herb L. Weinberg, Attorney at Law.

Oral and documentary evidence was presented and the matter was submitted for decision on September 26, 2017.

At the hearing, two amendments were made to the Accusation. At page 8, line 17, the following sentence was added: "Also, an ingredient in compounded preparation was found to be expired." Also, at page 10, lines 7 and 19, the underlined phrase was added: "Fusion IV Specialty Pharmacy has not been licensed by the Board at that time." The amendments were made to the Accusation in exhibit 1 by interlineation, and were initialed and dated by the ALJ.

FACTUAL FINDINGS

The Administrative Law Judge finds the following facts:

1. The Accusation was issued by complainant Virginia Herold in her official capacity as Executive Officer of the Board of Pharmacy (Board). Respondents filed a request for a hearing.

2. On June 9, 2009, the Board issued Pharmacy permit number PHY 49937 to Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX Compounding Pharmacy (respondent Pharmacy) with Navid Vahedi as the President and Pharmacist in Charge. The Pharmacy permit was in full force and effect at all times relevant to the charges and will expire on June 1, 2018, unless renewed.

3. On May 3, 2007, the Board issued Original Pharmacist license number RPH 59537 to Navid Vahedi (respondent Vahedi). On June 9, 2009, respondent Vahedi became the Pharmacist in Charge (PIC) for respondent Pharmacy. The Original Pharmacist license was in full force and effect at all times relevant to the charges and will expire on May 31, 2019, unless renewed.

Inspection of Pharmacy

4. In early 2015, the Board received a complaint concerning respondent Pharmacy. The investigation of the complaint was assigned to Jennifer Hall, Pharm. D., an inspector for the Board who holds a pharmacist license issued by the Board. On August 26, 2015, Inspector Hall and her colleague, Inspector Anna Kalantar, performed an unannounced inspection of respondent pharmacy at its facility at 2001 Westwood Boulevard, Los Angeles, California.

5. The inspectors spoke to pharmacist Rod Delijani and several other employees. Respondent Vahedi arrived later, during the inspection. During the inspection, Inspector Hall also spoke by telephone to respondents' attorney, Mr. Weinberg. The inspectors did not find sufficient information to substantiate the complaint. However, they found circumstances that resulted in the allegations set forth in the Accusation.

Operating Policies; Cooperation with Investigation

6. Licensed pharmacies are required to have written policies and procedures covering various subjects, including policies (a) to help patients with limited or no English proficiency understand the information on the label of a medication, and (b) for theft of a dangerous drug by an employee, or chemical, mental or physical impairment of an employee.

7. The inspectors requested copies of these policies. Neither respondent Pharmacy not respondent Vahedi provided copies of these written policies to the inspectors

at the inspection on August 26, 2015. On that date, Inspector Hall wrote a notice that these policies were required and requested that respondent Vahedi send to her a statement relating to the policies. Inspector Hall did not receive any response to that request.

8. At the hearing, respondent Vahedi testified credibly that these two policies could be found in notebooks maintained at the facility. He submitted copies of the policies, received in evidence as exhibit H. The policies had been implemented when respondent Vahedi sought accreditation in 2012 from the Pharmacy Compounding Accreditation Board (PCAB), a voluntary, national organization that sets standards for compounding pharmacies.

9. Respondent Vahedi testified credibly that, after the inspection, he purchased a set of operating policies in a manual compiled and sold by an attorney with expertise in pharmacy law. This manual has policies on both subjects (see ex. A, pp. 10 and 12). The new policies were attached to a letter from respondents' attorney, Mr. Weinberg, addressed to Inspector Hall and dated September 8, 2015 (ex. A, pp. 1 and 2). Mr. Weinberg's letter also addressed several of the inspector's findings of violations, and included other attachments (ex. A, pp. 3 through 14) relating to those findings, including a statement from pharmacist Delijani.

10. a. Inspector Hall did not receive the letter and attachments. In her report (ex. 4), she noted all of her contacts with respondents and Mr. Weinberg. Mr. Weinberg's September 8, 2015 letter is not noted. Inspector Hall noted in her report that she received a declaration sent directly from pharmacist Delijani. Inspector Hall also noted that, when she had not received any response to the notices in her inspection report from respondent Vahedi by October 1, 2015, she notified him that a response was necessary or she would cite him for subverting an investigation (ex. 4, p. 10). Respondent Vahedi sent an email that same day with an apology, indicating that his attorney was supposed to send the information earlier.

b. Respondent Vahedi sent a statement to Inspector Hall, received October 5, 2015. This statement addressed questions posed by Inspector Hall relating to the initial complaint. Although there was further correspondence between Mr. Weinberg or respondent Vahedi, on the one hand, and Inspector Hall, there was no other reference made to Mr. Weinberg's September 8, 2015 letter or its attachments. Inspector Hall first saw the letter and attachments during the administrative hearing.

11. Under these circumstances, it is found that respondents did not produce policies on both subjects to Inspector Hall from the time of the inspection to the time of the hearing.

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Sale of Drugs Lacking Quality and Strength

12. Under Business and Profession Code section 4342, subdivision (a),[1] the Board may take action to prevent the sale of drugs "that do not conform to the standard and tests as to quality and strength" by reference to named, standard texts.

13. a. During the inspection, Inspector Hall found 14 jars of an expired compounded medication, several other expired medications, and a compounded medication that contained an expired ingredient. Inspector Hall's testimony established that a medication with an expired ingredient does not meet the standards for quality and strength.

b. More specifically, the 14 jars were of a drug (fluticasone/ evocetirizine/ pentoxyfylline/ prilocaine/ caffeine) that was compounded on May 7, 2015. The expiration date was August 5, 2015, approximately three weeks before the inspection. Respondent Vahedi explained that the pharmacy would periodically gather expired medications and later dispose of them in authorized manners. However, respondent Vahedi did not establish that these 14 jars were identified for disposal. Rather, Inspector Hall was told that pharmacy employees made enough medication to last several months for the patient.

c. The inspection report notes "several expired drugs in the drug locker and two expired drugs in the refrigerator." (Ex. 4, p. 5.) Inspector Hall explained at the hearing that she found tablets and capsules that were expired, and that employees told her the medications were in an area of medications to be dispensed to patients. Respondent Vahedi noted that these medications had not been dispensed to patients.

d. Clear and convincing evidence established that respondents were prepared to dispense the 14 jars and the tablets and capsules that had expired, and therefore did not conform to the standard and tests as to quality and strength.

