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

In the Matter of the Third Amended Accusation Against: **IV SOLUTIONS, INC.** **Alireza Varastehpour, President** **Original Pharmacy Permit No. PHY 45885** **Original Sterile Compounding Permit No. LSC 99913** **and** **RENEE SADOW** **Original Pharmacist License No. RPH 27398** Respondents.	Case No. 3606 OAH No. 2011050988 ORDER GRANTING STAY OF EFFECTIVE DATE OF DECISION AND ORDER AS TO IV SOLUTIONS, INC. ONLY

ORDER GRANTING STAY OF EFFECTIVE DATE
(AS TO RESPONDENT IV SOLUTIONS ONLY)

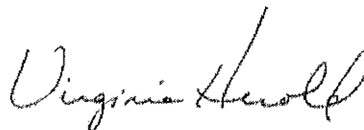
Respondent IV Solutions timely requested reconsideration of the decision in the above-entitled matter pursuant to section 11521 of the Government Code. No request for reconsideration was received pertaining to respondent Renee Sadow. Good cause appearing, in order to allow the board additional time to consider the petition, in accordance with the provisions of section 11521 of the Government Code,

IT IS HEREBY ORDERED that the effective date of the Decision and Order, in the above-entitled matter is further stayed until 5 p.m. on May 29, 2015, as to Respondent IV Solutions (PHY 45885 and LSC 99913), only.

In the absence of a petition for reconsideration from respondent Renee Sadow (RPH 27398), that portion of the decision will become effective May 21, 2015, as previously ordered.

IT IS SO ORDERED this 20th day of May, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By ______________________________
VIRGINIA HEROLD
Executive Officer

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

In the Matter of the Third Amended Accusation Against:

IV SOLUTIONS, INC.
Alireza Varastehpour, President

Original Pharmacy Permit No. PHY 45885
Original Sterile Compounding Permit No. LSC 99913

and

RENEE SADOW

Original Pharmacist License No. RPH 27398

Respondents.

Case No. 3606

OAH No. 2011050988

ORDER GRANTING STAY OF EFFECTIVE DATE OF DECISION AND ORDER

DECISION AND ORDER

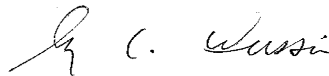
The Board of Pharmacy's (Board's) Decision adopting the Proposed Decision issued by Eric Sawyer, Administrative Law Judge, in the above-entitled matter was issued on April 17, 2015, to become effective on April 30, 2015. On April 20, 2015, pursuant to Section 11521(a) of the Government Code, Respondent IV Solutions requested a stay of the effective date of the Decision in order to permit it to file a petition for reconsideration of the Board's Decision and to allow the Board time to review such petition.

Good cause appearing therefor, in accordance with the provisions of Section 11521(a) 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 May 21, 2015.

IT IS SO ORDERED this 29th day of April 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By ______________________________
STAN C. WEISSER
Board President

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

In the Matter of the Third Amended Accusation Against: **IV SOLUTIONS, INC.** **Alireza Varastehpour, President** **Original Pharmacy Permit No. PHY 45885** **Original Sterile Compounding Permit No. LSC 99913** **and** **RENEE SADOW** **Original Pharmacist License No. RPH 27398** Respondents.	Case No. 3606 OAH No. 2011050988

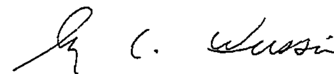
DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on April 30, 2015.

It is so ORDERED on April 17, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By ______________________
STAN C. WEISSER
Board President

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

In the Matter of the Third Amended Accusation Against: IV SOLUTIONS, INC. Alireza Varastehpour, President Original Pharmacy Permit No. PHY 45885 Original Sterile Compounding Permit No. LSC 99913, and RENEE SADOW Original Pharmacist License No. RPH 27398, Respondents.	Case No. 3606 OAH No. 2011050988

PROPOSED DECISION

This matter was heard by Eric Sawyer, Administrative Law Judge, Office of Administrative Hearings, State of California, on July 8-11 and 14-17, August 11-14, and September 2-4, 8-11, and 15-18, 2014, in Los Angeles.

Langston M. Edwards, Alvaro Mejia, and Thomas L. Rinaldi, Deputy Attorneys General, represented Virginia Herold (Complainant).

Jack A. Janov, Esq., and Kevin R. Warren, Esq. (on the brief only), represented Respondent IV Solutions, Inc., Alireza Varastehpour, President.

Bruce Stuart, Esq., represented Respondent Renee Sadow.

The record remained open after the hearing for the parties to present closing argument briefs, which were timely received and marked as follows: Complainant's initial brief, exhibit 83; Respondent IV Solutions' brief, exhibit 445; Respondent Sadow's brief, exhibit 501; and Complainant's reply brief, exhibit 84.

The record was closed and the matter was submitted for decision on February 4, 2015.

FACTUAL FINDINGS

Parties and Jurisdiction

1. Complainant brought the Third Amended Accusation in her official capacity as the Executive Officer of the Board of Pharmacy (Board), which is within the California Department of Consumer Affairs (Department).

2. Respondents timely submitted Notices of Defense to contest the allegations of the initial Accusation brought in this case, or were deemed by the Board to have done so. By operation of Government Code section 11507, Respondents were not required to submit new Notices of Defense, as the allegations in the amended accusations were deemed controverted.

3. A. On May 9, 2002, the Board issued Original Pharmacy Permit Number PHY 45885 to IV Solutions, Inc., with Alireza Varastehpour, aka Alex Vara, as President (Respondent IV Solutions). Mr. Vara is not a licensed pharmacist in this state or any other. The original pharmacy permit was in full force and effect at all times relevant and will expire on May 1, 2015, unless renewed.

B. At the time of the events in question, Respondent IV Solutions compounded sterile injectable products but did not possess an original sterile compounding permit. Respondent IV Solutions was exempt from obtaining such a permit because it had been accredited by the Joint Commission on Accreditation of Healthcare Organizations (now known simply as the Joint Commission), which is a Board approved accrediting agency.

C. On May 8, 2014, the Board issued Original Sterile Compounding Permit Number LSC 99913 to Respondent IV Solutions, which allows it to compound injectable sterile drug products. Effective July 1, 2014, all pharmacies involved in compounding sterile injectable products are required to obtain a sterile compounding permit.

D. Board records show that Jeannie Kim was the Pharmacist-in-Charge (PIC) for Respondent IV Solutions from November 25, 2008, to February 16, 2009, and that Respondent Renee Sadow was the PIC from February 16, 2009, to March 14, 2012. As of the commencement of the hearing, Board records showed that IV Solutions had no PIC.

4. Respondent IV Solutions has no prior record of discipline with the Board. However, administrative action was taken against Respondent IV Solutions in the form of three citations. In each instance, Respondent IV Solutions offered written explanations of the violations in question to the Board, but did not appeal the citations and instead paid the imposed fines. The Board accepted the payments as satisfactorily resolving each matter. Mr. Vara testified during the hearing that in those instances mistakes had been made and subsequently addressed. The three citations were as follows:

A. Citation No. 2006 32105, issued on September 25, 2007, imposed a $3,000 fine for violation of Business and Professions Code sections 4127.1 and 4301, subdivision (f).

B. Citation No. 2008 38272, issued on September 3, 2009, imposed a $5,000 fine for violation of Business and Professions Code section 4116 [non-pharmacist had a key and access to pharmacy] and California Code of Regulations, title 16, section 1714 [unsanitary storage of prescription items outside of pharmacy].

C. Citation No. 2008 38637, issued on December 28, 2009, imposed a $500 fine for violation of Business and Professions Code sections 4076, 4301 and 4078.

5. On August 25, 1971, the Board issued Original Pharmacist License Number RPH 27398 to Renee Sadow (Respondent Sadow). The license was in full force and effect at all times relevant and will expire on June 30, 2015, unless renewed. Respondent Sadow has no prior record of discipline or citations with the Board.

6. Board Supervising Inspector Janice Dang established through her credible and uncontroverted testimony that there are no prerequisites to procuring a pharmacy permit. A pharmacy permit applicant need only complete a financial affidavit and not have been convicted of a felony or misdemeanor related to drugs or arrested for driving under the influence of alcohol. There are no educational requirements of any kind nor is an applicant for a pharmacy permit subject to any testing requirements or required to possess any professional expertise.

Respondents' Background Information

7. A. Alireza Varastehpour was born in Iran in 1966 and came to this country with his family in 1975. English is not his first language. He uses the name Alex Vara because it is easier for others here to pronounce. Mr. Vara attended Santa Monica City College and the University of Southern California (USC) for two or three years, but he did not obtain a degree. He focused on business courses. After leaving school, he became involved in his family's business, real estate development, and then the textile industry.

B. In the 1990s, Mr. Vara became involved in healthcare, and has since remained in that field. He first did volunteer marketing for Apguard Medical, a company engaged in respiratory care and durable medical equipment for home healthcare. Mr. Vara next worked for Option Care in marketing and business development. Option Care was an infusion therapy home healthcare company. Typically, infusion therapy means that a drug is administered intravenously and is prescribed when a patient's condition is so severe that it cannot be treated effectively by oral medications. Option Care provided the infusion therapy at patients' homes. Mr. Vara next worked in marketing for Pacific Hospital in Long Beach, focusing on its home healthcare services. Mr. Vara next worked in marketing for the infusion services division of a Southern California affiliate of the Visiting Nurses Association (VNA). He next did marketing for IV League, a closed-door home infusion pharmacy, meaning the pharmacy was not open to the general public but rather catered to select clientele.

8. A. In 2000 or 2001, Mr. Vara left IV League to start his own business, IV Solutions, Inc. In 2002, the Board issued the pharmacy permit to Respondent IV Solutions. Mr. Vara is the sole owner and president of Respondent IV Solutions.

B. Respondent IV Solutions started with one pharmacist and five employees. It now employs 15-20 employees. Mr. Vara is in charge of business development. In August 2006, Mr. Vara hired Marlene Casillas to be the Chief Operating Officer. In that capacity, Ms. Casillas is in charge of human resources, billing and business operations. The PIC of Respondent IV Solutions is generally in charge of the prescriptions and clinical aspect of the pharmacy. At least 12 individuals served as PIC for Respondent IV Solutions from 2002 through 2014.

C. Respondent IV Solutions has always been a closed-door, clinical pharmacy, which provides home infusion therapy to patients. Mr. Vara and Ms. Casillas both describe IV Solutions as a low volume, high price, boutique pharmacy. In the past five years, Respondent IV Solutions has served an average of 1,000 patients per year.

9. A. Respondent Sadow became licensed by the Board to practice pharmacy in 1971. She worked her first few years as a pharmacist for government entities in Southern California. From 1976 to 2007, she worked as a pharmacist at Cedars-Sinai Medical Center. Respondent Sadow next worked as a pharmacist for Century City Doctors Hospital, until it closed in August 2008. She was thereafter recruited by a headhunter to apply for the PIC position at Respondent IV Solutions.

B. In January 2009, Respondent Sadow began working as a pharmacist at Respondent IV Solutions. In February 2009, she became the PIC. Throughout her tenure at IV Solutions, Respondent Sadow was only in charge of the clinical aspect of the business, i.e. filling prescriptions. She had no involvement in pricing, billing or business operations, which were handled by Ms. Casillas. Although Respondent Sadow interviewed and recommended prospective pharmacy technicians, the ultimate hiring of the technicians, as well as other pharmacists, was done by Mr. Vara and Ms. Casillas. Respondent Sadow had no power to fire any employee of IV Solutions, including clinical staff. Respondent Sadow essentially had no influence or power over the operations of Respondent IV Solutions, except in the filling of prescriptions. She quit her job at Respondent IV Solutions in March 2012, upset that her hours had been decreased after another pharmacist had been hired. Upon her exit, though, she voiced no complaints.

February 2008: Complaint from a Former Pharmacist-in-Charge

10. In February 2008, the Board received a complaint about Respondent IV Solutions from Ronald Rogers, who had served as its PIC from September 3, 2007, through January 16, 2008. The specifics of the complaint were not established. However, Ms. Casillas testified that Mr. Rogers left his employment at Respondent IV Solutions after a disagreement with Mr. Vara over the acquisition of the prescription medication Lovenox, which is used to treat thrombosis. When the complaint was received by the Board, Respondent IV Solutions had no PIC.

11. Board Inspectors Robert Venegas and Robert Kazebee were assigned to investigate Mr. Rogers' complaint. Inspectors Venegas and Kazebee are licensed pharmacists.

12. As part of their investigation, Venegas and Kazebee inspected Respondent IV Solutions' pharmacy premises on February 29, 2008. When the inspectors arrived at approximately 9:30 a.m. that day, no licensed pharmacist was present. The inspectors came into the IV Solutions business office, which was separated from the pharmacy by a locked door. Mr. Vara was called out to meet the inspectors and he was ordered to open the pharmacy for them. Mr. Vara had on his possession the pharmacy key. He complied with the command and opened the pharmacy. Mr. Vara was informed by the inspectors that he, as a non-pharmacist, was not allowed to keep the pharmacy key on his person; the key had to be kept in a sealed envelope signed by the pharmacist who last used it; and the pharmacy could not be opened until a pharmacist was present. Inspectors Venegas and Kazebee went inside the pharmacy and began their inspection.

13. A. While inspecting the pharmacy premises on February 29th, Inspector Venegas discovered that Respondent IV Solutions' staff had been creating and receiving pharmacy-related documentation in the name of "Stat Clinic Pharmacy" for approximately 25 patients. The documentation in question included contracts and agreements, medical forms, confidential medical records, and prescriptions. The Board has not issued a permit to any entity to act as a pharmacy in the name of "Stat Clinical Pharmacy," nor has it given permission to Respondent IV Solutions to engage in licensed activity under that name.

B. When questioned about this during the inspection, Mr. Vara advised Inspector Venegas that he used the name "Stat Clinical Pharmacy" as a billing company to serve patients of orthopedic surgeon Andrew Spitzer, because Dr. Spitzer would not refer patients to Respondent IV Solutions. Records obtained by Inspector Venegas indicated the name "Stat Clinical Pharmacy" also was used for patients referred by six other physicians. Inspector Venegas advised Mr. Vara that it was not appropriate to engage in licensed activity under another business name.

C. During the hearing, Mr. Vara and Ms. Casillas testified that Dr. Spitzer's staff knew he did not want his patients referred to Respondent IV Solutions because he was upset with Mr. Vara. They both testified that Dr. Spitzer's staff still referred patients because they preferred working with Respondent IV Solutions.

14. A. During the inspection on February 29th, Inspector Venegas found a number of prescription labels in a trash can located in the pharmacy. Inspector Venegas could not identify a licensed pharmacist listed on the labels. Many of the labels found in the trash showed the prescription was filled by "AVARA," an abbreviation used for Mr. Vara. As a result, Inspector Venegas suspected that Mr. Vara had filled those prescriptions.

B. When questioned about this by Inspector Venegas, Mr. Vara denied that he filled the prescriptions. He said his name appeared on the labels because he had opened the pharmacy to do billing and when he got into the computer software in question for that purpose, it automatically populated the document with his abbreviation, and that the pharmacist who later filled the prescription neglected to replace his name.

C. Inspector Venegas was concerned that Respondent IV Solutions used solely the computer system to identify the pharmacist who was responsible for filling prescriptions. Because he had seen so many labels in the trash that either had "PHARMACY" or "AVARA" in the "prescribed by" box, Inspector Venegas believed the computer system was not accurately recording the identity of the pharmacists responsible for filling prescriptions and/or that Mr. Vara was filling the prescriptions. Inspector Venegas advised Mr. Vara that a non-pharmacist's name could not be placed on a prescription label and that Respondent IV Solutions was required to have written procedures that identify each individual pharmacist responsible for filling a prescription and corresponding entry of such information into either an automated data processing system or a manual record system.

D. It was established by the testimony of Mr. Vara and Ms. Casillas that, at the time, Respondent IV Solutions had a manual record system to identify each individual pharmacist responsible for filling a prescription, where each pharmacist initialed and wrote down their name, prescription, drug, patient and date on the patient chart worksheet. The computer system was not used for that purpose. The prescription labels found by Inspector Venegas in the trash had been discarded and were essentially scrap paper not intended to be labels placed on medication containers or in the patient charts.

15. In response to Venegas' Inspection Report left with Mr. Vara upon completion of the February 29, 2008 inspection, Mr. Vara sent to the Board a letter dated March 19, 2008, which included copies of the requested documents, and assurances that the responsible pharmacists filling prescriptions were initialing all prescription records and that the name "Stat Clinical Pharmacy" would no longer be used.

16. Inspectors Venegas and Kazebee returned to inspect the premises on April 7, 2008, in part to verify if problems noted in the prior inspection had been addressed. The inspectors arrived at the premises on April 7th at about 10:30 a.m. At that time, there was not a licensed pharmacist present, although the inspectors believed that they saw a pharmacy technician mixing an IV solution in the pharmacy. However, it was not established by a preponderance of the evidence what exactly the pharmacy technician was doing at the time. (See Legal Conclusions 1-4.)

17. A. Because there was no pharmacist present upon his arrival on April 7th, Inspector Venegas presumed Mr. Vara had opened the pharmacy that morning. Unbeknownst to Inspector Venegas, pharmacist Jeannie Kim had opened the pharmacy earlier in the morning, but had left for a meal break shortly before the inspectors arrived. Thus, it was not established by a preponderance of the evidence that Mr. Vara opened the pharmacy for business without a pharmacist present. Nor was it established that Mr. Vara had a key to the pharmacy in his possession at the time the inspectors were present on April 7th. Nonetheless, when Jeannie Kim returned to the pharmacy at about 11:15 a.m., the inspectors told Ms. Kim that the pharmacy could not be open if she was not present. Ms. Kim did not respond or explain her absence other than to say that she would "take care of it." Ms. Kim was advised that the pharmacy needed written policies and procedures for temporary absences of the pharmacist during meal breaks.