14. a. Respondent Pharmacy had a four liter bottle of propylene glycol with two visible labels showing different expiration dates. The label printed by the manufacturer indicated lot 98256/A, with an expiration of 5/15. A label printed and affixed by respondents' employees indicated lot 115613/B, with an expiration of 6/30/19. Inspector Hall found several prescriptions and compounded medications filled after 2015 that contained propylene glycol.

b. Respondent Vahedi gave an explanation to Inspector Hall during the inspection, and testified consistently at the hearing. The testimony was credible. Due to the large size of the four liter bottle, when it was empty of the original lot, they ordered other four liter bottles of propylene glycol. They cleaned and sanitized the empty bottle and

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[1] All further statutory references are to the Business and Professions Code, unless noted otherwise. All references to a Regulation are to title 16 of the California Code of Regulations.

poured a portion of the new order into the empty bottle and labeled it with information related to the new propylene glycol. Therefore, the prescriptions and compounded medications found by Inspector Hall did not contain propylene glycol that expired in 2015; rather, they contained propylene glycol that would expire in 2019.

c. It was not established by clear and convincing evidence that the ingredient propylene glycol in the compounded preparations had expired.

d. During her testimony, Inspector Hall questioned other aspects of some of the compounded preparations containing propylene glycol; more specifically, she claimed that another ingredient in a prescription had expired. However, in her inspection report, Inspector Hall made no reference to this other ingredient. Respondents were given no notice that this alleged anomaly was an issue resulting from the inspection and to be included in the hearing. The amendment to the Accusation made on the first day of the hearing referenced "ingredient," a singular noun. This was apparently a reference to the propylene glycol. Under these circumstances, it would be a denial of due process to respondents to consider this additional evidence.[2]

Erroneous or Uncertain Prescriptions; Prescription Requirements

15. The third and sixth causes for discipline in the Accusation relate to prescriptions for human chorionic gonadotropin (HCG), a controlled substance. It is alleged that respondents filled prescriptions from an order form completed by a sales representative, that the drug and strength were preprinted on the order form, that physicians did not sign the form, and that the orders were transferred to a hard copy prescription by a technician and not completed or verified by the pharmacist. It is further alleged that these practices amount to violations of statutes and regulations relating to erroneous or uncertain prescriptions, and prescription requirements.[3]

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[2] Under Government Code section 11503, subdivision (a), an accusation must set forth "in ordinary and concise language the acts or omissions with which the respondent is charged, to the end that the respondent will be able to prepare his or her defense."

[3] During her testimony, Inspector Hall referred to Code section 4070, and the duty of a pharmacist to take an electronically transmitted prescription and reduce it to writing. The pharmacist can then fill the prescription or have it filled under his direction. However, the Accusation contains no allegation that respondents violated Code section 4070.

16. During the inspection, Inspector Hall found various prescription order forms that were "authorized" by a sales representative of MWC Medical Sales (MWC), a drug distributer. One such form, admitted in evidence as exhibit 8, has the name of a weight loss clinic and doctor (Curlee Ross, M.D.) filled in, but was not signed by the doctor. Under respondents' regular practices in such instances, the orders on the form were transferred to hardcopy prescriptions by a technician and not completed by the pharmacist. Mr. Delijani told Inspector Hall that he did not always check the prescriptions after the technician rewrote them, nor did he verify the prescriptions with the doctor. However, in his written statement, Mr. Deljani wrote (1) that he believed MWC was an authorized agent of the doctors, (2) that technicians would either phone the prescriber to verify the prescriptions or might choose not to call if the order was a repeat of, or similar to, prior orders, (3) that he examined and initialed the prescriptions written by the technicians, and (4) that the medications were prepared and verified by a second pharmacist before being sent to the doctor's offices. The rewritten prescription forms in exhibits 9 and 10 all have a pharmacist's initials, often of Mr. Delijani.

17. a. According to respondent Vahedi, MWC was employed by doctors to set up weight loss procedures for patients, including in-office drug dispensaries, and assure compliance with best practices. Respondent Vahedi also believed that MWC and the sales representative had been authorized by various doctors to submit the order forms when the doctor requested any of the medications already listed on the form. One of the attachments to Mr. Weinberg's letter is a letter from Dr. Lester Lee, indicating that MWC is an authorized agent of his practice and may relay orders to respondents. (Ex. A, p. 4.) Dr. Lee signed an MWC order form in evidence as exhibit 10.

b. With respect to the medication "MIC-Den" listed in the order form listing Dr. Ross in exhibit 8, respondent Vahedi believed this was for use in the doctor's office, not a prescription for a particular patient. The same order form indicated two bottles of HCG were ordered. Respondent Vahedi believed this was also for office use. However, as HCG is a controlled substance, respondent Vahedi believed it was a better practice to have specific references to the patient names on the order form. At his request, the HCG order forms included names of patients who would receive the HCG at the doctors' offices. Respondent Vahedi believed that, in this way, the controlled substance could be tracked to a particular patient by use of the CURES database, discussed in more detail below. Respondent Vahedi testified that he later learned that orders of HCG for a doctor's office use did not require reference to the patient names. However, respondent Vahedi admitted that, in the period of time that individual patient's names were associated with the orders, the orders were no longer considered to be for the doctors' office use and in each instance the requirements for individual prescriptions would apply.

c. Several other MWC order forms are in evidence as exhibit 10. One, several pages long listing numerous patients' names, is signed by Dr. Lee. Exhibit 10 also includes unsigned order forms related to other doctors. As noted above, Dr. Lee's letter includes that he authorized MWC to submit orders for his office.

d. In most instances of the rewritten prescription forms in evidence, a blank for "Phone by" is filled in with typed "MD." However, in exhibit 9 are two rewritten prescription forms for Dr. Ross, with the blank filled in as "Victoria." Respondent Vahedi believes this was an employee of Dr. Ross who confirmed the HCG prescriptions for the two patients written on the MWC order form in exhibit 8. Exhibit 10 contains numerous other order forms and rewritten prescription forms. The prescription forms for Dr. Chao and Dr. McKnight include a name in the "Phone by" blank. The forms for Dr. Fatemeh are filled in with "MD."