B. Respondent's expert witness on pharmacy procedures, Tony J. Park, who is a licensed doctor of pharmacy, credibly testified that a pharmacy does not have to cease all operations when a staff pharmacist is on a meal break away from the pharmacy.

18. A. During the inspection on April 7th, Inspector Kazebee found several vials of Lovenox stored in the pharmacy. Lovenox is a dangerous drug. The vials in question had been imported from Canada, as the boxes containing the vials were labeled "Not for Export," were in both English and French, and clearly indicated they were from Canada. In addition, the boxes did not contain the required phrase, "Caution: Federal law prohibits dispensing without a prescription." Inspectors Kazebee and Venegas later learned that the vials of Lovenox were restricted to sales in Canada and had been purchased from and delivered by Hometown Meds Pharmacy, which was not licensed to sell wholesale prescription medications in California. Inspectors Venegas and Kazebee informed Mr. Vara that the vials of Lovenox were misbranded and could not be dispensed. They instructed Mr. Vara to return the vials to a reverse distributor or the pharmacy from where they came.

B. At first, Mr. Vara advised the inspectors that he did not know where the Lovenox came from; he later admitted the vials came from Canada. He told the inspectors that was all the Lovenox at the pharmacy. As demonstrated by later events described below, Mr. Vara's responses to the inspectors was suspicious.

19. Mr. Vara was requested to produce invoices for the purchase of the Lovenox in question. One such invoice showed that 15 vials of the Canadian Lovenox were shipped from Canada to the attention of Mr. Vara's father at his father's home. This transaction constituted one in which an unlicensed wholesaler, Quality Specialty Products, sent dangerous drugs, Lovenox, to an unlicensed facility, Mr. Vara's father's home. Mr. Vara testified that this happened because he used his father's credit card to buy the Lovenox when his own credit card was over its limit; and that the drugs were shipped to his father's address because that was the address listed on the credit card used for the purchase. As demonstrated by the events described below, where illegal Lovenox was subsequently found at the IV Solutions premises, Mr. Vara's explanation for the 15 vials sent to his father's home is suspicious.

20. During the inspection on April 7th, Inspector Venegas requested Mr. Vara to print out daily logs from March through early April 2008. After initially having difficulty, Mr. Vara was able to do so. Inspector Venegas examined the logs printed by Mr. Vara. In examining the daily logs, Inspector Venegas saw that many entries still showed "PHARMACY" or "AVARA" in the box used to identify the pharmacist responsible for filling the prescription. Inspector Venegas was still under the impression that the computer system was the primary way Respondent IV Solutions identified the pharmacist responsible for filling prescriptions. Based on the daily logs he reviewed, Inspector Venegas believed Respondent IV Solutions had not rectified the problem he previously identified. However, as discussed above, Respondent IV Solutions had a manual system of identifying the pharmacist responsible for filling prescriptions. The computer system was not the primary way that was done.

21. Inspector Venegas' review of the printed daily logs also revealed that Respondent IV Solutions' staff had refilled a Schedule II controlled substance on March 14, 2008. According to the law at that time, which had been recently changed, a prescription for a controlled substance could not be refilled; rather, a new prescription must be submitted. The only exception was for processing a partial refill for a terminally ill patient. However, it was not established that the patient in question had a terminal illness.

22. Despite the above-described suspicions of Inspector Venegas, it was not established by a preponderance of the evidence that Respondent IV Solutions had any non-pharmacist, including Mr. Vara, fill prescriptions for controlled substances or dangerous drugs in March 2008.

23. In response to Venegas' Inspection Report left with Mr. Vara and Ms. Kim upon completion of the April 7, 2008 inspection, Mr. Vara sent to the Board a letter dated April 21, 2008, advising that all of the Lovenox vials had been returned to Hometown Meds Pharmacy in Canada; written policies and procedures had been created to address pharmacy operations during the temporary absence of the pharmacist and how to identify the pharmacist responsible for filling prescriptions; and assuring that any activity concerning a Schedule II controlled substance will be signed within 72 hours, kept in a binder and updated daily and semi-annually by a pharmacist. Copies of UPS shipping invoices and receipts were included to show the Lovenox had been returned. Copies of the newly created policies and procedures were also included. Finally, Mr. Vara advised that Jeannie Kim had assumed the responsibilities of PIC. Board records indicate that happened, effective April 17, 2008. However, Respondent IV Solutions' assurances that all the Canadian Lovenox had been returned and none had been reordered are suspicious, because it was established by a preponderance of the evidence that several syringes of illegal Canadian Lovenox was again found at the IV Solutions' facility during a Board inspection on October 12, 2012; those syringes had expiration dates in either 2008 or early 2009.

24. A. Inspector Venegas sent Respondent IV Solutions an audit report dated April 6, 2009, which discussed the above-described events. Inspector Venegas testified that the one-year delay in sending out that document was due to the press of business on other investigations, which he characterized as posing greater danger to the public.

B. By a letter dated April 20, 2009, Mr. Vara submitted a written response to Inspector Venegas' audit report, in which he reiterated much of the same information discussed above. In addition, Mr. Vara stated that he had a good faith belief that it was permissible to buy the Lovenox from a Canadian distributor because one of his major American distributor/vendors, Amerisource-Bergen, similarly purchased Lovenox manufactured from Hometown Meds Pharmacy in Canada. Mr. Vara also advised that after the February 29th inspection, the pharmacy key was stored in a locked file on-site, and required a pharmacist's signature when possession of the key was taken. Mr. Vara also explained that before the April 7th inspection, Jeannie Kim had opened the pharmacy and had left for lunch before the inspectors arrived. Mr. Vara denied that any non-pharmacist had filled prescriptions, and advised that new software was obtained to eliminate the problem Mr.

Vara described happening when he accessed computers in the pharmacy for billing. The identities of pharmacists responsible for filling the prescriptions shown in the daily log print-outs given to Inspector Venegas were also provided.

25. During the time period of the aforementioned inspections and audit, Respondent Sadow had not yet been hired by Respondent IV Solutions.

April 2010: Patient D.K.[1]

26. On February 23, 2010, D.K., a 75-year-old widowed male, had a right total knee replacement performed by orthopedic surgeon Richard Biama. By early March 2010, D.K. had developed a bone infection in his right leg which required extensive antibiotic therapy. On April 2, 2010, Dr. Biama prescribed a six-week regimen of Zosyn, an antibiotic medication, to be administered intravenously 24 hours per day, with doses of 3.375 grams delivered by a prism infusion pump every six hours. Each dose would be administered over a one-hour period.

27. On April 2, 2010, D.K.'s medication therapy was referred to Respondent IV Solutions. Respondent Sadow, who was then Respondent IV Solutions' PIC, filled the prescription. She initially noted that Dr. Biama's office had made an obvious error in the total daily dosage, which she corrected after calling Dr. Biama's office for clarification. Respondent Sadow programmed Curlin 4000 CMS pump #115698 to use Code 2, which would provide the doses every six hours and lock the pump to secure the prescribed regimen.

28. The Curlin 4000 CMS pump is an ambulatory infusion pump and a dangerous device which can only be obtained by prescription from a licensed practitioner.

29. On April 2, 2010, Respondent Sadow also used her clinical judgment in packing supplies that she felt D.K. would need for the initiation of the intravenous (IV) therapy. The supplies included 3 x 1000 ml Sodium Chloride Irrigation; 72 ABD Pads 7.5 x 8 inches; 10 adhesive removers; 1 admission packet; 200 Alcohol Prep Pads; 15 Alcohol Swabstix 3's; 50 Gauze soft sponges 2 x 2 6 Ply; 100 Gauze sponges 4 x 4 8 Ply; 12 Gauze Fluff Rolls 4.5 inches x 4.1 yards; 100 Gloves powder free latex (medium); 10 Povie Swabstix 3's; 10 Syringes with Catheter Tips; and 3 Tape Paper 2 inches.

30. On April 2, 2010, Respondent IV Solutions delivered to D.K. the aforementioned supplies, the pump and a five-day supply of the Zosyn medication. A delivery ticket documenting what was delivered to D.K. was also provided. D.K.'s son-in-law, Kevin G., signed for D.K., documenting that the supplies and medication had been received that day. D.K. was periodically restocked with new supplies of the Zosyn, usually in five-day intervals.

[1] Consumer and/or patient names, as well as their relatives, are omitted to protect their privacy and the confidentiality of their medical and personal information.

31. Respondent IV Solutions contracted with Good Hope Home Health Care, Inc. (Good Hope) to provide nursing services to assist D.K. with his IV medication therapy. Soon after the Zosyn was delivered to D.K., a nurse from Good Hope set up the pump, began the medication therapy and showed D.K. and his family how to change the medication bags attached to the pump. The bag was placed in a plastic pouch that was slung over D.K.'s shoulder and sat on his chest. D.K. spent most of his time in a leather lifting/reclining medical chair.

32. From April 2, 2010, through April 7, 2010, a nurse by the name of Comfort from Good Hope cared for D.K. She was supposed to visit the home each morning and she was generally able to do so. Because of the distances involved and the family's preference to have the nurse come early in the morning, Comfort was unable to continue caring for D.K. At the family's request, the nursing services were changed. Respondent IV Solutions retained Genus Home Care (Genus) to care for D.K. A nurse by the name of Glenda from Genus was assigned to care for D.K.

33. From April 2, 2010, through April 15, 2010, no complaint or problem was noted with the administration of the medication provided.

34. On Friday, April 16, 2010, Nurse Glenda from Genus came to the house. At that time, Kevin G. was temporarily living with D.K. to provide care and supervision for him. Kevin G. and his wife Carrie, who was D.K.'s daughter, had their home nearby. Kevin G. and D.K. were the only ones at the home on Friday.

35. Many of the specific events that occurred on Friday are unclear. That is because some of the pivotal witnesses did not testify, including Nurse Glenda, Nurse Comfort, Carrie G., and D.K. (who is deceased). Moreover, the witnesses who did testify, namely Kevin G. and his mother Donna G., either conflicted each other or their own accounts. Nonetheless, a few critical facts were established.

36. For example, Kevin G. testified that Nurse Glenda started a new IV bag containing a 24-hour cycle of Zosyn sometime at 1:00 or 2:00 p.m. on Friday afternoon. Although his mother Donna G. testified that the new bag was started sometime around 6:00 p.m., she was not at D.K.'s residence on Friday, so her testimony appears to be based on second-hand information. In contrast, Kevin G., who was home then, was clear in his testimony that the bag was started early Friday afternoon around that time.

37. A. In addition, it was established that the family encountered a problem with the pump Friday evening. Although Kevin G. testified that he remembered no problems with the pump Friday evening, Nurse Glenda's supervisor from Genus, Janet Haywood, testified that she received three telephone calls from Genus' answering service Friday evening from the family. The calls were received from 7:32 p.m. through 8:27 p.m., with messages indicating that Kevin G. and Carrie G. had called about the pump and needed help with the medication. Ms. Haywood spoke with Kevin and Carrie and advised them that she had been unable to reach Glenda and that they should take D.K. to the emergency room. However, D.K. remained at home Friday night.

B. Ms. Haywood's testimony was persuasive and corroborated by notes of those messages transcribed by her answering service and annotated in handwriting by her. Ms. Haywood's testimony concerning receiving telephone calls Friday evening was also corroborated by Donna G., who testified that she remembered receiving telephone calls from Kevin G. Friday evening about a problem with the pump and that he had been unable to reach Nurse Glenda.

38. The specific problem with the pump was not established. For example, Kevin G. and his mother Donna G. offered conflicting versions whether a pump alarm was sounding. However, in a written statement about this event submitted to Inspector Kazebee well after the events in question (ex. 26), Respondent IV Solutions wrote that Nurse Glenda had documented that the "patient could not set up 'prism' pump independently."[2] Regardless of the problem with the pump, Kevin G. has consistently maintained that when he checked on D.K. before he turned in for the evening at approximately 11:00 p.m. on Friday, the IV bag still "looked full."

39. Meanwhile, Respondent Sadow had received permission from Ms. Casillas and Mr. Vara to allow Jeannie Kim to be the "on-call pharmacist" the weekend of April 17-18, so that Respondent Sadow could attend the annual concert in Coachella Valley. That meant any emergency or after hour calls to be handled by a pharmacist during the weekend would be routed to Ms. Kim. Respondent Sadow left for the desert on April 16th and checked into her hotel. Respondent Sadow's adult son, and a friend, traveled with her.

40. A. Despite being off duty that weekend, at 4:50 a.m. on Saturday, April 17th, Respondent Sadow received a call from Respondent IV Solutions' answering service, indicating that Kevin G. was requesting a nurse. Respondent Sadow told the answering service that she was on vacation and for them to contact the pharmacist on call, Ms. Kim.

B. Respondent Sadow's testimony was persuasive and corroborated by her cellphone billing records for that month, which show the times she made/received calls and the numbers in question. In the written statement about these events sent to Inspector Kazebee during the Board's investigation, Respondent IV Solutions acknowledged that its answering service received a call at 4:49 a.m. on April 17th from Genus indicating that D.K.'s family was upset that the nurses were consistently late and needed to schedule early morning visits. In that same written statement to Inspector Kazebee, Respondent IV Solutions stated that Mr. Vara, who was the "administrator on call" that weekend, took the call at 4:52 a.m. and was told that "the patient's caregiver stated the pump was malfunctioning."

41. Kevin G. testified that when he awoke early in the morning of Saturday, April 17th, he found D.K. sleeping and the IV bag empty. Kevin G. testified that this happened sometime around 6:00 a.m., however, his mother Donna G. testified that he called her at

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[2] Although the cover letter and declaration form are signed by Respondent Sadow, the actual response was written by Ms. Casillas, with little assistance from Respondent Sadow.

about 5:00 a.m., which is more consistent with the telephone calls referenced above. Kevin G. testified that nothing else was unusual. Since the bag looked empty and there were several hours to go until 24 hours had lapsed from the when IV was started, Kevin G. became afraid that D.K. had received the full 24-hour cycle of Zosyn in much less than 24 hours.

42. Kevin G. immediately called his mother, Donna G., because she is a registered nurse. Donna G. testified that she arrived at D.K.'s home at about 6:00 a.m. on April 17th. At that time, D.K. was complaining only of a frontal lobe headache. Donna G. checked D.K.'s vital signs and found D.K. was in otherwise good condition. During the hearing, Respondent Sadow credibly testified that Donna G.'s description of D.K.'s status and symptoms that morning was inconsistent with a Zosyn overdose.

43. At 8:57 a.m. on April 17th, Respondent Sadow called Mr. Vara to confirm with him that she was away from town on vacation and was not on call that weekend. She advised Mr. Vara that Jeannie Kim was the pharmacist on call and that either Ms. Kim should be involved in the situation or Respondent Sadow could call the nurse if needed. Respondent Sadow testified that it was also possible that she advised Mr. Vara to send out a nurse to the home to check on the pump. At 9:02 a.m. Respondent Sadow was called by the answering service and told that she would receive no further calls that weekend.

44. Many of the involved witnesses described making and receiving several other telephone calls on Saturday, April 17th. Unlike the above-described telephone calls, few of the others were documented or corroborated. However, it is clear from the combined testimony of Kevin G., Donna G., and Janet Haywood (the owner of Genus), that the following calls were made:

A. D.K.'s family members called Genus several times that morning and early afternoon asking for nursing assistance with the pump.

B. Later in the morning and in the early afternoon, Kevin G. and Donna G. spoke to Mr. Vara several times. They complained about the pump and asked for the pump to be replaced. Mr. Vara consistently told them that there was nothing wrong with the pump and that instead Nurse Glenda was incompetent and she was to blame for the problem. When Donna G. asked to speak to a pharmacist, Mr. Vara told her that he was the owner of the pharmacy and was the proper person to speak to about the situation.

C. Early in the afternoon, both Kevin G. and Donna G. had heated telephone conversations with Mr. Vara concerning their requests to have the pump replaced. Mr. Vara cursed at them and hung up. For example, Mr. Vara told Kevin G. to "go fuck yourself and hire an attorney;" he told Donna G., "I don't give a shit."

45. Despite the conversations described above, and the fact that the family members had generally complained about the pump, it was not established that anybody advised Mr. Vara that the pump had "dumped" an excess amount of Zosyn into D.K. before the allotted time.

46. On April 17th, Mr. Vara was able to have Nurse Comfort from Good Hope return to care for D.K. When Nurse Comfort arrived at the home at 6:00 p.m. that evening, she was initially unable to get the pump to work as it had before. She was directed to call the Curlin manufacturing technician for direction. After that call, Nurse Comfort was able to program the pump and it worked the remainder of the evening without incident.

47. Kevin G. testified that sometime during the evening of April 17th, he spoke to a female pharmacist from Respondent IV Solutions named "Jean" or "Jeanine," presumably Jeannie Kim. The substance of their conversation was not established. Kevin G. testified he referred the female pharmacist to his mother Donna G.; Donna G. simply testified that the female pharmacist told her that the nurse would help the family with the pump.