18. With respect to all of the MWC order forms in evidence that were submitted on behalf of doctors other than Dr. Lee, it was established by clear and convincing evidence that the forms were not signed by the doctors and that respondents filled the prescriptions. With respect to the two patients of Dr. Ross identified in exhibits 8 and 9, and the patients of Drs. Chao, McKnight and Fatemeh, it was established that the doctor authorized the prescriptions. With respect to all of the MWC order forms admitted in evidence, it was not established by clear and convincing evidence that once the orders were transferred to hard copy prescriptions by a technician, the orders were not reviewed or verified by the pharmacist.

Unlicensed Activity of Fusion IV Specialty Pharmacy

19. Respondent Vahedi developed, sought and obtained licensure for another pharmacy. The Board issued a permit on October 15, 2015, for Fusion IV Pharmaceuticals, Inc., doing business as Fusion IV Specialty Pharmacy (Fusion IV), with respondent Vahedi as its chief executive officer, only shareholder, and PIC. The address of record is 1990 Westwood Boulevard, Los Angeles. (Fusion IV subsequently changed its name and PIC.)

20. During the inspection, Inspector Hall gathered documents indicating that respondents received prescriptions, and compounded and delivered a medication for patient MP on August 24, 2015, with all of the paperwork indicating the work was done by Fusion IV. (Ex. 12.) Inspector Hall also found a brochure for Fusion IV containing its address of record, and a phone number for Fusion RX. The brochure described Fusion IV as specializing in intravenous and other medications and infusion and other special services. The work to fill MP's prescription, including compounding the medication, was done by respondents' employees at the premises of Fusion RX.

21. Respondent Vahedi told Inspector Hall he had submitted an application for licensure for Fusion IV, but the license had not yet been issued. He testified he was preparing to open Fusion IV across the street and was training employees who would transfer to Fusion IV once it opened. He transferred some employees once Fusion IV was licensed and the new office was opened. The brochure was to market Fusion IV's services once it opened.

Reporting of Prescriptions for Controlled Substances

22. The Department of Justice (DOJ) operates a data base, California Utilization Review and Evaluation System, known as CURES, to collect data about prescriptions for controlled substances and dangerous drugs. Pharmacies contribute prescription data. A vendor gathers the data and submits it to CURES. One purpose is so that doctors and pharmacies can check, by patient name, to see the types of prescriptions filled for patients. Government agencies can also check on the types and quantities of controlled substance and dangerous drug prescriptions written by doctors, filled by pharmacies, and dispensed to patients.

23. In the tenth cause for discipline in the Accusation, complainant alleges that respondents failed to report to DOJ required information regarding controlled substances for the period from February 22, 2013 to May 2015. A CURES report obtained by Inspector Hall established respondents' failure to report to CURES during that period.

24. a. Respondent Vahedi testified that he and other employees of respondent Pharmacy would report required data to the vendor, Atlantic Associates, which was the exclusive company chosen by DOJ to transmit the data to DOJ for inclusion in CURES. He experienced numerous problems with the process, and heard of similar problems from other pharmacists. Respondent Vahedi acknowledged that he and respondent Pharmacy were doing business during the period of the gap, but did not know if controlled substances were dispensed during that period. The documentary evidence shows a relatively consistent level of reporting, each month other than the gap, of controlled substances dispensed during those months. Respondent Vahedi acknowledged that he did not know of any reason to believe that there were no controlled substances dispensed during the period of the gap.

b. Respondents submitted evidence of their history of CURES reports (ex. B), however this printout shows reporting during the period that CURES indicated no information was received. This supports respondent Vahedi's belief that information reported to the vendor was not being forwarded timely to CURES.

25, It was not established by clear and convincing evidence that respondents filled and dispensed prescriptions for controlled substances from February 22, 2013 to May 2015. Therefore, it was not established that respondents had any reportable information at that time.

26. As discussed in more detail below, on January 8, 2016, and numerous times thereafter, Inspector Hall requested that respondents provide a record of all medications dispensed from January 1, 2013, to January 1, 2016. Respondents acknowledged the request but claimed it was overly broad, not necessary, and would take too long to produce. The records requested were not produced. Presumably, those records would answer the question whether respondents dispensed controlled substances during the period of the gap.

Failure to Cooperate with Investigation

27. In the ninth cause for discipline in the Accusation, complainant alleges that, between August 26, 2015, and February 29, 2016, respondents subverted the investigation. More specifically, respondents allegedly failed to respond to multiple requests for documents, including a dispensing report of all products dispensed from January 1, 2013, to January 1, 2016, order forms for HCG, policies and procedures requested at the time of the inspection, and statements from the PIC.

28. As noted in Factual Finding 26, Inspector Hall requested a dispensing report and respondents replied that there were reasons why they would not provide it, including the time it would take and questions by Mr. Weinberg about why it was needed. The reasons given by respondents do not excuse respondents' duty to maintain and provide records for inspection.[4] Inspector Hall testified credibly that other pharmacies provided dispensing reports in other investigations she conducted, and that, to her knowledge, respondents' computer software could compile and print the requested information. By failing to provide the dispensing report, respondents subverted the investigation.

29. During the inspection, Inspector Hall requested that respondent Vahedi provide the hardcopy order forms that corresponded to rewritten prescriptions for HCG for which she did not find the order forms during the inspection. Inspector Hall had requested information from Mr. Delijani about the MWC forms, and received his written statement including that information. (See Inspector Hall's report, ex. 4, pp. 9 and 10.) Mr. Weinberg supplied one hardcopy order form (see ex. 10, pp. 38 and 39) that related to some, but not all, of the prescriptions she had gathered. Inspector Hall requested more hardcopy order forms. Neither respondent Vahedi nor Mr. Weinberg provided them.

30. As noted in Factual Findings 7 through 11, respondents did not provide the written policies and procedures relating to helping patients with limited or no English proficiency understand the information on the label of a medication, and theft of a dangerous drug by an employee, or chemical, mental or physical impairment of an employee. This is another instance of subverting the investigation.

Costs

31. Complainant incurred costs for the investigation ($9,611.75) and enforcement ($5,572.50). Inspector Hall's declarations described her tasks that totaled 79.75 hours. Billing summaries described the tasks that totaled 32.25 hours of work by Deputy Attorney General Friedman and 0.75 hours of work by a paralegal. The costs total $15,184.25, and are found to be reasonable.

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[4] Under Code section 4081, a licensee must make records related to dangerous drugs available to inspection during normal business hours.

Prior Citations

32. The Board has issued three citations to respondent Pharmacy, and three citations to respondent Vahedi, all of which are final.

a. On October 27, 2015, the Board issued Citation number CI 2013 59594 to respondent Pharmacy, and Citation number CI 2015 67653 to respondent Vahedi, based on violations of Regulation 1713 (participating in an arrangement where prescriptions or prescription medications are left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy), and Code section 4052, subdivision (a) and Regulation 1735.2 (compounded medications not for office use and in a quantity in excess of 72 hour supply of compounded medications). Respondent Pharmacy was ordered to pay $5,000. Respondent Vahedi was ordered to pay $2,000.

b. On September 10, 2015, the Board issued Citation number CI 2014 62948 to respondent Pharmacy, and Citation number CI 2015 66976 to respondent Vahedi, based on violations of Health & Safety Code section 111397, subdivision (a) (compounding with an unapproved foreign drug), and Code section 4169, subdivision (a), and Regulation 1735.3, subdivision (c) (prohibited act/obtaining compounding chemicals from unreliable source), and Regulation 1735, subdivision (d) (compounding commercially available drugs/patent infringement). Respondent Pharmacy was ordered to pay $3,000. Respondent Vahedi was ordered to pay $3,000.

c. On September 27, 2012, the Board issued Citation number CI 2011 50096 to respondent Pharmacy, and Citation number CI 2012 53992 to respondent Vahedi, based on violations of Code section, 4076 subdivision (a)(9) (prescription label date beyond manufacturing date), Health & Safety Code section 11165, subdivision (d) (failure to report to CURES), and Title 21 Code of Federal Regulations § 1304.11 (failure to take DEA inventory). Respondent Pharmacy was ordered to pay $1750. Respondent Vahedi was ordered to pay $1,250.

Although complainant submitted other citations in evidence, they were not included in the Accusation and, therefore, are not considered herein. (See Gov. Code, § 11503; Factual Finding 14, fn. 2.)

Mitigation, Rehabilitation and Other Relevant Evidence

33. Respondent Vahedi received his Pharm. D. degree in 2006 from Rosemead University in Nevada. He worked as an intern and staff pharmacist at Longs Drug until 2009. He then worked at Rite Aid as a PIC and, at the same time, developed, marketed and obtained the license for respondent Pharmacy. He is married, with two children ages four and five. His wife is not employed.

34. Respondent Vahedi has focused on the development, licensing and marketing of first respondent Pharmacy and then Fusion IV. His efforts are largely focused on the activities necessary to successfully run the businesses. He is often present at the premises of respondent Pharmacy and, on occasion, will fill prescriptions and work with employees related to filling prescriptions. He relies upon other pharmacists and technicians that he employs to do the bulk of the work relating to filling prescriptions.

35. Respondent Vahedi gave detailed testimony about pharmacy operation standards of California and other groups, and spoke specifically about the operating manuals and policies used at respondent Pharmacy. His goal was to operate under the highest standards and receive certifications at that level. He stated that the red notebook, which included the two policies discussed in Factual Findings 6 through 11, was in his office at the time of the inspection. Respondent Vahedi stated he was not aware of the request for the policies during the inspection, and that his employee Pablo, who may have been asked, was recently employed and may not have known of the binder. Respondent Vahedi did not explain why, when Inspector Hall reviewed with him the notices and corrections from her report at the end of the inspection, he did not inform her of the policies and show them to her.

36. Respondent Vahedi stressed in his testimony that there was no evidence that some of the medications containing expired drugs were dispensed to any patient, and that in some instances the medication, if taken as directed, would have been exhausted before the expiration date. He referred to drug removal and destruction polices and contracts that were in place at the time of the inspection as well as new, more robust policies in place since then, including a color-coding system and monthly disposal. He also spoke at length about the steps involved in documenting the process of compounding medications, including labeling and inventory control through software programs designed to notify a pharmacist if a component drug either had expired or would expire during the period covered by a prescription for administration of the medication. However, when asked how this system allowed a prescription to be filled with an expired medication, respondent Vahedi stated he had no reasonable explanation. Respondents have upgraded their software systems.

37. Propylene glycol is not an active ingredient. It is a viscous liquid, and it was easier for respondents' employees to use a lesser amount poured from a re-used container than to pour from a full four liter bottle. Complainant did not offer any statute or regulation that would prevent the reuse of a container in this manner. It was not established that the propylene glycol did not conform to the standard and tests as to quality and strength. Inspector Hall did advise that respondents should not make such a transfer to prevent errors or misbranded drugs.

38. The inspection report provided to respondents at the conclusion of the inspection (ex. 23) indicates that several of respondents' operating polices were reviewed. However, the two policies discussed in Factual Findings 6 through 11 were not produced or reviewed.

39. Respondent Vahedi was candid in his testimony regarding the orders from MWC and his desire to have HCG orders reference particular patients, even though the intent was for the HCG to be provided for the doctors' office use. Respondent Vahedi thought it would be better to have individual patient names assigned to the orders. He later learned that this was not necessary. Respondents discontinued the practice. After the inspection, respondents no longer accepted order forms that referred to, or were received from, MWC. Order forms now come directly from the doctors' offices.

40. Respondent Vahedi realized he was wrong to process prescriptions under the name of Fusion IV before that entity was licensed. In his words, a handful of prescriptions were processed before licensure, and "we jumped the gun." After Fusion IV was licensed, its employees moved into its separate facility.