48. Although the family never took D.K. to the emergency room, they decided to take him off the IV medication regimen a few days later because of the events of April 16th and 17th. D.K. completed his antibiotic regimen by taking oral medications. The pump was returned to Respondent IV Solutions on or about April 22, 2010.

49. Mr. Vara describes his role on April 17th as being the "administrator on call." He likes to receive all of the after-hours calls so he knows where the problem areas are in his business. As the administrator on call, he triages the calls received after regular business hours. Mr. Vara testified that many such calls relate to billing or delivery issues, as opposed to a request for a pharmacist to exercise clinical judgment, and therefore do not need to be referred to a pharmacist. Mr. Vara determines whether and where to direct the calls after receiving them.

50. After speaking with Respondent Sadow briefly before 9:00 a.m. on Saturday, April 17th, as well as the Curlin manufacturing technician and Ms. Haywood of Genus later that morning, Mr. Vara decided that there was nothing wrong with the pump in question, but rather that Nurse Glenda had done something to the pump on Friday that was causing a problem. Mr. Vara believed the pump problem could be rectified by a nurse. Having lost confidence in Nurse Glenda, Mr. Vara believed that if Nurse Comfort from Good Hope returned to service on the D.K. matter, she could restore the pump to functioning status.

51. Ms. Haywood of Genus was clear in her testimony that when she spoke with Mr. Vara on April 17th, he identified himself to her "as the pharmacist." Yet, Mr. Vara was just as clear in his testimony that he did not represent himself as a pharmacist when he spoke with Ms. Haywood and that instead he probably said, "This is the pharmacy." Under these circumstances, it was not established by a preponderance of the evidence that Mr. Vara represented himself as a pharmacist to Ms. Haywood. As the owner of the business that had contracted with Genus to provide nursing services to D.K., there is no apparent reason for Mr. Vara to make such a misrepresentation. Moreover, it was Mr. Vara's custom and practice to answer calls after-hours, "This is the pharmacy." No other evidence suggests Mr. Vara had, before or since, represented himself as a pharmacist. No motive was presented to explain why he would have done so on this occasion. Under these circumstances, it is likely that Ms. Haywood simply misunderstood Mr. Vara's greeting, "This is the pharmacy."

52. A. After discovering the IV bag was empty early the morning of April 17th, and based on the events that had unfolded on both April 16th and 17th, D.K.'s family came to believe that the Curlin pump had "dumped" a 24-hour dose of 13.5 grams of Zosyn antibiotic into D.K. in far less than 24 hours.

B. It was not established by a preponderance of the evidence that the Curlin pump had malfunctioned. Whether the last 24-hour cycle of Zosyn had been started on Friday the 16th at 1:00 p.m. or 6:00 p.m., it is clear that the bag still appeared "full" at 11:00 p.m. on Friday evening when Kevin G. last checked on D.K. before going to bed. If the pump had been incorrectly set on a continuous cycle, it is doubtful that the bag would have appeared full either five or ten hours later, depending on when the bag had been started.

C. The most believable version of events is based on Kevin G.'s testimony, in which he pin-pointed that the IV bag was started Friday at 1:00 p.m. Based on the credible expert opinions expressed by both Respondent Sadow and Respondent IV Solutions' expert witness on pharmacy practices, licensed doctor of pharmacy Tony J. Park, it is likely that at 5:00 or 6:00 a.m. on Saturday morning, the IV bag would have appeared empty when in fact it was not. That is because the pump would have cycled at least three doses, occurring at 1:00 p.m., 7:00 p.m., and 1:00 a.m. In order to keep the line moist where inserted into D.K.'s leg to protect the connection, the pump also continuously trickled small amounts of medication. In addition, the way in which the bag was slung flat over D.K. would have made the remaining contents appear less than if the bag was hung vertically off a pole. Thus, by the time Kevin G. saw the bag in the morning, more than likely it would have appeared empty, even if there was one quarter dose, or less, remaining. Complainant presented no expert opinion evidence to the contrary, other than the observation of Donna G., who is a registered nurse and familiar with IV bags. Yet, when Board Supervising Inspector Janice Dang testified in Respondent IV Solutions' case-in-chief, she agreed that after three-quarters of the bag was administered, there would likely be two ounces of fluid left. Because the family had believed the medication should not be completed until 1:00 p.m. or later, it is likely that they simply viewed the depleted bag as being completely empty, when it probably had much less than one-quarter remaining.

D. If the pump had been inadvertently set on the continuous mode of administration, there is no explanation why the bag would have appeared full at 11:00 p.m. on Friday, five to ten hours after it was started, and yet appear to be completely empty at 6:00 a.m. on Saturday, six to seven hours later.

53. A. On Monday, April 19th, Respondent Sadow returned to work from her weekend holiday. A pharmacy technician mentioned something to her about the pump problem experienced by D.K. and his family over the weekend. She heard no other particulars about the situation. Respondent Sadow testified that she never spoke to a nurse from Genus or Good Hope or any of D.K.'s family members; no evidence was presented to the contrary. Although Ms. Casillas testified that she heard on her return to work Monday morning that there was a reported pump failure over the weekend at D.K.'s home, she did not testify that she relayed any information to Respondent Sadow.

B. Respondent Sadow did not follow up on her return to work and nobody at Respondent IV Solutions followed up with her. Because Respondent Sadow was under the impression that the pump problem had been resolved over the weekend, and she did not know that the family believed the pump had "dumped" an over-dose of medication into D.K., she never considered whether or not to conduct a quality assurance review of the situation.

54. On April 19th, Donna G. submitted an online complaint to the Board concerning the D.K. situation. Inspector Kazebee was assigned to conduct an investigation, which he began on April 30, 2010.

55. A. During his investigation of the D.K. matter, Inspector Kazebee requested and obtained documents from Respondent IV Solutions. Some of the documents he obtained showed that on April 2 and 7, 2010, Respondent Sadow used prescription labels that represented the name of the pharmacy as "IV Solutions Clinical Pharmacy," instead of "IV Solutions Inc." The Board has not issued a license for "IV Solutions Clinical Pharmacy." Inspector Kazebee told Mr. Vara, Ms. Casillas and Respondent Sadow that they could not do business under a name other than what was stated on the pharmacy permit.

B. Mr. Vara could not remember whose idea it was to use that name style. It does not appear that this name style was used at the direction of Respondent Sadow. Instead, it appears that Respondent Sadow simply went along with the practice. In any event, the intention behind using the name style "IV Solutions Clinical Pharmacy" was to denote that this was a closed, clinical pharmacy that mixed its own IV solutions and medications. There is no evidence indicating that there was any intention of deceiving the public. Ms. Casillas and Respondent Sadow were surprised to learn that it was improper to use that name style. They stopped using that name style immediately after being so advised.

C. This name style did cause some initial confusion in the D.K. matter. Donna G. testified that when she began researching the matter after the events of April 17th, she saw the name style "IV Clinical Solutions Pharmacy" on the label of the Zosyn bag in question, but was initially unable to find such an entity in telephone directories or on the Board's website. That made her suspicious whether Respondent IV Solutions was a Board-licensed pharmacy. However, based on how rapidly she filed her complaint with the Board, it appears that Donna G. was able to find the correct information for Respondent IV Solutions.

D. In order to find a licensed pharmacy on the Board's website, the exact name of the business as it is listed on its license must be used in the search. One cannot find a licensed entity using a search that "looks like" or includes part of the licensed name. Both Mr. Vara and Ms. Casillas testified that they now realize using a different name style could have been confusing under these circumstances.

56. A. As part of his investigation of the D.K. matter, Inspector Kazebee visited Respondent IV Solutions' office on August 11, 2010. During that visit, he interviewed Respondent Sadow. Since so many months had transpired from the events in question, and Respondent Sadow had not been closely involved with the situation, she forgot she was out-of-town the weekend of April 17-18, and she did not disclose that fact to Inspector Kazebee.

She did not remember that fact until one year later. For that reason, although she spoke with Inspector Kazebee for approximately two hours, Respondent Sadow could only provide to him vague details about the events based on IV Solutions' records.

B. Inspector Kazebee also requested Respondent Sadow to provide him with a list of all dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocols for the supplies and/or dangerous drugs sent to D.K. Inspector Kazebee only made this request of Respondent Sadow, and not Ms. Casillas or Mr. Vara; as the PIC, Inspector Kazebee felt Respondent Sadow was solely responsible for meeting his request. Respondent Sadow provided Inspector Kazebee with what she believed he requested.

57. A. When Inspector Kazebee had previously met with and interviewed Donna G. about the events in question, she gave him a copy of a delivery ticket given to the family when the initial supply of Zosyn and wound care supplies were delivered on April 2nd. Inspector Kazebee noticed that that particular delivery ticket had not been provided to him by Respondent Sadow on August 11th. On September 16, 2010, Inspector Kazebee requested copies of various records, including documents concerning drugs and supplies delivered and billed to D.K. Respondent Sadow, with the assistance of Ms. Casillas, responded.

B. In her response, Respondent Sadow failed to provide Inspector Kazebee with a copy of the April 2nd delivery ticket. It was not established that her omission was intentional; if anything, it appeared to be inadvertent. Through several inspections and investigations by the Board before and after the events in question, Respondent IV Solutions had always complied and been cooperative; the same is true of the investigations of the matters involved in this case. The one delivery ticket in question is the only document apparently not provided by the Respondents to the Board when requested. The delivery ticket in question contains the same information otherwise contained in Respondent IV Solutions' patient file for D.K. Copies of all the other delivery tickets with the same type of information were provided to Inspector Kazebee.

C. No reason or motive was presented explaining why Respondent Sadow would purposefully secrete the one document in question in light of the fact that all the other information was presented and all of the information contained in the one missing ticket was contained in the other documents provided.

58. On or about August 23, 2010, Ms. Casillas sent Respondent IV Solutions' formal response to Inspector Kazebee concerning this incident. Attached to the response was IV Solutions' "Billing Notes" allegedly entered by Mr. Vara concerning this incident on April 17-18, 2010. In that note, Mr. Vara documented that D.K.'s family complained the pump "was malfunctioning"; the settings of the pump did not match what was on the order label; Respondent Sadow told Mr. Vara to call Curlin; somebody at Curlin told Mr. Vara that somebody at the house had changed the pump settings; Nurse Glenda could not follow their instructions to reprogram the pump; Respondent Sadow told Mr. Vara to send Nurse Comfort back to the home; and upon Nurse Comfort's return to the home, the pump was "O.K. last

night, with no further incidents." Interestingly, none of the information in the "Billing Notes" was contained in D.K.'s patient worksheet or chart. To the extent this information conflicts with the findings above, that information is disregarded.

59. Respondent IV Solutions' expert witness on pharmacy practices, Dr. Park, opined that the standard of care permits pharmacists to refer patients with questions about a device like the Curlin pump to the manufacturer if they cannot answer the question. This is because most pharmacists do not have the technical knowledge to answer such questions. However, Dr. Park testified that if a patient question involves clinical judgment related to the medical therapy provided by the device, the pharmacist should handle the question instead of referring the patient to the manufacturer. Dr. Park admitted that in some instances deciding whether an infusion pump functioned properly could be a clinical matter for the pharmacist. Dr. Park also opined that if a pharmacy contracts with a nursing agency to assist with the infusion therapy, it is within the standard of care to delegate patient consultation to the nurse. However, Dr. Park did not specifically opine whether Respondent IV Solutions met the standard of care in D.K.'s case in these regards.

October 2010: Patient C.R.

60. C.R. is a 78-year-old married woman who lives in the San Diego area. In June 2010, she fell and hurt her left foot. Her foot worsened over the following weeks. In August 2010, a tendon in her foot ruptured. In September 2010, she met with orthopedic surgeon Sharon M. Dreeben, who concluded an operation was necessary to repair the damage. An operation for C.R. was scheduled for October 7, 2010.

61. On October 5, 2010, and in anticipation of the surgery, Dr. Dreeben prescribed C.R. to receive antibiotics and pain medication (morphine) by an infusion pump at home after she was released from the hospital. On that same day, Dr. Dreeben's office requested Respondent IV Solutions to provide the home infusion services to C.R.

62. On October 5 or 6, 2010, Respondent IV Solutions retained Care South Home Health Service (Care South) to provide nursing services for C.R. in her home in conjunction with the infusion pump therapy. Respondent IV Solutions would use a Curlin infusion pump, similar to the one used in the D.K. matter discussed above. A manager of Care South, Stephanie Phillips, had previously requested IV Solutions provide Care South nurses in-service training on how to use the Curlin pump, since the Care South staff was not familiar with that medical device. Mr. Vara refused to do so. He felt it was the manufacturer's responsibility to do any in-service training, since it was their device; and that, as licensed professionals, registered nurses and their employing agencies should know how to use such equipment. Instead, Respondent IV Solutions provided a manufacturer's DVD to Care South which demonstrated how to use the Curlin pump.

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63. In compliance with the Pharmacy Law, Respondent IV Solutions has written policies and procedures (P&Ps) covering the various aspects of its pharmacy and business operations. The following, which were effective in October 2010, apply to C.R.'s situation:

A. P&P No. 8.2-03-- Home Medical Equipment: Delivery & Setup. The policy is for "[s]taff who have been properly trained and are competent will setup [*sic*] home medical equipment and instruct the patient/caregiver in its use," and "[s]taff will setup [*sic*] and instruct the patient in the use of home medical equipment per the physician's orders."

B. P&P No. 8.2-04-- Home Medical Equipment: Patient/Caregiver Training. The policy is that "[s]taff who have been properly trained and are qualified in providing home medical equipment will setup [*sic*] and instruct the patient/caregiver in the use of equipment," and that "[s]taff will provide patient both verbal and written instructions on the safe, effective and appropriate use as prescribed by the patient physician." The procedures include that a clinical associate or delivery person will provide instructions on how to use the equipment and reinforce those instructions; will ensure the patient/caregiver can set up the equipment and troubleshoot problems by asking questions and having the patient/caregiver demonstrate an ability to operate the equipment, as well as make sure they know who to call in the event of a problem; and complete a checklist to make sure that the patient/caregiver has been provided with the appropriate instruction.

C. P&P No. 5.9-- On-Call (After Hours Care). The policy provides that at least one qualified health care professional from each clinical discipline will be available at all times. Patients are to be trained how to access the on-call system at the initial home visit. Other health care professionals involved in the patient's care are to be similarly informed. The procedures include one pharmacist being available at all times for patient-related questions and service, and the same for one registered nurse. At the end of each business day, an employee will be responsible for forwarding calls to an answering service. It is the responsibility of the person on call to "intermittently check the answering service for messages."

64. Respondent IV Solutions' documents indicate that the medications, infusion equipment and supplies were delivered to C.R.'s home on October 5 or 6, 2010. C.R.'s husband signed the delivery receipt. C.R. and her husband were not verbally instructed at the time of delivery how to use the infusion equipment.

65. On October 7, 2010, Dr. Dreeben performed successful surgery to repair C.R.'s ruptured tendon. C.R. remained in the hospital that day.

66. On Friday, October 8, 2010, Dr. Dreeben released C.R. from the hospital. C.R. arrived home early in the morning. C.R. was still under the effects of pain medication given to her at the hospital, so she was not experiencing much pain. A registered nurse from Care South arrived later that morning, at approximately 9:00 a.m. The nurse set up the infusion equipment and started C.R.'s antibiotic therapy. Because C.R. was not experiencing pain at that time, she told the nurse that she did not want the morphine.

67. It was not established that at any time on October 8th the nurse or anyone acting on behalf of Respondent IV Solutions engaged in the activities required by the above-described P&Ps, including explaining how to use the infusion pump, how to troubleshoot or to have C.R. or her husband demonstrate how to use the pump. There is no documentation in Respondent IV Solutions' file for C.R. indicating that any such activity or instruction occurred; noticeably absent is the aforementioned checklist used to show that C.R. and/or her husband were provided with the instruction required by the P&Ps.

68. On October 8th, one of Care South's registered nurses, Celia, was instructed to watch the DVD showing how to use the Curlin pump because she would be assigned to visit C.R.'s home the following day. Nurse Celia did so.

69. A. Very early in the morning of Saturday, October 9, 2010, C.R. experienced increasing pain in her foot. It became harder for her to sleep and she now wanted the morphine. Presumably because she had not been instructed on how to set up and use the home infusion equipment, C.R. awaited the arrival of her nurse to receive the morphine. Nurse Celia arrived Saturday morning at approximately 9:00 a.m. C.R. told Nurse Celia that she was eager to receive the morphine.

B. Nurse Celia began to administer morphine via the Curlin pump to C.R. However, after hooking up the IV bag of morphine, Nurse Celia became hesitant. She advised C.R. that she was not familiar with the Curlin pump and had to check something before beginning the morphine dose.

C. Nurse Celia decided to call Respondent IV Solutions for assistance. Nurse Celia used all of the phone numbers known to her for IV Solutions, but was unable to reach anyone because the phone calls were not being answered. After Nurse Celia advised C.R. what was happening, both C.R. and her husband also tried to contact Respondent IV Solutions several times by calling the phone number provided to them. They were unable to speak with anybody or leave a message. Nurse Celia called Ms. Phillips and advised her that she was having a problem with the Curlin pump and could not reach Respondent IV Solutions for assistance. Ms. Phillips used all the phone numbers she had for Respondent IV Solutions but was also unable to get an answer or leave a message. C.R. testified that when she tried to call, she got a message to the effect that the number was no longer in service. When Ms. Phillips called, she just heard ringing and did not get an answer.

D. As a result of this situation, C.R. decided to forego the morphine via the pump and instead relied on pain pills prescribed by her physician.

70. Ms. Phillips continued trying to contact IV Solutions but was unsuccessful. She finally reached Mr. Vara by phone on Monday, October 11, 2010. Ms. Phillips explained to Mr. Vara what happened and that she was not able to reach him over the weekend. Ms. Phillips testified that when they spoke that day, Mr. Vara told her the business phone had been "out all weekend," which he did not know about it until he arrived at the office that day. The content of Ms. Phillips' testimony, as well as her demeanor when providing it, was credible, and was amply corroborated by the information about these events discussed below.

71. Early in the week of October 11th, C.R. advised Respondent IV Solutions that she no longer needed the pump or their medications. She spoke with Mr. Vara to complain about the situation. Mr. Vara expressed skepticism that nobody had been able to contact Respondent IV Solutions on Saturday. C.R. was upset with Mr. Vara and felt he was accusing her of lying. C.R. arranged to have the equipment and the medications picked up from her house. She requested a refund, but Mr. Vara denied her request.

72. It was not established that there was any defect with the Curlin pump or that it was improperly programmed. The evidence established that Nurse Celia simply was unfamiliar with it and had a problem getting the pump started.

73. A. On February 18, 2011, C.R. submitted a written complaint to the Board about this situation. By April 2011, Board Inspector Anna Yamada was assigned to investigate C.R.'s complaint. In the course of her investigation, Inspector Yamada subpoenaed records from Respondent IV Solutions' answering service and interviewed a manager from the company. Those records revealed that the answering service received no calls for Respondent IV Solutions on October 9th (Saturday), and did not begin receiving calls again until 10:00 a.m. on October 10th (Sunday). However, those records showed that the answering service received calls and messages for Respondent IV Solutions both days of the weekend preceding the one in question, as well as both days of the next two weekends.

B. Based on the information she received, Inspector Yamada concluded that Respondent IV Solutions' staff simply forgot to activate the phone system's roll-over of after-hours calls to its answering service the evening of October 8th when the business office closed. Her conclusion is consistent with the comment Mr. Vara made to Ms. Phillips when they discussed the situation on October 11, 2010. In addition, no evidence was presented indicating that anybody from IV Solutions intermittently contacted the answering service for messages on October 8th or 9th, which may have alerted the caller to a roll-over problem.

74. During her investigation, Inspector Yamada also received the following information from Respondent IV Solutions about this situation:

A. In a letter dated July 5, 2011, Respondent IV Solutions indicated that when a Curlin pump is delivered to a patient, an instruction manual with graphics is provided. "There is no need to inservice the patient or nursing other than this instructional." The instructions further advise that if problems are encountered, the patient should contact the pharmacist or Curlin's technical assistance number.

B. In a letter dated February 10, 2012, Respondent IV Solutions indicated that Care South and C.R. were provided with written instructions on how to use the pump, which contained a toll-free telephone number to contact Curlin for 24-hour technical assistance. Respondent IV Solutions also provided information from its answering service indicating that no calls from C.R. were received that weekend, that one call was received by them on Saturday, October 9th, and that they experienced no problems with their phone system that weekend. However, the information from the answering service relayed by Respondent IV Solutions is suspect, because the aforementioned records subpoenaed from the company

showed no calls logged on October 9th. Moreover, it is not clear that the answering service would be aware of "any problems" if Respondent IV Solutions staff had simply failed to activate the system that would roll-over calls to the answering service.

75. During the hearing, Mr. Vara testified that if a phone call to IV Solutions is not rolled over to its answering service and rings nine times, the call defaults to his voicemail and he receives a page indicating that he has a message. Mr. Vara's testimony was not persuasive because it was self-serving and he failed to provide any corroboration. Moreover, Mr. Vara admitted that although he typically receives "zero to 15 calls on Saturdays," he received none on the Saturday in question. If the phone system was working as he described, he would have received a message from C.R., her husband, Nurse Celia and/or Ms. Phillips. Though it is possible one of those individuals dialed the wrong number, it is highly unlikely that all four did repeatedly. In any event, Mr. Vara's testimony is undercut by his admission to Ms. Phillips that the phone system "went down" that weekend. When he testified during the hearing, Mr. Vara did not discuss his conversation with Ms. Phillips. Finally, Mr. Vara did not indicate in his testimony that he attempted to check in with the answering service the Saturday in question to see if he had any messages.

76. A. As referenced above regarding patient D.K., Dr. Park opined that the standard of care permits pharmacists to refer patients with questions about a device like the Curlin pump to the manufacturer if they cannot answer the question. This is because most pharmacists do not have the technical knowledge to answer such questions. However, Dr. Park testified that if a patient question involves clinical judgment related to the medical therapy provided by the device, the pharmacist should handle the question instead of referring the patient to the manufacturer. Dr. Park also opined that if a pharmacy contracts with a nursing agency to assist with the infusion therapy, it is within the standard of care to delegate patient consultation to the nurse. However, Dr. Park did not specifically opine whether Respondent IV Solutions met the standard of care in C.R.'s case in these regards.

B. Dr. Park's general opinions were not contested by the other parties and they seem reasonable. However, Dr. Park failed to address the issue of how the standard of care is effected if a pharmacy has P&Ps requiring verbal instruction to the patient on how to operate equipment and confirmation that the patient understands, and yet that instruction is not provided to the patient. Another limitation to Dr. Park's testimony is that nobody from the nursing agency or C.R.'s family was able to contact IV Solutions after they had problems with the pump. For that reason, they were never referred to Curlin. Compounding things, it was not established that anybody instructed C.R.'s family or Care South to contact Curlin for technical assistance if they experienced a problem with the pump. Written instructions with that information may have been left at C.R.'s home, but the P&Ps required verbal confirmation with the patient/caregiver concerning such important information. Although Respondent IV Solutions was apparently within the standard of care by delegating the pump consultation duties to Care South, Respondent IV Solutions did little to insure that Care South nurses were trained or competent to operate the Curlin pump, even though its P&Ps required that. This was so even after Care South specifically requested in-service training for the Curlin pump because their nurses were unfamiliar with it.

C. Based on the above, it is clear that on the day in question, a nurse who was unfamiliar with the Curlin pump, and improperly trained in how to use it, was sent to C.R.'s home. C.R. was also unable to work the pump. After experiencing problems with the pump, neither the nurse nor the patient knew to contact the manufacturer for technical assistance and were unable to contact Respondent IV Solutions for help.

77. During her investigation of the C.R. matter, Inspector Yamada learned that from about January 1, 2009, to about January 1, 2012, Respondent IV Solutions obtained Curlin Medical 4000 CMS pumps from an unlicensed wholesaler, Ardus Medical (Ardus), located in Cincinnati, Ohio, on at least 38 occasions. Because the Curlin pump is a dangerous device, Respondent IV Solutions was not permitted to purchase, trade, sell, or transfer dangerous drugs and devices at wholesale with a person or entity that was not licensed with the Board as a wholesaler or pharmacy. (See Bus. & Prof. Code, § 4169, subd. (a)(1).)

78. At the time, Respondent IV Solutions did not know that it could not obtain Curlin pumps from Ardus because it was not licensed to supply such equipment in California. In fact, Ardus' management did not know that either. Because Ardus was not required by the state of Ohio to have a license to supply Curlin pumps to persons or entities in that state, Ardus' management did not think a license was needed to do that in other states. Once Ardus employees were advised by Inspector Yamada that a wholesaler license was needed to supply the Curlin pumps in California, Ardus immediately submitted an application for such a license. Inspector Yamada described this situation as an "honest mistake" made by Ardus.

79. Inspector Yamada advised Respondent IV Solutions about the problem with Ardus. Mr. Vara and Ms. Casillas were under the same erroneous understanding as Ardus. Once they were directed by the Board to stop obtaining Curlin pumps from Ardus unless and until it had a wholesaler license, Respondent IV Solutions asked Inspector Yamada for assistance in finding a licensed wholesaler who could provide the pumps. Respondent IV Solutions ultimately was able to find one after some difficulty.

80. It was not established that any of the Curlin pumps sent to Respondent IV Solutions while Ardus was unlicensed posed a safety problem.

81. Although she was the PIC at the time, Respondent Sadow was not directly involved in the C.R. matter. It was not established that she filled the prescription or programmed the Curlin pump. It was not established whether she was the on-call pharmacist on October 8th; Respondent Sadow provided no evidence concerning who was the on-call pharmacist that day. However, Respondent Sadow was on vacation from October 10-15, 2010. None of the subsequent calls made to Respondent IV Solutions by C.R. or Ms. Phillips were ever directed to Respondent Sadow. In fact, Inspector Yamada did not contact or interview Respondent Sadow during her investigation of the C.R. matter. For these reasons, Respondent Sadow was unaware of the C.R. situation until she received the Second Amended Accusation.

82. Respondent Sadow was similarly unaware that Ardus needed a wholesaler license to supply the Curlin pumps in California. Respondent IV Solutions was obtaining Curlin pumps from Ardus before Respondent Sadow became the PIC. She was legally required to evaluate IV Solutions' compliance with all state and federal laws pertaining to pharmacy within 30 days of assuming the position of PIC and every year thereafter, and therefore Respondent Sadow had multiple opportunities to research the Ardus situation. (See Cal Code Regs., tit. 16, § 1715.) However, Ms. Casillas was generally in charge of handling IV Solutions' licensing and permits. Respondent Sadow believed that Ms. Casillas was adept at making sure the required licenses and permits were procured and maintained. Thus, Respondent Sadow assumed that Ardus was legally able to provide the pumps. Once she was advised that the Curlin pumps could not be obtained from Ardus unless and until it had a wholesaler license, she stopped ordering Curlin pumps from Ardus.

2009 through 2011: Prescription Drugs Furnished to Patients J.M. and R.M.

A. Patient J.M.

83. J.M. lives in Los Angeles County with his wife of 35 years, R.M. (She will be referred to as "J.M.'s wife" to avoid confusion with patient R.M. who is discussed below.) In 2009, J.M. was diagnosed with Hepatitis C. He was advised by his physician, Dr. Paola Tempesti, that a liver transplant was foreseeable given his situation.

84. On November 5, 2009, J.M. visited Dr. Tempesti's office. On that day, Dr. Tempesti prescribed an aggressive IV regimen of several medications to be administered for one year to hopefully spare a liver transplant.

85. For reasons not established, Dr. Tempesti referred J.M.'s IV treatment to Respondent IV Solutions, who was not within the network of providers for J.M.'s insurance company. Respondent IV Solutions delivered the first IV medications and supplies to J.M. on Saturday, November 6, 2009, and continued to do so thereafter.

86. Neither J.M.'s referring physician nor Respondent IV Solutions revealed to J.M. or his wife that IV Solutions was out of network. Respondent IV Solutions did not disclose the cost of care to J.M. or his wife in advance of rendering services, the anticipated charges to them or the co-insurance amount before services commenced.

87. On a date not established, but by or before January 29, 2010, Respondent IV Solutions sent charges to J.M.'s health insurance company for treatments provided from November 7, 2009, through January 4, 2010. Those charges triggered J.M.'s insurance company to issue an Explanation of Benefit Payments (EOB) on January 29, 2010. The EOB showed the total amount billed by Respondent IV Solutions, as well as that J.M.'s insurance company had only agreed to pay $21.67 of those charges. J.M.'s wife became alarmed when she received the first EOB because she believed IV Solutions' charges were excessive and the insurance company had indicated that it would pay very little.

88. J.M.'s wife contacted IV Solutions and spoke with an employee named Andrew, who advised her that there had been a "coding error" that would be fixed. Since the family did not receive another EOB until approximately one year later, neither J.M. nor his wife took any further action at that time.

89. Although J.M. was supposed to stay on the IV regimen until November 2010, he suffered a reaction to the medications and became seriously ill in September 2010; at that time he stopped receiving the IV treatment and it was never resumed.

90. During the period of November 6, 2009, through September 2010, Respondent IV Solutions furnished several prescription dispensings for medications, including Pegasys, Ribavirin, Procrit and Neupogen. Respondent IV Solutions sent bills to J.M.'s health insurance company totaling $2,031,446.10. Respondent IV Solutions incurred an acquisition cost of approximately $34,187.87 for those medications.

91. It was established by a preponderance of the evidence that Respondent IV Solutions sent most of its bills to J.M.'s insurance in January 2011. In late January and early February 2011, J.M. received multiple EOBs from his insurance company which, when added together, revealed that Respondent IV Solutions had charged in excess of $2 million for the treatment. In response, J.M.'s insurance company provided checks payable to J.M.'s wife totaling approximately $900,000 as reimbursement for those charges. J.M.'s wife became enraged upon discovering this situation, because she believed the charges were excessive and she was fearful that her family would be responsible for paying the $1.1 million difference between what their insurance had been billed and paid.

92. J.M.'s wife immediately contacted Respondent IV Solutions' staff, including Ms. Casillas. J.M.'s wife was advised that IV Solutions' charges in the matter were "usual and customary." J.M.'s wife researched price comparisons of the average wholesale price (AWP) of an in-network pharmacy and retail cash price (Walgreens) and compared them to Respondent IV Solutions' price of the same medications charged to her husband and found Respondent IV Solutions' charges were approximately 50 times greater than AWP. She immediately complained to her insurance company and the Board.

93. A dispute between J.M.'s wife and Respondent IV Solutions quickly ensued. J.M.'s wife demanded bills showing line-by-line charges. IV Solutions employees, including Ms. Casillas, advised her that it would not be seeking payment from the family, but rather from their insurance, and for that reason they demanded that J.M.'s wife endorse and deliver the checks from the insurance company. When J.M.'s wife subsequently met with employee Andrew in person, he expressed interest in the checks and informed her that "it does not matter" in response to her concerns over not having a bill. When J.M.'s wife requested billing information from Ms. Casillas, she was informed, "you have checks. We want those checks." Ms. Casillas told J.M.'s wife that IV Solutions did not create or have itemized statements for it services. Instead, Ms. Casillas offered to meet with J.M.'s wife on a Saturday morning and go through the IV Solutions bills sent to insurance line-by-line and explain how they related to the EOBs. Ms. Casillas also said she would then decide the items

for which she would hold J.M. harmless. On the other hand, Respondent IV Solutions' staff viewed the insurance company's checks as essentially their property and they did not understand why J.M.'s wife would not turn them over.

94. In response to the stalemate, J.M. and his wife retained an attorney, J.M.'s brother, who demanded documentation from the pharmacy. Respondent IV Solutions filed a civil action in the Superior Court of the State of California against J.M. and his wife, demanding over $2 million for the services it provided to J.M. The family filed a cross-complaint against Respondent IV Solutions. The parties later submitted the dispute to arbitration, where they settled their claims, including that J.M. would pay Respondent IV Solutions $710,000, and IV Solutions waived the remaining amount from J.M. and his wife. The rest of the insurance proceeds were used by J.M. and his wife to pay their attorney.

B. Patient R.M.

95. R.M. is a 63-year-old man who lives in Los Angeles County. He began suffering serious problems with his knees in 2003. At first he had arthritic sepsis in one knee, which required antibiotic treatment. He had a knee implant, which later became infected and had to be replaced. (He had his other knee replaced in 2009.) In 2006, R.M. suffered another knee infection, which required IV antibiotic treatment for the first time. In 2008, he reinjured the same knee and was put back on IV antibiotic treatment, which cost $20,000. In April 2009, his knee again became infected. His artificial knee joint was temporarily removed (and later replaced) and he was again placed on IV antibiotic treatment, which cost $18,000. Pharmacies within his health insurance company's network supplied the antibiotics.

96. In spring 2011, R.M. had a patella tendon transplant. The area became infected, so his orthopedic surgeon decided to remove the transplant. R.M. was again placed on an IV antibiotic treatment after the transplant was removed. For reasons not established, R.M.'s physician referred R.M. to Respondent IV Solutions for the IV antibiotic treatment. IV Solutions was not within the network of providers for R.M.'s insurance company.

97. Neither R.M.'s physician nor Respondent IV Solutions informed R.M. that IV Solutions was an out of network provider. Respondent IV Solutions did not disclose the cost of care to R.M. in advance of rendering services, the anticipated charges to him or the co-insurance amount before services commenced.

98. From April 22, 2011, to May 28, 2011, Respondent IV Solutions furnished several dispensings of the antibiotic medication Cubicin to R.M. and billed his insurance plan in the amount of $12,755.00 for each day's drug treatment, for a total of approximately $471,935.00. Respondent IV Solutions incurred an acquisition cost of approximately $177.27 for each day, for a total of $6,559.04.

99. Respondent IV Solutions submitted bills to R.M.'s insurance company dated May 25, 2011, June 2, 2011, June 15, 2011, and July 23, 2011. The date(s) upon which the bills were submitted to insurance was/were not established. However, based on the timing of the submission of the bills, R.M.'s insurance company did not issue EOBs until late June

2011, which was after his treatment ended. R.M. testified that he did not receive the EOBs through the mail, but that he later accessed them on-line. When R.M. finally read the EOBs and saw the total charges sent to his insurance company by Respondent IV Solutions, he became upset and believed he had been the "victim of fraud." That was because IV Solutions' charges for the IV antibiotics were, by multiples, so much greater than what had been charged on previous occasions for similar treatments by other pharmacies. In October 2011, R.M. complained to the Board about Respondent IV Solutions' charges.