41. Respondent Vahedi has turned over PIC responsibility to others. He has employees who are responsible to assist in assuring compliance with statutes, regulations, best practices, and certification requirements. He assures the Board that, if he can maintain his license, respondents will comply with applicable statutes and regulations.

42. Respondent Vahedi provided three character reference letters (ex. G) from colleagues, received in evidence as administrative hearsay.[5] William Letendre is respondent Vahedi's business mentor who helped him in areas of industry standards, training, supplies and marketing. Mr. Letendre supplements and explains evidence of respondent Vahedi's professionalism, high level of clinical knowledge, quality control and accreditation under PCAB standards. H. Eric Feinstein holds a Ph.D. in chemistry. He comments favorably on respondent Vahedi's high level of customer satisfaction and knowledge of quality control and compliance. Respondent Vahedi interned with Leslie Ziontz Shaffer, a licensed pharmacist who is now his employee. She compliments his knowledge of chemistry and compounding, dedication to his business and the practice of pharmacy, and the growth and competency of the work done at respondent Pharmacy.

LEGAL CONCLUSIONS

Based upon the foregoing factual findings, the Administrative Law Judges makes the following legal conclusions:

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[5] The term "administrative hearsay" is a shorthand reference to the provisions of Government Code section 11513, subdivision (d), to the effect that hearsay evidence that is objected to, and is not otherwise admissible, may be used to supplement or explain other evidence but may not, by itself, support a factual finding. It may be combined with other evidence to provide substantial evidence sufficient to support a finding. (*Komizu v. Gourley* (2002) 103 Cal.App.4th 1001.)

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 Code section 4300, subdivision (a), the Board may suspend or revoke a license or registration for violation of statutes or regulations.

Lack of Written Policies

3. a. Pharmacies and pharmacists are required to have certain policies and procedures in place, including policies regarding (a) helping patients with limited or no English proficiency understand the information on the label of a medication, and (b) for the theft of a dangerous drug by an employee, or chemical, mental or physical impairment of an employee.

b. Regulation 1707.5 subdivision (d), requires a pharmacy to have a policy "to help patients with limited or no English proficiency understand the information on the label . . . in the patient's language." Other details of the policy are described in the regulation.

c. Code section 4104, subdivision (a), states:

> Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

4. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Regulation 1707.5 subdivision (d), and Code section 4104, subdivision (a), for failing to provide proof to the Board inspector that they had the required policies, as set forth in Factual Findings 6 through 11.

Sale of Drugs Lacking Quality and Strength

5. Code section 4342, subdivision (a), states:

> The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to

quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

6. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Code section 4342, subdivision (a), to prevent the sale of expired drugs, as set forth in Factual Findings 12 and 13. It is not a defense that the medications were not dispensed. They were available for sale.

7. Cause does not exist to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's pharmacist license relating to the repackaging of propylene glycol, as complainant did not provide clear and convincing evidence that this practice does not conform to the standard and tests as to quality and strength, as set forth in Factual Findings 14 and 37.

Erroneous or Uncertain Prescriptions; Prescription Requirements

8. The requirements for a prescription to be filled are found in numerous statutes and regulations, only some of which are relevant to this matter.

9. Regulation 1761 states:

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

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

10. Code section 4040, subdivision (a), defines "prescription" and lists certain requirements, including that the prescription, if written, to be signed by the prescriber or by the pharmacist in some circumstances (subd. (a)(F)).

11. a. A prescription for controlled substances must include the requirements under Health and Safety Code section 11164, subdivision (a)(1), including that it be signed in ink on a special prescription form and include "the name, quantity, strength, and directions for use of the controlled substance prescribed." However, under subdivision (b)(1), controlled substances can be dispensed "upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provision s

of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription."

b. Health and Safety Code section 11164, subdivision (b)(2) states:

> The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

12. Respondents' practices concerning the HCG orders and prescriptions did not sufficiently comply with these requirements. The problem was not that there were preprinted order forms. Nor was it a problem that respondent Vahedi concluded that the prescribing doctors had authorized the use of the forms, as the prescriptions were confirmed when respondents' employees contacted the offices of the prescribing doctors. However, the pharmacist did not, as required, verify the information and produce and sign the prescription when it was rewritten from the order form. These are considered to be technical violations.

13. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Regulation 1761, Code section 4040, subdivision (a)(1)(F), and Health and Safety Code section 11164, subdivisions (a)(1) and (b), as set forth in Factual Findings 15 through 18, and 39.

Unlicensed Activity of Fusion IV Specialty Pharmacy

14. Complainant seeks imposition of discipline concerning the operations of Fusion IV under the following authority.

Code section 4110, subdivision (a), states:

> No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred

Under Code section 4301, the Board shall take action against a licensee who is guilty of unprofessional conduct, which includes, under (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."

Under Code section 4301, subdivision (g), unprofessional conduct includes: "Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts."

15. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Code section 4110, subdivision (a), because respondents conducted business requiring a license as Fusion IV before Fusion IV was licensed, as set forth in Factual Findings 19 through 21, and 40.

16. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Code section 4301, subdivision (f), because respondents did acts involving dishonesty and deceit by representing that Fusion IV was capable of performing acts requiring a license before Fusion IV was licensed, as set forth in Factual Findings 19 through 21, and 40.

17. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's Pharmacist license under Code section 4301, subdivision (g), because respondents conducted business requiring a license using documents under the name Fusion IV before Fusion IV was licensed, as set forth in Factual Findings 19 through 21, and 40.

Reporting of Prescriptions for Controlled Substances

18. The goal of CURES to monitor controlled substances, and many of the reporting requirements, is set forth in Health and Safety Code section 11165, subdivision (d)(1-10), which states that a dispensing pharmacy "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." Subdivision (d)(1-10) references the required information, including but not limited to: name, address, and telephone number of the ultimate user; the prescriber's category of licensure and license number; pharmacy prescription number, license number, NPI number, and federal controlled substance registration number; National Drug Code (NDC) number of the controlled substance dispensed; quantity of the controlled substance dispensed; number of refills ordered; date of origin of the prescription; and date of dispensing of the prescription.