100. R.M.'s insurance paid almost all of what was billed by Respondent IV Solutions for the IV antibiotic treatment.

C. <u>Duty to Disclose Pricing/Billing Information to Both Patients</u>

101. Official notice was taken that, in 2014, the Board's website stated:

> There are types of complaints that are not within the authority of the [B]oard, such as the pricing of prescription drugs and complaints involving prescription billing disputes with insurance carriers. . . . Generally, the [B]oard has no jurisdiction over drug prices charged by a pharmacy.

102. Supervising Inspector Janice Dang in her testimony explained the meaning of the message on the Board's website. While she agreed that the Board does not have jurisdiction to investigate and take disciplinary action on purely pricing or billing issues, the Board does have jurisdiction to do so when the pricing or billing involves fraud, deceit or moral turpitude.

103. In this case, Complainant contends that the aforementioned charges made by Respondent IV Solutions to J.M.'s and R.M.'s insurance companies were deceitful because it had a duty to disclose certain pricing and billing information to the patients at the outset of their relationship but intentionally failed to do so.

104. The disclosure of pricing/billing information is an issue covered by the Joint Commission when it accredits a pharmacy. At the times in question, Respondent IV Solutions did not have a Board-issued sterile compounding permit, but instead was allowed to engage in such activity because it was accredited by the Joint Commission.

105. Joint Commission accreditation is commercially desirable to in-home infusion pharmacies, like IV Solutions, because most referring sources, such as physicians and hospitals, prefer to use pharmacies with such accreditation. In this field, accreditation from the Joint Commission means that a pharmacy's facility and practices meet or exceed certain standards. Ms. Casillas conceded as much when she testified that having Joint Commission accreditation was a marketing advantage because the accreditation reflected a pharmacy's adherence to high standards, which was well known in the health care community. For those reasons, Respondent IV Solutions prominently displayed its Joint Commission accreditation on its website and in marketing efforts.

106. As part of the accreditation process, Respondent IV Solutions was required to formulate P&Ps that are approved in advance by the Joint Commission. As a condition of accreditation, Respondent IV Solutions was required to follow those pre-approved policies and procedures. The Joint Commission thereafter monitors accredited pharmacies to make sure they follow their P&Ps.

107. In compliance with the Joint Commission, Respondent IV Solutions created P&Ps which addressed provision of charging and billing information to patients. The following P&Ps were effective during the events involving patients J.M. and R.M.:

A. P&P No. 1.1—Patient Rights and Responsibilities. The stated purpose of this P&P was "to inform individuals who have been accepted for service by the organization that they have rights regarding their home care services." The stated policy included that the patient will receive written information regarding "any costs of care the patient will be responsible for;" the patient will be given a Bill of Rights and Responsibilities, which will "be explained to the patient;" and once the patient has read, reviewed and verbalized understanding of his/her rights, the patient will sign the requisite forms acknowledging the same. The form "Patient Bill of Rights and Responsibilities" that was to be used in executing this P&P described various rights the patient had, including the right to "be informed in advance of potential reimbursement for services under Medicare, Medicaid, or other third party insurers based on your condition and insurance, of any financial obligations for services not fully reimbursed," and to "receive an itemized explanation of charges."

B. P&P No. 5.5—Staff Assignments. The stated procedures of this P&P included, "7. The cost of care and patient's/family's payment responsibilities will be explained in writing to the patient by the Intake Coordinator or their designee."

108. The Joint Commission conducted a monitoring survey of Respondent IV Solutions in November 2011, just a few months after the situation concerning patient R.M. concluded. Among a few areas the Joint Commission felt IV Solutions needed to improve was "Rights and Ethics," in which the Joint Commission surveyor noted that "the process that patients receive information about charges for which they will be responsible is inconsistent and ambiguous."

109. Complainant's expert witness, John D. Jones, is a pharmacist, former president of the Board, and currently the vice president of a company involved in professional pharmacy practice and policy. Mr. Jones established by a preponderance of the evidence, through his credible expert opinion testimony, that the aforementioned P&Ps resulting from the Joint Commission accreditation process created a duty for IV Solutions to disclose certain information to their patients at the outset of their relationship. None of Respondent IV Solutions' three expert witnesses rebutted Mr. Jones' testimony.

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110. Mr. Vara and Ms. Casillas readily admitted in their testimony that it is the policy of IV Solutions to not disclose its status as an out of network provider, the price of medications to be administered or the charges submitted to insurance at any time to a patient, unless specifically asked by the patient.

111. With regard to patients J.M. and R.M., the "Patient Rights and Responsibilities" documents provided to them by Respondent IV Solutions did not comply with Joint Commission requirements or IV Solutions' own P&Ps. In each document, the pertinent language regarding disclosure of billed charges had been diluted. Instead of providing the disclosure required in P&P No. 1.1 quoted above, the documents simply stated, "As a client you have the right to know in advance if you will be responsible for any cost other than your co-payment and yearly deductible that are predetermined by your medical insurance policy and Medicare/MediCal regulations."

112. On the other hand, other documents provided to J.M. and R.M. stated, "I understand that I am personally and financially responsible for all billed charges, including interest, and late fees for all products and services provided by IVS that are for any reason whatsoever not reimbursed by my insurance, or Medicare/Medical/CalOptima." At no time did anybody from Respondent IV Solutions explain that provision to the two patients or make clear to them that they could or would be held responsible for any charges not reimbursed by their insurance.

113. Contrary to the aforementioned P&Ps, at no time did a representative of IV Solutions do any of the following for or with J.M. or R.M:

- explain to them the Bill of Rights and Responsibilities documents provided to them, including attached documents that indicated they may be liable for charges not reimbursed by third party insurers;
- ask them to verbalize that they understood their rights;
- inform them in advance of potential reimbursement for services under Medicare, Medicaid, or other third party insurers based on condition and insurance;
- provide them with an itemized explanation of charges; or
- provide them with a written explanation of the cost of care.

114. Respondent IV Solutions did not have a good explanation for these short-comings or their ramifications. Both Mr. Vara and Ms. Casillas simply testified that because they looked only to the patients' insurance to pay their charges, and did not anticipate billing the patients, they did not need to make the aforementioned financial disclosures. However, that explanation is problematic for the following reasons:

A. Ms. Casillas conceded that there was nothing in IV Solutions' P&Ps that prevented it from balance billing a patient, i.e., billing a patient for whatever charges insurance did not pay. However, if a patient had not been advised beforehand that such was possible, retaining the right to balance bill a patient is inconsistent with the policy described by Ms. Casillas. While she testified that Respondent IV Solutions does not balance bill patients with insurance, Ms. Casillas could not explain why patients were provided a document that advised them they would be financially responsible for charges not paid by insurance if IV Solutions did not balance bill. This situation provided paperwork essentially allowing Ms. Casillas to unilaterally decide for which charges IV Solutions would hold J.M. harmless. Tellingly, when IV Solutions sued J.M. and his wife for the full amount of the charges it billed to insurance, and not just the lesser amount J.M.'s insurance company had decided to pay, Respondent IV Solutions in essence balance billed J.M.

B. Ms. Casillas could not explain why the cost of care information was not provided to the patients, other than to say that the charges sent to the patients' insurance qualified as such. That explanation is unpersuasive because P&P No. 1.1 describes that information being provided at the outset of services, not in the end; moreover, the patients never received any statements from IV Solutions and the charges sent to insurance without being provided to the patients simply cannot be considered compliance with P&P No. 1.1.

C. Although Ms. Casillas alluded to a change in the policy made by IV Solutions in these regards, that policy change never made it into the P&Ps.

115. Based on the above, it was established by a preponderance of the evidence that Respondent IV Solutions intentionally withheld from patients J.M. and R.M. the financial information discussed above, and thereby breached the duty to do so established by its P&Ps.

116. Mr. Jones opined that it was deceitful to not provide such financial information to a patient at the outset of service when required to do so by its own P&Ps, especially when those P&Ps were required as a condition of becoming Joint Commission accredited. Respondent IV Solutions' expert, Dr. Park, was sympathetic to Mr. Jones' position, when he agreed during cross-examination that if a pharmacy's P&Ps required disclosure of its costs and charges to a patient at the initiation of their relationship, its failure to do so would call into question the ethics of the pharmacy.

117. Beside the disclosures required by its own P&Ps and the Joint Commission accreditation process, Mr. Jones also opined that pharmacy industry standards required a pharmacy to disclose its prices and status as an out of network provider to a patient prior to rendering services. The heart of Mr. Jones' opinion is: (a) prices charged by Respondent IV Solutions were 50 times the AWP for the same drugs and therefore shockingly excessive; (b) such prices could only be charged by IV Solutions since it was an out of network provider not limited by a network agreement with the insurance companies in question that would have undoubtedly lowered its prices; and (c) out of network providers are usually more expensive and therefore patients should be aware of the significant financial exposure before the services begin.

118. A. In contrast, one of IV Solutions' experts, Dylan Roby, Ph.D., persuasively opined that gaps frequently occur which cause the absence of network providers in some areas of expertise or geography, or for providers in some networks to fall out of network; and that many consumers will intentionally select out of network providers because of a perceived higher quality of service or simply out of personal preference. Dr. Roby is an adjunct professor at UCLA and the Director of its Health Economics and Evaluation Research Group. He has done research on this issue in California and nationally. He pointedly testified that he is not aware of any standard requiring disclosure of such information to patients. Dr. Roby also opined that the actual charges submitted by an out of network provider are not important; rather, without a network agreement in place, it is up to the insurance company to decide what price it will pay. Dr. Roby testified that in those situations, insurance companies will typically pay what the fair market will bear for such services and that there is no reason to suspect that insurance companies will voluntarily pay more than fair market value. In this case, while R.M.'s insurer paid most of the charges, it is worth noting that J.M.'s carrier paid less than 50 percent of the total charges submitted.

B. Another IV Solutions expert witness, Randy Farber, is a health care management consultant intimately familiar with provider and payor health plans, health care networks and the health insurance industry. Mr. Farber similarly testified that he is aware of no standard requiring upfront disclosures of price and network status, and he offered several reasons in support of his opinion. Mr. Farber also testified that he is aware of several pharmaceutical providers who charge 50 times or more the CMS Medicare Allowable provider reimbursement rate, which is comparable to AWP. He was also skeptical of the assertion made by Mr. Jones that pharmacies generally only charge two or three times AWP.

C. Respondent IV Solutions' third expert witness, Dr. Park, similarly testified that he is aware of no standard in California requiring such disclosure. Dr. Park was a practicing pharmacist, and now is an attorney involved in teaching pharmacy laws and consulting on pharmacy regulatory compliance. Of IV Solutions' three expert witnesses, he was the most credible and persuasive. On cross-examination, Dr. Park did seem to indicate that a pharmacy had a duty to make such initial disclosures under certain circumstances. However, Dr. Park seemed to qualify that duty to when a pharmacy's own P&Ps required such disclosure (as discussed above) or when the pharmacy knew upfront that the patient would be liable for paying the bill. Since IV Solutions intended to seek compensation for its services from the patients' insurance, it is not clear that Dr. Park believed such a duty, outside of the P&Ps, was created for patients J.M. or R.M. Dr. Park opined that while IV Solutions' was "very expensive," there was nothing unlawful with it charging such prices.

119. Based on the above, it was not established by a preponderance of the evidence that industry standards required a pharmacy to disclose its prices and status as an out of network provider of services to a patient prior to rendering those services. Mr. Jones' opinion was rebutted by three credible experts opposing him. While Mr. Jones' reasons for arriving at his opinion were reasonable, so too were the reasons his opponents offered. Mr. Jones offered no research, literature or facts tending to show his opinion is more persuasive than his opponents' opinions. In this situation, the various experts' opinions created a stalemate.

D. Delayed Bills for J.M.

120. As discussed above, J.M. and his wife received billing information after three months of treatment for an insignificant amount of the total charges. It was not until several months after J.M.'s treatment concluded that most of the $2 million charges were submitted to his insurance company. Complainant contends Respondent IV Solutions intentionally delayed submitting the bulk of its charges to J.M.'s insurance company until after his treatment had concluded in order to suppress any further complaints the patient and his wife would have about its charges.

121. In their testimony, Mr. Vara and Ms. Casillas generally denied that IV Solutions delayed submitting charges to insurance until after treatment ended and they specifically denied that happened with respect to patient J.M. However, that testimony was not persuasive for the following reasons.

A. Mr. Vara testified that for patients receiving treatment lasting four to six weeks, bills may not be generated until after treatment ends. Mr. Vara testified that for patients requiring treatment over several years, IV Solutions would bill insurance on regular intervals. Mr. Vara also testified that the default mode for IV Solutions was to generally send all bills to insurance together to avoid confusion and payment delays. Mr. Vara noted that in his experience, splitting up the bills was problematic because the insurance company processing them may not aggregate the bills with the corresponding authorization number and treatment dates. Thus, in explaining his general standard procedure for billing, Mr. Vara essentially admitted that IV Solutions waits until treatment is over until billing insurance; the only exception would be for patients receiving treatment expected to last for years, in which case the pharmacy would periodically submit charges.

B. Patient R.M.'s situation was not consistent with Mr. Vara's explanation. R.M.'s treatment lasted approximately six weeks. However, several bills with different dates were prepared and sent to R.M.'s insurance. Records from R.M.'s insurance company indicate that it processed the bills on different dates. The insurance company also issued EOBs on different dates. Those facts demonstrate by a preponderance of the evidence that Respondent IV Solutions' bills were not all submitted on the same date.

C. Patient J.M's situation was not consistent with Mr. Vara's explanation. Bills were submitted to J.M.'s insurance company three months after treatment began for a regimen expected to last one year. J.M.'s wife contacted IV Solutions to express concern after receiving the initial EOBs and was advised by staff that there had been a coding error. J.M.'s insurance company did not receive any more charges until months after his treatment ended. Neither Mr. Vara nor Ms. Casillas specifically explained the timing of the bills submitted to J.M.'s insurance company, so it was not established that the initial submission of bills was mistaken or that the subsequent submission of bills after the treatment ended was inadvertent.

122. Mr. Jones conceded that there is no legal limitations period for submitting charges to insurance. However, he opined that a delay in submitting bills is atypical for pharmacies, as there are no advantages for doing so. On the contrary, cash flow is an important component of pharmacy operations. Mr. Jones therefore opined that he was unable to ascertain any legitimate reason for Respondent IV Solutions to delay submitting charges for its services rendered.

123. On the other hand, Respondent IV Solutions presented expert opinion testimony on this topic from Dr. Roby and Mr. Farber. Both experts have impressive qualifications and expertise in this area. Dr. Roby testified that it is common for health care providers to submit claims to insurance six to twelve months after treatment is rendered. Mr. Farber agreed that it was not unusual for health care providers to wait and submit all of their billing claims to insurance at once; accuracy of the billing is more important than the speed of submission.

124. Based on the above-described expert opinion testimony, it was established that there is no limitation period within which a health care provider must submit charges to insurance, nor is there any standard of care for doing so. It was therefore not established by a preponderance of the evidence that delaying the submission of bills until treatment is complete is necessarily an illegitimate business practice.

125. Based on the above, it was established by a preponderance of the evidence that Respondent IV Solutions intended to delay submitting most of its charges to J.M.'s insurance until after his treatment had ended. While it was not established that that decision violated any law or standard of care regarding the timing of insurance claims' submission, it was established by a preponderance of the evidence that the decision was made in a concerted effort to avoid providing J.M.'s wife with information about its charges while IV Solutions was still providing treatments to J.M.

E. J.M.'s Agreement and Consent Form

126. Complainant contends that Mr. Vara forged the agreement and consent form that is contained in Respondent IV Solutions' file for J.M., and that he did it to support his position in the lawsuit against J.M. and his wife. Mr. Vara denies doing so. The agreement and consent form in question bears the purported signature of J.M.'s wife and is dated November 5, 2009. J.M.'s wife testified that she was never presented with such a document when pharmacy services commenced and is certain that the signature on the document is not hers. J.M.'s wife further testified that the date on the document (November 5, 2009) itself demonstrates it is not genuine because the couple was unaware of the involvement of Respondent IV Solutions until it began services the following day, November 6, 2009. Finally, J.M.'s wife testified that J.M. was at Dr. Tempesti's office the afternoon of November 5th and that he did not return home until late that evening.

127. The testimony of J.M.'s wife is inconsistent with the fact that IV Solutions had a standard operating procedure of getting a patient or caretaker to sign agreement and consent forms when medications and supplies were first delivered to a patient's home at the commencement of services. Such was established through the testimony of Ms. Casillas, Mr. Vara, and more importantly, the circumstances of the other three patients involved in this case, where there was no question of the timing and authenticity of their signatures.

128. The date written on the document in question is not dispositive. J.M.'s wife testified that IV Solutions delivered J.M.'s materials to the family home in a brown paper bag on November 6th. Although she was not explicit, she seemed to indicate in her testimony that she was at home on November 5th while her husband was visiting Dr. Tempesti. She testified that she did not sign anything on November 5th and that she does not remember signing for anything on November 6th. In light of these circumstances, the fact that the document in question is dated November 5th can be explained by two other possibilities: a) the items were delivered to the family home on November 5th when J.M.'s wife was home but her husband had not arrived home from Dr. Tempesti's office; or b) the items were delivered on November 6th but the signatory simply got the date wrong. The issue concerning the authenticity of this document did not arise until the parties were embroiled in the aforementioned litigation at least two years later, so it is possible that J.M.'s wife forgot she signed for anything on either day. Finally, it is hard to imagine that a forger seeking to secure advantageous evidence for use in litigation two years later would forge the signature of the caregiver instead of the actual patient; or would use the wrong date in doing so.

129. Respondent IV Solutions countered with the testimony of handwriting expert James Blanco, who opined that it is highly probable that J.M.'s wife signed the document in question. Mr. Blanco has impressive qualifications and expertise in handwriting analysis. His testimony was persuasive and reasonable. Mr. Blanco reviewed several versions of J.M.'s wife's signature contained on various types of documents, including checks and a consumer purchase contract. Mr. Blanco credibly explained why important features of the letters in the signature in question match those on other documents signed by J.M.'s wife. Mr. Blanco also credibly explained that many individuals have three distinct signatures, depending on the type of document signed: a formal signature for formal documents, such as a contract or will; an everyday signature for important items signed every day, such as checks; and a rapid signature for simple and rapid transactions, such as signing a UPS delivery form. In this case, the fact that the signature in question does not resemble the formal signature of J.M.'s wife on her checks or contracts is easily explained by the resemblance it bears to her rapid signatures, like when she signed several boxes acknowledging that she read material in a long consumer purchase agreement. The fact that the document in question was related to signing for delivery of medical supplies corroborates the rapid signature theory. In all respects, Mr. Blanco credibly explained and supported his opinion.

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130. Complainant's attempt to discredit Mr. Blanco's testimony was not persuasive.

A. Mr. Blanco could not state with "100 percent certainty" that the signature on the document was that of J.M.'s wife. But that limitation is a function of the industry standard, where a handwriting expert cannot use that level of certainty if not given access to the original document in question. In this case, Mr. Blanco was not shown the original document for reasons not established.

B. Mr. Blanco was previously expelled from the American Academy of Forensic Sciences (AAFS) for violating two sections of their Code of Ethics. That is obviously concerning. However, it was established that after Mr. Blanco sued the AAFS in federal court concerning his expulsion, the parties settled that lawsuit by the AAFS vacating its findings of violations and Mr. Blanco resigning his membership and agreeing to never apply for reinstatement. Under these circumstances, the only thing proven is that those two parties do not care for each other.

C. While Mr. Blanco admitted to a few inconsistencies between aspects of the exemplar signatures of J.M.'s wife and the document in question, such inconsistencies were not material and are to be expected in a situation where many signatures of different types of documents are analyzed.

D. Complainant failed to present her own handwriting expert.

131. Based on the above, it was not established by a preponderance of the evidence that the signature of J.M.'s wife on the agreement and consent form in question was forged.[3]

F. Representing That Their Charges Are "Usual and Customary"

132. Employees of Respondent IV Solutions represented to Board inspectors that the amounts billed for their services were "usual and customary." Because IV Solutions' charges with respect to patients J.M. and R.M. were magnitudes more than the AWP, Complainant contends that IV Solutions' representations in this regard were deceptive.

133. Complainant's expert, Mr. Jones, testified that the term "usual and customary" refers to prices generally charged by pharmacies in a certain community or geographic location. On the other hand, one of IV Solutions' experts, Dr. Roby, testified that Mr. Jones was confused and that the term referred to a pharmacy's own billed charges. Under these circumstances, it was not established by a preponderance of the evidence exactly what the term referred to.

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[3] Complainant's reliance on a federal district court order (ex. 82) in unrelated litigation involving IV Solutions and Mr. Vara is misplaced. The limited purpose of which official notice of that document was taken does not establish Mr. Vara engaged in any wrongdoing in that case or this one.

134. In this case, when Respondent IV Solutions' employees used the term "usual and customary," they were referring to the company's usual charges for a given medication, not to charges made by pharmacies in the broader community. Based on the above, it was not established that staff comments to Board inspectors were deceptive in this regard.

G. Respondent Sadow's Involvement in Pricing/Billing

135. Respondent Sadow was IV Solutions' PIC during the events involving patients J.M. and R.M.

136. Board Inspector Joseph Wong, as well as Supervising Inspector Dang, testified that a PIC is generally responsible for a pharmacy's compliance with all applicable state and federal statutes and regulations pertaining to the practice of pharmacy. (See also Bus. & Prof. Code, § 4113, subd. (c).)

137. Complainant's expert witness, Mr. Jones, opined that the PIC must be aware of all practices in the pharmacy, whether or not it is owned by the pharmacist or another individual. Mr. Jones also opined that the PIC must make sure that Joint Commission standards, if applicable, are adhered to, including those pertaining to billing, and that a PIC may not simply cede control over billing to the pharmacy's owner. Finally, Mr. Jones opined that the PIC may still be responsible for the actions of others, including improper billing, if she knew or should have known that those practices were occurring.

138. Respondent's expert, Dr. Park, simply testified that a PIC is absolutely liable for what happens in a pharmacy, which is why licensed pharmacists now are reluctant to act as a PIC. Dr. Park testified that the pricing of medications is a business decision for the pharmacy owner and not the PIC, if the pharmacy is not owned by the PIC. However, Dr. Park did not opine specifically on whether a PIC is responsible for billing improprieties engaged in by the pharmacy owner.

139. Based on the above, it was established by clear and convincing evidence that while pharmacy billing is within the province of business decisions to be made by a non-pharmacist owner, the pharmacy's PIC may not cede total control over billing and instead should become involved if the pharmacy is engaging in inappropriate billing activity. If the PIC knew or should have known that billing improprieties happened, the PIC may become liable for such activity, even if she were not engaged in it directly.

140. In this case, Respondent Sadow was not involved in IV Solutions' pricing decisions. It was specifically excluded from her duties as the PIC. She was not consulted by Mr. Vara or Ms. Casillas on pricing issues, and she did not ask to be heard on them. Respondent Sadow did not testify that she ever inquired into the Joint Commission standards applicable to IV Solutions, nor was it otherwise apparent that she did. However, Mr. Vara testified that the billing methodology and rates used by IV Solutions was not a secret and that given the small size of the company, it would have been readily known to Respondent Sadow had she inquired. Ms. Casillas testified that Respondent Sadow had access to the billing system and codes.

141. Respondent Sadow testified that she filled J.M.'s prescription, but she did not recall doing that for R.M. She had no other knowledge or recollection about the charges submitted to those two patients' insurance companies.

142. Under these circumstances, it was established by clear and convincing evidence that Respondent Sadow did not know IV Solutions failed to adhere to Joint Commission standards and its own P&Ps applicable to how it informed patients of its charges and how their insurance companies would be billed, nor of the particular situations concerning patients J.M. and R.M. However, as the PIC, it was Respondent Sadow's duty and obligation to inform herself of the fact that the Joint Commission standards applied to IV Solutions, the nature of IV Solutions' P&Ps, and whether IV Solutions was adhering to them. Therefore, even though Respondent Sadow did not know what was happening with regard to patients J.M. or R.M., she should have known.

H. Damages

143. Patients J.M. and R.M. would not have selected Respondent IV Solutions had they known the prices charged for the services rendered. This is based on the fact that patient R.M. had essentially the same IV regimen in prior years by other pharmacies at a fraction of the price charged by IV Solutions. This is also based on the immediate outrage expressed by patient R.M. and patient J.M.'s wife after first seeing the charges submitted to insurance by Respondent IV Solutions.

144. At the time in question, J.M.'s lifetime insurance benefit was $2 million. Respondent IV Solutions' bills exceeded that amount. Because J.M. was still facing the prospect of a liver transplant, as well as other medical treatment for his condition, J.M.'s wife became concerned that IV Solutions' charges had depleted their health insurance. This caused the couple significant distress.

145. R.M. was also concerned about his lifetime insurance benefit cap, because he had suffered so many problems with his knees and had required so much medical care. The amount of his lifetime insurance benefit cap was not established. However, given the amount of Respondent IV Solutions' charges, R.M. reasonably feared that if he continued to suffer similar problems with his knees in the future, he may not have enough insurance left to cover all of the necessary treatments.

146. Pursuant to the language of IV Solutions' agreement and consent forms provided to both patients, each were financially responsible for any portion of the bills not reimbursed by insurance, which potentially could have caused catastrophic financial consequences. In J.M.'s case, Respondent IV Solutions sought more than $2 million in its civil lawsuit against him. J.M. and his wife were forced to hire an attorney to defend themselves in that lawsuit. As a result of the resolution of that lawsuit, insurance proceeds were used to compensate their attorney.

147. Beginning in 2012, health insurance companies doing business in California stopped enforcing lifetime insurance benefit caps. Subsequently, the federal Affordable Care Act has abolished such caps. Therefore, neither patient currently has any adverse consequence caused by IV Solutions' charges billed to their insurance. Those subsequent events do not change the fact that in 2009-2011, both patients were exposed to these adverse financial consequences.

Other Relevant Facts

148. The three citations previously issued to Respondent IV Solutions are not considered to be discipline by the Board.

149. Respondent Sadow has no prior disciplinary history with the Board.

150. Respondent Sadow had never been a PIC before she accepted that position with IV Solutions. Her failings here are partially due to her naiveté. While she had limited authority as PIC at IV Solutions, it was not established that she pushed for more authority or objected to being isolated by Mr. Vara and Ms. Casillas. Even after Board inspectors' presence at the pharmacy continued to be prevalent, no evidence suggests Respondent Sadow asked questions or engaged in any meaningful examination of IV Solutions' practices. Respondent Sadow quit her job at Respondent IV Solutions over a pay cut. In summary, Respondent Sadow did not ask; Mr. Vara and Ms. Casillas did not tell.

151. When she testified during the hearing, Respondent Sadow appeared candid and without guile. When she performed her clinical duties as a pharmacist, she was professional and capable. Her clinical knowledge of pharmacy is impressive. Her testimony on such matters was credible for these reasons. There is no concern with her clinical performance; there is concern over her ability to act as a PIC.

Costs

152. The Board incurred the following costs in the investigation and prosecution of this matter:

A. Total investigative costs of Board inspectors/consultant	$66,165.95
B. Total prosecution costs of the Attorney General's Office	$112,180.00
Total costs	$178,345.95

153. The Board's investigative costs include the following:

A. Former Inspector Robert Kazebee's costs for 101.25 hours at $102.00 per hour	$10,327.50
B. Inspector Robert Venegas' costs for 214.50 hours at $102.00 per hour	$21,879.00

C. Inspector Joseph Wong's costs for 201.25 hours at $102.00 per hour — $20,527.50

D. Inspector Anna Yamada's costs for 67.25 hours at $102.00 per hour — $6,859.50

E. Expert Consultant Roger S. Klotz's costs for 2013-2014 — $6,572.45

154. The following reductions from the Board's investigative costs are warranted, as the enumerated activities are not reasonable:

A. Inspector Wong wrote two investigative reports. However, only one such report (ex. 46) was offered and received into evidence. Inspector Wong's testimony focused narrowly on his investigation of how much it cost Respondent IV Solutions to acquire the medications dispensed to patients JM and RM, and what the AWP was for those medications. It appears that the evidence derived from Inspector Wong is less than the scope of his investigation. It is not reasonable to charge Respondents with investigative costs not associated with the prosecution of this matter. Since Inspector Wong's declaration in support of his charges is vague, a 50 percent reduction is warranted, i.e., $10,263.75.

B. Roger S. Klotz was designated as an expert witness who would testify during the hearing. However, Mr. Klotz did not testify and his report was not offered into evidence. Although various invoices he submitted to the Board for payment of his services were received in evidence, the bulk of those invoices appear related to the preparation of his report. Some of the invoices intimate that he assisted Board inspectors with their investigation, but it is not clear how and to what extent. Nor is it clear why the Board inspectors needed that type of assistance. It is not reasonable to charge Respondents for work product generated by an expert witness who never testified or for work which may likely have duplicated efforts of the Board inspectors. None of his charges are reasonable.

155. Records from the Office of the Attorney General (AGO) indicate that this case was initially handled by Deputy Attorney General (DAG) Kimberly King. DAG King appeared at each of the Prehearing Conferences for this matter, including the last one conducted just a few months before the hearing commenced. Yet, inexplicably, DAG King was replaced at the hearing by three other prosecutors. DAG King's charges billed to the Board were $7,182.50 for the 2010-2011 fiscal year; $10,157.50 for the 2011-2012 fiscal year; $15,937.50 for the 2012-2013 fiscal year; and $36,635.00 for the 2013-2014 fiscal year. The total amount of DAG King's charges is $69,912.50. Based on the size and complexity of this case, that amount appears reasonable.

156. There are a number of other charges billed to the Board by other deputy attorneys general who have not appeared in this matter. Those charges do not appear to be reasonable. There are a significant amount of charges billed to the Board by the three prosecutors who replaced DAG King at the hearing. It appears that most, if not all, of this

time was spent replicating the prior efforts of DAG King. It is not reasonable to charge Respondents with the costs incurred by the AGO's staffing changes made shortly before the hearing after the matter had been litigated for several years. Therefore, none of the charges billed by those other than DAG King are reasonable.

157. Taking into account the aforementioned reductions, it was established that the Board has incurred reasonable costs of the investigation and prosecution of this matter in the amount of $119,242.25. This amount is comprised of the Board's reduced investigative costs of $49,329.75 and the AGO's reduced prosecution costs of $69,912.50.

LEGAL CONCLUSIONS

Burden and Standards of Proof

1. As the party bringing administrative charges and seeking discipline against the respective licensees in this case, Complainant bears the burden of proof. (*Parker v. City of Fountain Valley* (1981) 127 Cal.App.3d 99, 113; *Brown v. City of Los Angeles* (2002) 102 Cal.App.4th 155.)

2. A. It is well established that the applicable standard of proof depends upon the nature of the license at issue. In this case, discipline is sought against two separate and distinct licenses: the pharmacy permit of Respondent IV Solutions and its owner Mr. Vara, and the pharmacist license of Respondent Sadow.

B. In an action seeking disciplinary action against a professional license, the governing agency bears the burden of establishing cause for discipline by clear and convincing proof to a reasonable certainty. (*Ettinger v. Board of Med. Quality Assurance* (1982) 135 Cal.App.3d 853, 857.) This is because a professional license represents the licensee's fulfillment of extensive education, training and testing requirements; the licensee has an extremely strong interest in retaining the license that she has expended so much effort in obtaining. The same cannot be said for a licensee's interest in retaining a non-professional license. Thus, the revocation of a nonprofessional license requires only the preponderance of the evidence standard. (*Imports Performance v. Dept. of Consumer Affairs, Bur. of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889.)

3. In this case, there is no dispute, factual or legal, that the standard of proof applicable to Respondent Sadow is clear and convincing proof to a reasonable certainty, given that she possesses a pharmacist license, which is a professional license. (Factual Findings 1-5 & 9.)

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4. A. On the other hand, the evidence established that anyone meeting the basic criteria outlined by Supervising Inspector Dang can obtain a pharmacy permit. Absent extensive education, training and testing requirements, it cannot be concluded that a pharmacy permit is a professional license requiring a higher standard of proof. Accordingly, the standard of proof applicable to Respondent IV Solutions is the lower preponderance of the evidence standard. (Factual Findings 1-8.)

B. Respondent IV Solutions' argument that the higher clear and convincing standard applies to a pharmacy permit is rejected. Although Respondent IV Solutions cites a number of appellate cases involving this Board and others, none of those cases held that a pharmacy permit is a professional license requiring the higher standard. That was certainly not the holding in the case of *Sashihara v. State Board of Pharmacy* (1935) 7 Cal.App.2d 563. Respondent IV Solutions' citation to the case of *Owen v. Sands* (2009) 176 Cal.App.4th 985 is misplaced. That case held that the lower preponderance of the evidence standard is used in all citation cases involving a monetary fine or order of correction, and that the clear and convincing standard is used in disciplining a contractor's license. In that respect, the *Owen* case is distinguishable from the instant one because a contractor's license can only be obtained after demonstrating requisite training, prior experience in the trade in question and passing examinations. The *Owen* decision says nothing about the requirements for obtaining a pharmacy permit. In any event, the record is bereft of evidence that Mr. Vara has any prior training, skills or experience required to be demonstrated to the Board in order to obtain a pharmacy permit.

C. Respondent IV Solutions argues it would be unfair to apply different standards to it and Respondent Sadow in the same case, since arguably each is responsible for the conduct of the other. For example, a PIC is generally responsible for a pharmacy's compliance with all applicable state and federal statutes and regulations pertaining to the practice of pharmacy pursuant to Business and Professions Code section 4113, subdivision (c). On the other hand, a pharmacy licensee is generally liable for the acts of its agents, whether the agent is an independent contractor or an employee. (*California Assn. of Health Facilities v. Department of Health Services* (1997) 16 Cal.4th 284, 296.) However, the situation in this case is easily addressed. Respondent Sadow's discipline is only based on requisite facts established by clear and convincing evidence. Discipline against Respondent IV Solutions is only based on facts established by a preponderance of the evidence or greater. Interestingly, Respondent Sadow does not object to the application of two different standards of proof in this case; she simply argues that she is subject to the higher standard of proof.

D. For purposes of clarity, all of the factual findings in this decision were established by clear and convincing evidence, except where expressly stated to have been established by a preponderance of the evidence, including any factual findings involving Respondent IV Solutions and/or Mr. Vara but not Respondent Sadow.

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Cause for Discipline Regarding Patients J.M. and R.M.

5. A. First Cause for Discipline as to Respondent IV Solutions (Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code section 4301, subdivision (f),[4] which prohibits 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. (Factual Findings 83-147.)

B. Complainant premises discipline against both Respondents under section 4301, subdivision (f), based on alleged acts involving moral turpitude and/or deceit arising from the billing of patients J.M. and R.M. Complainant argues Respondent IV Solutions directly engaged in the acts in question, and that Respondent Sadow is vicariously liable for discipline since she was the PIC of IV Solutions at the times in question.