19. Complainant did not present clear and convincing evidence that respondents prescribed controlled substances for the period from February 22, 2013 to May 2015. Without such proof, complainant did not establish that respondents were required to report to CURES in that period.

20. Cause does not exist to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's pharmacist license under Health and Safety Code section 11165, subdivision (d), for failure to make CURES reports, as set forth in Factual Findings 22 through 25.

Cooperation with Investigation

21. Under Code section 4301, subdivision (q), unprofessional conduct includes: "Engaging in any conduct that subverts or attempts to subvert an investigation of the board."

22. Respondents did not comply with repeated requests to provide documentation.

23. Cause exists to suspend or revoke respondent Pharmacy's permit and respondent Vahedi's pharmacist license under Code section 4301, subdivision (q), for subverting the investigation by virtue of their failure to cooperate, as set forth in Factual Findings 7 through 11, 27 through 30, and 35.

Costs

24. Under Code section 125.3, the Board may request the administrative law judge to direct a licentiate 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 $15,184.25, as set forth in Factual Finding 31.

25. In *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the Supreme Court rejected a constitutional challenge to a cost recovery provision similar to Code section 125.3. In so doing, however, the Court directed the administrative law judge and the agency to evaluate several factors to ensure that the cost recovery provision did not deter individuals from exercising their right to a hearing. Thus, the Board must not assess the full costs where it would unfairly penalize the respondent who has committed some misconduct, but who has used the hearing process to obtain the dismissal of some charges or a reduction in the severity of the penalty. The Board must consider a respondent's subjective good faith belief in the merits of his or her position and whether the respondent has raised a colorable challenge; the Board must consider a respondent's ability to pay; and the Board may not assess disproportionately large investigation and prosecution costs when it has conducted a disproportionately large investigation to prove that a respondent engaged in relatively innocuous misconduct. (*Id.* At p. 45.)

26. These factors support a reduction in costs. Respondents used the process to obtain conclusions that some of the causes for discipline were not supported by the evidence. The investigation encompassed all of the charges, although complainant was not successful in proving some of the conduct.

27. Under these circumstances it is reasonable to reduce the costs by 25 percent; that is, to $11,388.19.

Discipline

28. Under Regulation 1760, the Board developed *A Manual of Disciplinary Guidelines and Model Disciplinary Orders* (*Guidelines*). The *Guidelines* recommend ranges of discipline for certain violations. Under the *Guidelines*, the Board recognizes that individual cases may necessitate a departure from the *Guidelines*. Sections of the *Guidelines* include factors to be considered in determining penalties, rehabilitation evidence, and recommended penalties for the proven violations.

29. To determine whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following are the relevant factors to consider: actual or potential harm to the public or to any consumer, prior disciplinary record or warnings, including citations, number and/or variety of current violations, nature and severity of the offenses, aggravating evidence, mitigating evidence, rehabilitation evidence, time passed since the offenses, whether the conduct was intentional or negligent, and whether there was financial benefit to the respondent from the misconduct.

30. Evidence a respondent may submit to demonstrate rehabilitative efforts and competency may include written statements from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent.

31. The *Guidelines* divide violations into four categories for purposes of setting forth recommended minimum and maximum disciplinary outcomes. In all instances, the recommended maximum outcome is revocation. Category I discipline is recommended for violations which are relatively minor. Category IV violations are substantial. The violations established in this matter are in Category II and Category III.

32. As relevant here, the minimum recommended discipline for Category II violations is revocation stayed, three years' probation, with standard terms and conditions and optional terms and conditions as appropriate. The Category II violations established in this matter are: (1) Code section 4301, unprofessional conduct in the nature of acts involving dishonesty or deceit (subd. (f)), making a document which falsely represents a state of facts (subd. (g)), and subverting an investigation (subd. (q)); (2) Health and Safety Code section 11164 regarding prescriptions for controlled substances; and (3) Regulation 1761, subdivision (a), regarding erroneous or uncertain prescriptions with respect to a pharmacist.

33. As relevant here, Category III discipline is recommended for knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances, or fraudulent acts committed in connection with the licensee's practice. The minimum recommended discipline for Category III violations is

revocation stayed, 90 days actual suspension for a pharmacist and 14-28 days suspension for a pharmacy, three to five years' probation, with standard terms and conditions and optional terms and conditions as appropriate. The Category III violations established in this matter are: (1) Code section 4081,[6] records of dangerous drugs kept open for inspection and maintenance of records; (2) Code section 4110, license requirements; and (3) Regulation 1761, subdivision (a), regarding erroneous or uncertain prescriptions with respect to a pharmacy

34. Respondents present a complex scenario for purposes of determining the appropriate level of discipline. To reference some of the relevant factors, there was potential harm to the public or customers, but no actual harm. There were prior citations, including some related to CURES reporting, with which respondents complied. There are several present violations, although respondents in some ways brought the prescription violations upon themselves by treating orders for doctors' office use as prescriptions for individual patients. Respondent contended that the actual sale of the expired prescriptions was not proven, and that the policies were required to be on site but not necessarily available to inspection. These contentions are not convincing, as the Board's authority in these subjects clearly covers the circumstances found by the inspectors. Respondents' conduct was, largely, negligent. However, the operation of Fusion IV before it was licensed was intentional.

35. Under all of the circumstances, outright revocation of the licenses would be an overly severe outcome. Probationary licenses, with appropriate terms and conditions, will provide proper protection to the public. The *Guidelines* recommend slightly different conditions for a pharmacist and a pharmacy, so separate orders are issued. The license suspensions will be equalized.

ORDER

Respondent Navid Vahedi

License number RPH 59537 issued to respondent Navid Vahedi is revoked; however, the revocation is stayed and respondent is placed on probation for four years upon the following terms and conditions:

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[6] Code section 4081 is referenced in the Accusation under the section "Jurisdiction," but is not alleged as a basis for any specific allegation of wrongdoing. It is included here as a reference to the nature and severity of the violations, towards determining the level of discipline to be imposed.

Suspension

As part of probation, respondent is suspended from the practice of pharmacy for thirty (30) days beginning the effective date of this decision.

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

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

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

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

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:

a. 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

b. a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment

c. a conviction of any crime

d. 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 case number 5899 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5899

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 5899 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 5899 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 $11,388.19. Respondent shall make said payments on a schedule to be determined by the board. The obligation to pay costs is joint and several with respondent Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX Compounding Pharmacy

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.

9. Probation Monitoring Costs

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

10. Status of License

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

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

11. License Surrender While on Probation/Suspension

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

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

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

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

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

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 30 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 30 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 30 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 30 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. Remedial Education

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to prescriptions, licensing, policies, and ethics. The program of remedial education shall consist of at least twenty (20) hours, which shall be completed within one year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

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

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

17. Supervised Practice

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

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 5899 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 5899 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

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

18. Report of Controlled Substances (For pharmacist owners and pharmacists-in-charge)

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

19. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a

pharmacist-in-charge, respondent shall retain an independent consultant at his own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

Respondent Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX Compounding Pharmacy

License number PHY 49537 issued to respondent Dr. N. Vahedi Pharmacy Inc., doing business as Fusion RX Compounding Pharmacy is revoked; however, the revocation is stayed and respondent is placed on probation for four years upon the following terms and conditions:

Suspension

License number PHY 49537 issued to respondent is suspended for thirty (30) days beginning the effective date of this decision. Respondent shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

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:

a. 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

b. a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment

c. a conviction of any crime

d. 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 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 his 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 $11,388.19. Respondent owner shall make said payments on a schedule to be determined by the board. The obligation to pay costs is joint and several with respondent Navid Vahedi.

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.

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, including any period during which suspension or probation is tolled. 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 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 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.

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 premise 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 a 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 960) days.

Respondent owner may not reapply 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. All outstanding costs of investigation and prosecution shall be paid prior to 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 terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such a 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, either by posting a notice of the terms and conditions, circulating such 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 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 to the board shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post approbation 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 as to the nature of and reason for the probation of the licensed entity.

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

12. Violation of Probation

If respondent owner 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 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. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such a file or make it available to inspection shall be considered a violation of probation.

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15. Report of Controlled Substances

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

DATED: October 26, 2017

DocuSigned by:
David B. Rosenman
[illegible]
DAVID B. ROSENMAN
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Accusation Against: **DR. N. VAHEDI PHARMACY INC. DBA FUSION RX COMPOUNDING PHARMACY;** **NAVID VAHEDI, president** **12001 Westwood Blvd., Suite A** **Los Angeles, CA 90025** **Pharmacy Permit No. PHY 49937** **and** **NAVID VAHEDI, (PIC)** **12001 Westwood Blvd Ste A.** **Los Angeles, CA 90025** **Pharmacist License No. RPH 59537** Respondents.	Case No. 5899 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about June 9, 2009, the Board of Pharmacy issued Pharmacy Permit Number PHY 49937 to Dr. N. Vahedi Pharmacy Inc. dba Fusion Rx Compounding Pharmacy with Navid Vahedias the President and Pharmacist in Charge (Respondent Pharmacy). The Pharmacy Permit

was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

3. On or about May 3, 2007, the Board of Pharmacy issued Original Pharmacist License Number RPH 59537 to Navid Vahedi (Respondent Vahedi). On June 9, 2009, Respondent Vahedi became as PIC for Respondent Pharmacy. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION

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

5. Section 4040 of the Code states in pertinent part:

"(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:(1) Given individually for the person or persons for whom ordered that includes all of the following:

. . . .

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6."

6. Section 4081 of the Code states in pertinent part:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and

Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

. . . . .

7. Section 4101 of the Code states in pertinent part:

"(a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. A pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status."

8. Section 4110 of the Code states in pertinent part:

"(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred."

9. Section 4301 of the Code states:

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

. . . .

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

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

. . . . .

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board."

10. Section 4342 of the Code states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

11. Section 11162.1 of the Health and Safety Code states in pertinent part:

"(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

. . .

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one."

12. Section 11164 of the Health and Safety Code states in pertinent part:

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

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

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the

prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

. . . .

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

13. Section 11165 of the Health and Safety Code states in pertinent part:

. . .

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical

license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription."

13. Section 11167 of the Health and Safety Code states in pertinent part:

"Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall

make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Department of Justice.

(e) This section shall become operative on January 1, 2005."

REGULATIONS

14. 16 California Code of Regulations Section 1707.5 states in pertinent part:

. . . .

"(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter."

15. 16 California Code of Regulations Section 1761 states:

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

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

COST RECOVERY

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

FIRST CAUSE FOR DISCIPLINE

(Policies for Interpretive Services)

17. Respondents Pharmacy and Vahedi are subject to disciplinary action under California Code of Regulations section 1707.5 subdivision (d) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to provide Board inspectors with policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language during an inspection by the Pharmacy Board on August 26, 2015 or on a date thereafter.

SECOND CAUSE FOR DISCIPLINE

(Sale of Drugs Lacking Quality and Strength)

18. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4342 subdivision (a) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy, were selling pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength. The circumstances of the violation are that on August 26, 2015, during a Board inspection, Respondent Pharmacy had fourteen (14) jars of expired compounded medications on the stock medication shelves. In addition, several expired medications were found in the drug closet and refrigerator.

THIRD CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

19. Respondents Pharmacy and Vahedi are subject to disciplinary action under California Code of Regulations section 1761 subdivisions (a) and (b) in that on August 26, 2015, during a Board inspection, it was discovered that Vahedi, as PIC, and owner of Respondent Pharmacy, was filling prescriptions for HCG (a controlled substance) from an order form completed by a sales representative. The drug and strength were preprinted on the order form and the physician did not sign the form. In addition, the orders were transferred to a hard copy prescription by an technician and not completed or verified by the pharmacist

FOURTH CAUSE FOR DISCIPLINE

(Unlicensed Activity: License Required)

20. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4110 subdivision (a) in that during an inspection by the Pharmacy Board on August 26, 2015, it was determined that Respondent Vahedi, as PIC, and owner of Respondent Pharmacy was operating an unlicensed pharmacy, called "Fusion IV Specialty Pharmacy," on the same premises as Respondent Pharmacy.