C.1. While the Pharmacy Law does not expressly define the terms deceit or moral turpitude, they are defined elsewhere. For instance, deceit is defined in Civil Code section 1710 as meaning either: 1) the suggestion, as a fact, of that which is not true, by one who does not believe it to be true; 2) the assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true; 3) the suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact; or, 4) a promise, made without any intention of performing it.

C.2. Case law has generally found that actionable concealment in civil cases consists of various elements, including that the aggrieved party has sustained damages. (*Blickman Turkus, LP v. MF Downtown Sunnyvale, LLC* (2008) 162 Cal.App.4th 865, 868.) However, the purpose of an administrative disciplinary proceeding is to protect the public. (*Fahmy v. Medical Bd. of California* (1995) 38 Cal.App.4th 810, 817.) By contrast, the purpose of a civil proceeding for medical malpractice is to compensate financially for a particular loss occasioned by negligence. (*Id.*) Thus, a civil action for damages does not serve the purpose intended by license disciplinary proceedings. (*Id.*) More specifically, it has been held that no showing of patient injury or harm must be established in order to warrant discipline against a licensed physician for unprofessional conduct. (*Kearl v. Board of Medical Quality Assurance* (1986) 189 Cal.App.3d 1040, 1053.) Read in this context, proof of damages should not be required in a disciplinary action premised, in part, on deceitful conduct under section 4301. Nonetheless, it was established that patients J.M. and R.M. were injured by Respondent IV Solutions' conduct, as explained in more detail below.

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[4] All further statutory references are to the Business and Professions Code unless otherwise noted.

C.3. The definition of "moral turpitude," notwithstanding the frequency of use as a legislatively imposed standard of conduct for purposes of discipline, defies any attempt at a uniform and precise definition. However, courts have previously defined moral turpitude as "an act of baseness, vileness or depravity in the private and social duties which a man owes to his fellowmen, or to society in general, contrary to the accepted and customary rule of right and duty between man and man" (citation omitted) or "everything done contrary to justice, honesty, modesty or good morals" (citations omitted). (*Golde v. Fox* (1979) 98 Cal.App.3d 167, 184-185.) Section 4301 may be broadly applied, in that it states discipline for moral turpitude is warranted "whether an act is committed in the course of relations as a licensee or otherwise." However, case law has consistently required that where a licensing statute does not require a showing of a nexus between the licensee's conduct and the licensee's fitness or competence, the statute must be read to include this "nexus" requirement to ensure its constitutionality. (*Griffiths v. Superior Court* (2002) 96 Cal. App.4th 757, 770.) In this case, there is no doubt or dispute that Respondent IV Solutions' conduct in question directly related to its licensed activity.

D.1. It was established by a preponderance of the evidence that Respondent IV Solutions had a duty to disclose its pricing and billing information to patients J.M. and R.M. but intentionally failed to do so. Such a duty was created by becoming accredited by the Joint Commission. Such accreditation was desirable to IV Solutions and Mr. Vara because it allowed the company to do sterile compounding without a Board permit and the accreditation was an important marketing tool to increase its business. Through the accreditation process, Respondent IV Solutions was required to create P&Ps covering various topics, including pricing and billing. The P&Ps created by IV Solutions through this process required it to disclose to patients J.M. and R.M. at the outset of services and thereafter various types of information, including the costs of care they would be responsible for; to be informed in advance of the potential for insurance reimbursement, and of any financial obligations for services not reimbursed by insurance; to receive an itemized explanation of charges and written explanation of the cost of care and the patient's responsibility for them; and that these rights and obligations would be explained to the patients by an IV Solutions employee or agent. None of this information or counseling was provided to patients J.M. or R.M. at the outset of services or anytime thereafter. In fact, Respondent IV Solutions intentionally withheld this information from these patients.

D.2. Exacerbating the situation was the fact that although some of the involved paperwork actually submitted to the patients indicated that IV Solutions would only provide this information to them if they would be held financially responsible for some or all of the service charges, other documents the patients were required to sign contained their agreement to be financially responsible for any costs not reimbursed by insurance. This paperwork, created by Respondent IV Solutions, put its patients at its mercy for billing decisions, a situation that would not have existed had it complied with its own P&Ps.

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D.3. The P&Ps did not require informing patients of IV Solutions' out of network status, and there was no general duty to disclose that information to the patients. Nonetheless, IV Solutions' out of network status allowed it to charge more for its drugs, by many multiples, than if it had a contract as a network provider with the insurance companies in question. This situation provided the motive for Respondent IV Solutions to not provide the information required by its own P&Ps to its patients, for had it provided the required information to J.M. and R.M. at the outset or early in its treatment, those two patients would have surely complained to IV Solutions and their insurance companies about the exorbitant prices, and would have immediately stopped the treatment early in the process.

D.4. With respect to patient J.M., Respondent IV Solutions intentionally delayed and withheld most of its bills until after its treatment had ended. To be clear, there was no duty created by its P&Ps or time limit required by law for submitting its charges to insurance. However, it was established that in the case of J.M., IV Solutions intentionally delayed submitting his bills to insurance in a concerted effort to not alert J.M.'s wife as to its actual charges until after insurance had made its reimbursement decisions.

D.5. As discussed above, Complainant is not required to establish that either patient suffered damages, injury or harm. Nonetheless, both patients suffered harm at the time of the events in question, including exhausting or significantly eroding their lifetime maximum insurance benefit amounts when their health was such that significant future medical services would be required; being subjected to catastrophic financial consequences due to the inappropriate documents they were required to execute by IV Solutions; the emotional turmoil, upset, and outrage of not being provided with required information initially, only to receive notice of exorbitant charges well after-the-fact; and (for J.M.) being embroiled in litigation due to IV Solutions' conduct.

E. Under these circumstances, it was established by a preponderance of the evidence that Respondent IV Solutions intentionally acted in a deceitful manner as to patients J.M. and R.M. by concealing information from them that it had a duty to provide, which conduct was motivated by a desire to maximize charges to the patients' insurance companies. By engaging in such conduct, Respondent IV Solutions acted contrary to justice, honesty, modesty or good morals, which constitutes moral turpitude. For those reasons, it was established by a preponderance of the evidence that Respondent IV Solutions violated section 4301, subdivision (f).

F1. Respondent IV Solutions argues the Board has no jurisdiction over purely pricing issues or disputes involving insurance. It is correct. However, this cause for discipline does not address those issues, but instead involves acts of deceit and moral turpitude in how Respondent IV Solutions treated two patients. As discussed above, section 4301 is broad. The Board has jurisdiction to investigate and prosecute cases involving deceit and acts of moral turpitude by a licensee, in whatever form they take. Regardless, this cause for discipline involves Respondent IV Solutions' failure to provide information to its patients that it had a duty to provide; this cause for discipline is not premised on the prices charged by Respondent or how their insurance was accessed.

F2. For the above reasons, the fact that there is no statute or regulation that limits the prices a pharmacy can charge for drugs does not prevent discipline from being imposed for a licensee's acts involving deceit and moral turpitude. It is also true that the Joint Commission accreditation procedures are not law or regulation. But cause for discipline here is not premised on such a notion. Instead, by becoming accredited by the Joint Commission, Respondent IV Solutions was required to formulate and implement certain policies and procedures. Respondent did so. The problem here is that IV Solutions subsequently ignored its own policies and procedures. The basis for discipline is that once so formulated, Respondent IV Solutions had a duty to follow its own policies and procedures, but it refused to do so. Failure to follow its own policies and procedures, in part, resulted in findings that Respondent IV Solutions acted deceitfully and with moral turpitude. There are no findings or conclusions herein that the Joint Commission procedures are law.

6. First Cause for Discipline as to Respondent Sadow. It was not established by clear and convincing evidence that Respondent Sadow is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivision (f), for the commission of acts involving moral turpitude and/or deceit. Many of the pivotal factual findings establishing that Respondent IV Solutions engaged in acts involving deceit and moral turpitude were based on the lower preponderance of the evidence standard, which is not applicable to Respondent Sadow. In addition, it was established by clear and convincing evidence that Respondent Sadow did not know that Respondent IV Solutions failed to adhere to Joint Commission standards and its own P&Ps applicable to how it informed patients of its charges and how their insurance companies would be billed, nor of the particular situations concerning patients J.M. and R.M. Under these circumstances, it cannot be concluded that cause for discipline was clearly and convincingly established against Respondent Sadow for engaging in acts of deceit or moral turpitude in violation of section 4301, subdivision (f). (Factual Findings 83-147.)

Cause for Discipline Regarding Obtaining Curlin Pumps from an Unlicensed Wholesaler

7. Second Cause for Discipline (Obtaining a Dangerous Device from an Unlicensed Wholesaler). Respondents IV Solutions and Sadow are subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), and (p), in conjunction with section 4169, subdivision (a)(1), which states that a person or entity may not purchase, trade, sell, or transfer dangerous drugs and devices at wholesale with a person or entity that is not licensed with the Board as a wholesaler or pharmacy. It was clearly and convincingly established that Respondents violated section 4169, subdivision (a)(1), in that from about January 1, 2009, to about January 1, 2012, Respondent IV Solutions obtained Curlin 4000 CMS pumps from an unlicensed wholesaler located in Cincinnati, Ohio. Although Respondent Sadow was not directly involved in these events, she was responsible for this misconduct pursuant to section 4113, subdivision (c), since she was serving as the PIC for IV Solutions during the time in question. In addition, pursuant to California Code of Regulations, title 16, section 1715, Respondent Sadow was required to evaluate the pharmacy's compliance with all state and federal pharmacy laws every year, which she failed to do sufficiently so as to discover the situation. (Factual Findings 77-82.)

Cause for Discipline Regarding Patient D.K.

8. A. Third Cause for Discipline as to Respondent IV Solutions (Performing the Duties of a Pharmacist without a License). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), and (p), in conjunction with California Code of Regulations, title 16, section (Regulation) 1793.1, subsection (b), which states that only a pharmacist may consult with a patient or his agent regarding a prescription. (Factual Findings 26-59.)

B. More specifically, on April 17, 2010, Mr. Vara, a non-pharmacist, performed the duties of a registered pharmacist without being licensed, by having calls delivered to him and responding to calls delivered to the pharmacy concerning the Curlin pump delivered to patient D.K. The patient's son-in-law, Kevin G., and later his mother, Donna G., had called the pharmacy to complain about the Curlin pump, which they believed had malfunctioned. The pump was needed to administer the prescribed drugs to patient D.K., and is itself considered a dangerous device.

C. When Mr. Vara was initially notified of this problem early that morning, he spoke with Respondent Sadow, but after realizing that she was off-duty and on vacation, he decided to handle the matter himself. When Mr. Vara spoke with Donna G. later that day, she specifically requested to speak to a pharmacist. Mr. Vara refused Donna G.'s request, telling her that he would handle her call. Both Kevin G. and Donna G. requested that the pump be replaced. Mr. Vara made the decision to deny those requests.

D. Although Mr. Vara correctly assessed that the pump had not malfunctioned, that was not his determination to make. The decision regarding the equipment involved in dispensing medication prescribed to patient D.K. was a decision for a licensed pharmacist to make. Though Mr. Vara was certainly in his right to take the initial calls and decide where to direct them, his failure to involve a licensed pharmacist in the decision-making related to this situation meant that he consulted with a patient's family members concerning a prescription. When Donna G. directly requested to speak with a pharmacist, she should have been put in touch with one. There is no evidence in the record establishing that at any time a licensed pharmacist became involved to hear the family's complaint and make a determination as to what was happening with the pump or whether there was a problem to address. Although pharmacist Jeannie Kim phoned the family later that evening, she simply acted as a messenger and not a decider. It was not established that she was otherwise involved in the decision-making process. Finally, the testimony of Respondent IV Solutions' expert witness, Dr. Park, did not satisfactorily address whether Mr. Vara acted appropriately in this particular instance and was therefore not convincing.

E. It was not established, as alleged, that Regulation 1793.1, subsection (e), was violated. Subsection (e) states that only a pharmacist may consult with a prescriber, nurse or other health care professional or authorized agent. Although Donna G. was a registered nurse, it was not established that she participated in this situation as anything other than a concerned relative of the patient.

9. A. Third Cause for Discipline as to Respondent Sadow (Performing the Duties of a Pharmacist without a License). No cause exists to subject Respondent Sadow to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), or (p), in conjunction with Regulation 1793.1, subsection (b), for the way in which Mr. Vara handled the inquiries from patient D.K.'s family members on April 17, 2010.

B. As mentioned above, a PIC is generally responsible for a pharmacy's compliance with all applicable state and federal statutes and regulations pertaining to the practice of pharmacy pursuant to section 4113, subdivision (c). But that statute is not so elastic as to stretch over the contours of the extreme situation presented here. Not even Complainant argues as much in her closing briefs. Respondent Sadow reasonably satisfied her duties and obligations by obtaining permission to go on vacation the weekend in question and have another pharmacist cover for her. After receiving the initial phone calls concerning patient D.K., Respondent Sadow was subsequently told that she no longer needed to be involved in the situation. As a matter of fact and law, there was nothing more for Respondent Sadow to do. Nor is there any indication in the Pharmacy Law, including section 4113 or Regulation 1793.1, that a PIC should be held responsible for a situation like this. (Factual Findings 26-59.)

10. A. Fourth Cause for Discipline as to Respondent IV Solutions (Performing the Duties of a Pharmacist without a License). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (f), (j), (o), and (p), in conjunction with Regulation 1793.1, subsection (g), which states that only a pharmacist may perform functions which require professional judgment. For the same reasons explained in Legal Conclusion 8 above, cause for discipline was established when Mr. Vara exercised the type of professional judgment required of a licensed pharmacist when he responded to the situation concerning the Curlin pump delivered to patient D.K. and solely engaged in the decision-making process of determining how to respond to the family's contacts and concerns. (Factual Findings 26-59.)

B. Respondent IV Solutions argues that questions over the pump, as opposed to the medication infused by the pump, fall outside the licensed pharmacist consultation requirement of Regulation 1707.2 and therefore a non-pharmacist, such as Mr. Vara, was free to consult with D.K.'s family members regarding the Curlin pump. However, there is nothing in Regulation 1707.2 that states that required consultations are limited solely to "medications." In fact, Regulation 1707.2, subdivision (d)(4), specifies that when a pharmacist deems a consultation warranted, it shall include "precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy." This suggests equipment or supplies necessary to using the medication in question shall be included in a consultation when the pharmacist deems it appropriate. Moreover, the pump itself was a dangerous device that could not be obtained without a prescription. In this case, the evidence indicates that Mr. Vara removed his pharmacists from the decision-making process. Patient D.K. would have no way of receiving his prescribed medications if the pump was not functioning correctly. Regulation 1707.2 does not support Respondent's argument.

11. Fourth Cause for Discipline as to Respondent Sadow (Performing the Duties of a Pharmacist without a License). No cause exists to subject Respondent Sadow to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (f), (j), (o), or (p), in conjunction with Regulation 1793.1, subsection (g), which states that only a pharmacist may perform functions which require professional judgment. For the same reasons explained in Legal Conclusion 9 above, Respondent Sadow should not be responsible for the conduct of Mr. Vara simply by virtue of her role as the PIC of IV Solutions. (Factual Findings 26-59.)

12. Fifth Cause for Discipline (False Representation of Licensure). No cause exists to subject Respondent IV Solutions to disciplinary action for unprofessional conduct within the meaning of sections 4301, subdivisions (f), (j), (o), or (p), and 4322, in that it was not established by a preponderance of the evidence that Mr. Vara falsely represented himself as a pharmacist to Janet Haywood on April 17, 2010. (Factual Findings 26-59.)

13. Sixth Cause for Discipline (False and Misleading Label on Prescription). Respondents IV Solutions and Sadow are subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (f), (j), (o), and (p), in conjunction with section 4078, subdivision (a)(1), which states that no person shall place a false or misleading label on a prescription; and section 4076, subdivision (a)(6), which states, in pertinent part, that a pharmacist shall not dispense a prescription except in a container that is correctly labeled with the name and address of the pharmacy. Specifically, it was established by clear and convincing evidence that on April 2 and April 7, 2010, Respondent Sadow used prescription labels on RX 1813 and RX1837 that falsely represented the name of the pharmacy as "IV Solutions Clinical Pharmacy" an unknown, unlicensed pharmacy, instead of "IV Solutions Inc.," which was the correct pharmacy name identified on pharmacy permit PHY 45885. (Factual Findings 26-59.)

14. Seventh Cause for Discipline (Records of Dangerous Drugs and Devices Kept Open for Inspection). Respondents IV Solutions and Sadow are subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), and (p), in conjunction with section 4081, subdivision (a) and (b), by failing to make all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices available for inspection by the Board as requested. Specifically, it was established by clear and convincing evidence that a Board inspector made a request for a category of documents which included a copy of the April 2nd delivery ticket of medications and supplies delivered to patient D.K.'s home but such a copy was never provided to the inspector. (Factual Findings 26-59.)

15. Eighth Cause for Discipline (Medication Error). No cause exists to subject Respondents IV Solutions and Sadow to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), or (p), in conjunction with Regulation 1716. Specifically, it was not established by either standard of proof that on April 2, 2010, Respondent Sadow programmed Curlin pump #115698 to use the intermittent setting but failed to lock down the settings to secure the prescribed dosing regimen as

required; or that on April 17, 2010, the total 24 hour dose of Zosyn antibiotic had been delivered to patient D.K. by an unsecured Curlin pump on the continuous setting instead of the intermittent setting of four divided doses every six hours. (Factual Findings 26-59.)