FIFTH CAUSE FOR DISCIPLINE

(Theft and Impairment: Pharmacy Procedures)

21. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4104 subdivision (a) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were unable to produce a policy for theft or impairment of an employee during an inspection by the Pharmacy Board on August 26, 2015 or at a later date.

SIXTH CAUSE FOR DISCIPLINE

(Prescriptions Requirements)

22. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4040 subdivisions (a)(l)(F) in conjunction with Health and Safety Code section 11164 subdivisions (a)(1)(b) in that on August 26, 2015, the Board conducted an inspection of Respondent Pharmacy where it was discovered that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were filling prescriptions for HCG (a controlled substance) from an order form completed by a sales representative. The drug and strength were preprinted on the order form and the physician did not sign the form. In addition, the orders were transferred to a hard copy prescription by a technician and not completed or verified by the pharmacist.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Dishonesty, Fraud and/or Deceit)

23. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 (f) for engaging in any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, in that during a Board inspection on August 26, 2015, it

was determined that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were operating another pharmacy called "Fusion IV Specialty Pharmacy," from the same location as Respondent Pharmacy. The drugs were dispensed from Respondent Pharmacy with a label for Fusion IV Specialty Pharmacy. The brochure and intake papers for Fusion IV Specialty Pharmacy had a different address (1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025) and claimed to be a pharmacy in full operation. Fusion IV Specialty Pharmacy has not been licensed by the Board.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – False Certifications)

24. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 (g) for unprofessional conduct for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts. Specifically, during a Board inspection on August 26, 2015, it was determined that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were operating another pharmacy called "Fusion IV Specialty Pharmacy," from the same location as Respondent Pharmacy. The drugs were dispensed from Respondent Pharmacy used a label for "Fusion IV Specialty Pharmacy." The brochure and intake papers for Fusion IV Specialty Pharmacy had a different address (1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025) and claimed to be a pharmacy in full operation. Fusion IV Specialty Pharmacy has not been licensed by the Board.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Cooperate with Investigation)

25. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 subdivision (q) in that between August 26, 2015 and February 29, 2016 Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to respond to the Board's multiple requests for documents including a dispensing report of all products dispensed from January 1, 2013 to January 1, 2016, order forms for HCG, policies and procedures requested at the time of the inspection, and statements from the pharmacist-in-charge.

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TENTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substances to Cures)

26. Respondents Pharmacy and Vahedi are subject to disciplinary action under Health and Safety Code section 11165(d)(l-10) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to report identified information relating to controlled substances that required under the code for controlled substances to the Department of Justice CURES program from February 22, 2013 to May 2015.

DISCIPLINE CONSIDERATIONS

27. To determine the degree of discipline, if any, to be imposed on Respondents Pharmacy and Vahedi, Complainant alleges as follows:

Fusion Rx Compounding Pharmacy

a. On or about October 27, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 59594 based on violations of CCR, Title 16, § 1713 [Participating in an arrangement where prescriptions or prescription medications is left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy] and Bus. & Prof. Code § 4052(a) and CCR, Title 16, § 1735.2 [Compounded medications not for office use and in quantity for advanced male medical in excess of 72 hour supply of compounded medications.] Respondent was ordered to pay $5,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

b. On or about September 10, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2014 62948 based on violations of Health & Safety Code § 111397 (a) [Compounding with an Unapproved Foreign Drug], Bus. & Prof. Code § 4169(a) and CCR, Title 16, § 1735.3(c) [Prohibited act/obtaining compounding chemicals from unreliable source] , 1735(d) [Compounding commercially available drugs/patent infringement] and ordered Respondent to pay $3,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

c. On or about September 27, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2011 50096 based on violations of Bus. & Prof. Code § 4076(a)(9)

[Prescription label date beyond manufacturing date], Health & Safety Code § 11165(d) [Failure to Report to Cures], and Title 21 CFR § 1304.11 [Failure to take DEA Inventory] and ordered Respondent to pay $1750.00. That Citation is now final and is incorporated by reference as if fully set forth.

Navid Vahedi

d. On or about October 27, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 67653 based on violations of CCR, Title 16, § 1713 [Participating In An Arrangement Where Prescriptions Or Prescription Medications Is Left At, Picked Up From, Accepted By, Or Delivered To Any Place Not Licensed As A Retail Pharmacy] and Bus. & Prof. Code § 4052(a) and CCR, Title 16, § 1735.2 [Compounded medications not for office use and in quantity for advanced male medical in excess of 72 hour supply of compounded medications.] Respondent to pay $2,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

e. On or about September 10, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 66976 based on violations of Health & Safety Code § 111397 (a) [Compounding with an Unapproved Foreign Drug], Bus. & Prof. Code § 4169(a) and CCR, Title 16, § 1735.3(c) [Prohibited Act/Obtaining Compounding Chemicals from Unreliable Source] , 1735(d) [Compounding Commercially Available Drugs/Patent Infringement] and ordered Respondent to pay $3,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

f. On or about September 27, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53992 based on violations of Bus. & Prof. Code § 4076(a)(9) [Prescription label date beyond manufacturing date], Health & Safety Code § 11165(d) [Failure to Report to Cures], and Title 21 CFR § 1304.11 [Failure to take DEA Inventory] and ordered Respondent to pay $1250.00. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

28. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number

PHY 49937 issued to Fusion Rx Compounding Pharmacy, Navid Vahedi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49937 is placed on probation or until Pharmacy Permit Number PHY 49937 is reinstated if it is revoked.

29. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49937 issued to Fusion Rx Compounding Pharmacy while Navid Vahedi had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Navid Vahedi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49937 is placed on probation or until Pharmacy Permit Number PHY 49937 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 49937, issued to Fusion Rx Compounding Pharmacy, with Navid Vahedi as the President, Pharmacist in Charge and owner;

2. Revoking or suspending Pharmacist License Number RPH 59537, issued to Navid Vahedi;

3. Prohibiting Navid Vahedi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49937 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 49937 is revoked;

4. Ordering Fusion Rx Compounding Pharmacy, and Navid Vahedi jointly and severally, 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;

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

DATED: 1/30/17

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

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