16. Ninth Cause for Discipline (Quality Assurance Review Not Initiated). No cause exists to subject Respondents IV Solutions and Sadow to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), or (p), in conjunction with section 4125, subdivision (a), which requires a pharmacy to establish a Quality Assurance Program to review medication errors, and Regulation 1711, subsection (d), which requires all medication errors discovered to be subject to a quality assurance review to commence within two business days from the date of discovery. Specifically, it was not established by either standard of proof that on April 17, 2010, Respondent Sadow was required to conduct a quality assurance review, because it was not established that, as alleged, the Curlin pump had continuously infused the total 24 hours dose of Zosyn into patient D.K. instead of intermittently as prescribed. (Factual Findings 26-59.)

17. Tenth Cause for Discipline (Subvert or Attempt to Subvert an Investigation). No cause exists to subject Respondents IV Solutions and Sadow to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivision (q), for engaging in conduct that subverted or attempted to subvert an investigation of the Board. Specifically, it was not established that Respondents subverted or attempted to subvert a Board investigation by intentionally failing to provide the April 2nd delivery ticket for patient D.K. when requested to do so by a Board inspector. Instead, Respondents inadvertently failed to give a copy of that document to the inspector. (Factual Findings 26-59.)

18. Eleventh Cause for Discipline (Unprofessional Conduct-Misuse of Education). No cause exists to subject Respondent Sadow to disciplinary action for unprofessional conduct within the meaning of section 4306.5, subdivision (a), for improper exercise of education, training or experience as a pharmacist. Specifically, it was not established by either standard of proof that on April 2, 2010, Respondent Sadow erroneously programmed a Curlin pump to use the intermittent setting but failed to lock down the settings to secure the prescribed dosing regimen as required. (Factual Findings 26-59.)

Cause for Discipline Regarding Patient C.R.

19. A. Twelfth Cause for Discipline (Failure to have Consultation Available). Respondents IV Solutions and Sadow are subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j), (o), and (p), in conjunction with Regulation 1751.6, subsection (a), which states that consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (Factual Findings 60-82.)

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B. Specifically, patient C.R. and her nurse and her nurse's supervisor attempted to contact Respondent IV Solutions for a consultation concerning how to operate the pump that would administer the morphine prescribed to C.R. Such a consultation was necessary because Respondent IV Solutions neglected to follow its own policies and procedures by improperly training its staff (the nurse assigned to help C.R.) in how to set up the infusion equipment and instruct C.R. how to use it. Nor was the nurse or C.R. provided with information how to contact the pump manufacturer in the event of a problem, contrary to the testimony of Mr. Vara. Despite attempts by C.R. and her nurse for a consultation on how to use the pump, one did not happen because Respondent IV Solutions' staff forgot to roll-over their after-hours phone line to their answering service, and apparently failed to follow their own policy and procedure to periodically check the answering service for messages. C.R. and her nurse were never able to reach IV Solutions and obtain a consultation; and C.R. was never able to use the morphine prescribed to her.

C. Respondent IV Solutions argues that pursuant to Regulation 1707.2 a consultation was not required because the attempted contact only involved the pump and not the medication dispensed by it. That argument is rejected for the same reasons explained above in Legal Conclusion 10. More importantly, Regulation 1751.6 clearly requires a pharmacy to provide a consultation on "proper use of sterile injectable products and related supplies furnished by the pharmacy." The pump furnished by Respondent IV Solutions to infuse the medications prescribed to patient C.R. is just the sort of supply contemplated by Regulation 1751.6. Thus, assuming arguendo that Regulation 1707.2 did not require a consultation in this case concerning the pump, that regulation still would not trump Regulation 1751.6, which clearly required providing a consultation when requested about supplies furnished by the pharmacy.

D. Respondent IV Solutions also argues its expert witness on pharmacy practices, Dr. Park, testified that only "medicine related 'consults'" are required. However, IV Solutions' closing brief on this topic discusses the facts related to patient D.K., not C.R. In any event, while Dr. Park generally testified what a pharmacy should do when it receives a contact concerning a medical device such as an infusion pump, his testimony was insufficient on this point. For example, Dr. Park did not specifically opine as to C.R.'s situation, he failed to address the unusual facts of her case, he did not touch on the application of Regulation 1751.6, and he failed to address Respondents' failure to follow their own P&Ps.

E. Respondent Sadow was not directly involved in this situation but she is culpable due to her position as IV Solutions' PIC. Many of the failures involving patient C.R. were systemic, i.e., the way in which Respondent IV Solutions trained staff in how to work the pump and/or advise patients to do so. Pursuant to section 4113, a PIC is generally responsible for a pharmacy's adherence to state and federal laws pertaining to pharmacy practice. Moreover, as the PIC, Respondent Sadow would have been responsible for making sure systems were in place to confirm the answering service roll-over was activated and checked thereafter. In reality, Respondent Sadow allowed Mr. Vara total control over such activities when she was required to be involved. Thus, this situation is different from the one involving patient D.K.

Cause for Discipline Regarding the Inspections in February and April 2008

20. Fourteenth Cause for Discipline (Making of False Documents).[5] Respondent IV Solutions is subject to disciplinary action under section 4301, subdivisions (f) and (g), in that IV Solutions, through its owner, Mr. Vara, falsely represented an unlicensed facility, Stat Clinic Pharmacy, as a pharmacy and provided pharmacy services to approximately 25 patients, which included creating and receiving pharmacy-related documentation with patients and/or their physicians, such as contracts and agreements, medical forms, confidential medical records and prescriptions. (Factual Findings 10-25.)

21. Fifteenth Cause for Discipline (Violation of State Law Governing Pharmacy/ Receiving and Holding Misbranded Dangerous Drugs). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (i) and (o), in conjunction with Health and Safety Code section 111440, for importing several vials of Lovenox, which were dangerous drugs from Canada, that were both misbranded and restricted to sales in Canada. (Factual Findings 10-25.)

22. Sixteenth Cause for Discipline (Noncompliant Ordering and Delivery to an Unlicensed Facility). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j) and (o), in conjunction with section 4059.5, subdivision (a), for ordering Lovenox, a dangerous drug, from an unlicensed wholesaler in Canada, and having that drug delivered to an unlicensed premise, Mr. Vara's father's home. Mr. Vara's testimony concerning the wholesaler inadvertently sending the ordered drugs to his father's home was unconvincing. (Factual Findings 10-25.)

23. Seventeenth Cause for Discipline (Noncompliant Security). Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j) and (o), for violating Regulation 1714, subsections (d) and (e), in that it was established that Mr. Vara was in personal possession of the pharmacy key on February 29, 2008. Mr. Vara is not a pharmacist and Regulation 1714 prohibits pharmacy keys from being in the possession of a non-pharmacist absent an applicable exception. Respondent IV Solutions argues that Mr. Vara comes within the emergency exception provided by Regulation 1714, subsection (e), in that he was commanded to open the pharmacy by the Board inspectors. Here the problem was not that Mr. Vara opened the pharmacy upon command of the inspectors. The problem was that Mr. Vara was in personal possession of the pharmacy key before being so ordered. Moreover, it was not established that Mr. Vara took the security precautions required by Regulation 1714, subdivision (e), such as keeping the key in a sealed, tamper-evident container which identified those who previously had taken the key. However, it was not established that on April 7, 2008, Mr. Vara was in possession of the pharmacy key or that he opened the pharmacy that morning. (Factual Findings 10-25.)

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[5] The thirteenth cause for discipline was withdrawn by Complainant.

24. A. Eighteenth Cause for Discipline (Pharmacy Operating without a Pharmacist Present). No cause exists to subject Respondent IV Solutions to disciplinary action for unprofessional conduct within the meaning of sections 4301, subdivisions (j) or (o), and 4081, for violating sections 4113, subdivision (b), and 4305, subdivision (b), and Regulation 1793.1, in that it was not established by a preponderance of the evidence that the pharmacy operated without a pharmacist present when one was required. (Factual Findings 10-25.)

B. It was not established that Mr. Vara had opened the pharmacy for business on February 29, 2008, without a pharmacist present, or that any activity was occurring within the pharmacy at that time requiring the presence of a pharmacist for purposes of Regulation 1793.1. Although the business office was open that day, it was not established that the pharmacy had been opened by Mr. Vara until he was ordered to do so by Board inspectors.

C. Nor was it established that on April 7, 2008, Mr. Vara opened the pharmacy without a pharmacist present, or that any activity was occurring within the pharmacy at that time requiring the presence of a pharmacist for purposes of Regulation 1793.1. Although the Board inspectors saw a pharmacy technician in the pharmacy when no pharmacist was present at the facility, it was not established that the technician was mixing an IV solution or engaging in any activity described in Regulation 1793.1.

25. Nineteenth Cause for Discipline (Noncompliant Pharmacist Identification). No cause exists to subject Respondent IV Solutions to disciplinary action for unprofessional conduct within the meaning of section 4301, subdivisions (j) or (o), for violating Regulation 1717, subsection (f), in that it was not established by a preponderance of the evidence that during a Board investigation of the pharmacy on February 29, 2008, the pharmacy did not have a system to identify which pharmacist was responsible for the filling of a prescription; or that on April 7, 2008, the pharmacy had not implemented a system after having been ordered to do so. (Factual Findings 10-25.)

26. Twentieth Cause for Discipline (Non-Pharmacist Filling Prescriptions). No cause exists to subject Respondent IV Solutions to disciplinary action under section 4051, subdivision (a), in that it was not established by a preponderance of the evidence that during a Board investigation, the pharmacy was found to have non-pharmacists filling multiple prescriptions for controlled substances and dangerous drugs from March 1, 2008, to March 20, 2008. (Factual Findings 10-25.)

27. Twenty-First Cause for Discipline (Noncompliant Refilling of Controlled Substance). Respondent IV Solutions is subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Health and Safety Code section 11200, subdivision (c), in that it was established by a preponderance of the evidence that a Schedule II controlled substance had been refilled on March 14, 2008. According to the law at that time, which had been recently changed, a prescription for a controlled substance could not be refilled; rather, a new prescription must be submitted. Although an exception allowed for processing a partial refill for a terminally ill patient, it was not established that the patient in question had a terminal illness. (Factual Findings 10-25.)

Disposition

28. Since cause for discipline was established, the level of discipline must be determined. In reaching a decision on disciplining a licensee, the Board's Disciplinary Guidelines [Rev. 10/2007] (Guidelines) are to be considered. (Cal. Code Regs, tit. 16, § 1760.) The Guidelines divide the various types of violations into four categories, ranging from the least serious, Category I, to the most serious, Category IV. The Guidelines state "[t]hese categories assume a single violation. . . . For multiple violations, the appropriate penalty shall increase accordingly." If there are violations in more than one category, "the minimum and maximum penalties shall be those recommended in the highest category."

29. In this case, Respondents' violations are scattered throughout Categories I through III. While there are a few Category I violations (the 17th & 21st causes for discipline), a few Category II violations (the 1st & 14th causes for discipline), and a few Category III violations (the 7th, 15th & 16th causes for discipline), the remaining violations can be classified as either Category II or III, depending on the circumstances. Those violations are the second, third and fourth (only as to IV Solutions), sixth and twelfth causes for discipline. However, since there are multiple violations in multiple categories, the Guidelines suggest treating the totality of the violations to be in the highest category, here Category III. Such treatment appears warranted given the fact that the bulk of violations are in or near Category III. Moreover, the difference between the two categories is without significant distinction. The suggested discipline for both categories ranges from a minimum of probation for a number of years under various terms and conditions to a maximum of revocation.

30. The Guidelines list 15 factors to be considered in determining the appropriate level of discipline. These factors are applied to Respondents as follows:

1. *Actual or potential harm to the public.* Potential harm to the public was demonstrated by the fact that misbranded vials of Lovenox illegally maintained by IV Solutions could have been sold to the public.

2. *Actual or potential harm to any consumer.* Actual and potential harm to consumers was demonstrated. Dr. Spitzer was defrauded when his patients were referred to IV Solutions over his express objections through the trickery of using the name "Stat Clinical Pharmacy." Patient D.K. received only two of his six-week regimen of antibiotics because of the confusion over whether his Curlin pump malfunctioned, which was created, in part, by Mr. Vara's handling the situation without involving a pharmacist. Patient C.R. received no benefit from her morphine prescription, despite paying for the initial supply, because of her inability to obtain a consultation concerning the pump. As chronicled in detail above, patients J.M. and R.M. sustained significant harm. It must be noted that Respondent Sadow is blameless for much of the harm summarized here.

3. *Prior disciplinary record, including level of compliance with disciplinary order(s).* Neither Respondent has a prior disciplinary record with the Board.

4. *Prior warnings of record(s), including citation(s) and fine(s)*. Respondent Sadow has no prior record of warnings. Respondent IV Solutions received three citations from 2007 through 2009.

5. *Number and/or variety of current violations*. There are numerous violations of various types and categories.

6. *Nature and severity of the act(s), offense(s) or crime(s) under consideration*. Many of the acts in question involved serious misconduct, including deceit and moral turpitude, performing the acts of a pharmacist without a license, failing to provide a pharmacist consultation to two patients who wanted a consultation, making false documents to fool a physician regarding his patients referred to IV Solutions, and importing drugs from Canada that were misbranded and restricted to sales in Canada.

7. *Aggravating evidence.* In aggravation, Lovenox was found at the pharmacy on multiple occasions, despite Board inspectors ordering the drug to be returned and Mr. Vara's assurance that he had done so. Even worse was the deplorable treatment of Mr. Vara to Kevin G. and Donna G. He was rude, dismissive and used vulgarities without provocation. Mr. Vara was similarly rude to patient C.R. and refused to provide her with a refund despite the fact that IV Solutions was to blame for her situation. And while Respondent IV Solutions is not subject to discipline because of the exorbitant prices it charged to patients J.M. and R.M., those situations highlight the fact that IV Solutions' deceitful acts were done with the goal of maximizing their profits. By being accredited by the Joint Commission, Respondent IV Solutions was able to capitalize financially and avoid having to obtain a sterile compounding permit from the Board. Yet, IV Solutions failed in many respects to fulfill the promise made to the Joint Commission to abide by certain policies and procedures. Finally, Mr. Vara seriously undercut and prevented his PICs from exercising their lawfully mandated discretion and exercise of judgment in pharmacy matters, essentially making the PIC of IV Solutions a figurehead. The fact that IV Solutions has had so many PICS over the last few years is probably indicative of that situation.

8. *Mitigating evidence.* Respondents presented mitigating evidence which lessened the seriousness of some of the violations. Respondents cooperated with Board investigative efforts and inquiries at all times. The failure to produce patient D.K.'s one delivery ticket was inadvertent. Respondents generally followed orders of the Board inspectors, such as no longer ordering pumps from Ardus, no longer using business names not reflected in the pharmacy permit, etc. Although Respondents were ultimately at fault for the C.R. situation, it must be remembered that the pivot of the problem was that somebody forgot to roll-over after-hours calls to the answering service. It was not established that any of the four patients involved in this case sustained any physical injuries as a result of their situations. It was not established that any of the pumps obtained from the unlicensed wholesaler were defective or caused any patient harm. It was not established that patient R.M. had any out-of-pocket damages incurred as a result of IV Solutions' conduct.

9. *Rehabilitation evidence.* Respondents essentially provided none. No evidence was presented at the hearing indicating that Respondents are now doing things differently in light of this case. In fact, Mr. Vara accepted very little responsibility for his misconduct. Instead, in their pre-trial motions and closing briefs, Mr. Vara and IV Solutions have accused the Board of wrongdoing; and in her closing brief Respondent Sadow has characterized herself as a "victim," ignoring the plight of the four patients mistreated while she was the PIC. Not even Respondent Sadow's departure from employment at IV Solutions can be characterized as indicative of rehabilitation: she left because she was unhappy with a cut in her pay.

10. *Compliance with terms of any criminal sentence.* This factor is not applicable.

11. *Overall criminal record.* This factor is not applicable.

12. *If applicable, evidence of proceedings for case being set aside and dismissed pursuant to section 1203.4 of the Penal Code.* This factor is not applicable.

13. *Time passed since the act(s) or offense(s).* Respondent IV Solutions' misconduct began in 2008, when regulatory violations were discovered during two Board inspections of the pharmacy. The misconduct continued from 2009 through 2012, when Respondents ordered pumps from an unlicensed wholesaler. The misconduct involving the four patients occurred from 2009 through 2011. Thus, the violations can be described as having moderate proximity.

14. *Whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct.* Much of Respondent IV Solutions' misconduct was knowing and intentional. Respondent Sadow's misconduct mainly consisted of her failure to exercise discretion vested in her as the PIC, and thus is better described as a disregard of her duties.

15. *Financial benefit to the respondent from the misconduct.* Respondent Sadow did not appear to financially benefit from the misconduct. Respondent IV Solutions financially benefitted greatly from the misconduct, in that it charged exorbitant prices for its services, including the services that were subject to complaints and problems encountered by the four patients involved in this case. Moreover, IV Solutions was only able to service Dr. Spitzer's several patients due to the fraud that its staff perpetrated on Dr. Spitzer.

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31. Respondent IV Solutions. It is abundantly clear that Respondent IV Solutions was the moving force behind all of the violations established in this case. Most of those violations were serious and intentional, the result of dishonesty, deceit or a conscious decision by Mr. Vara to exclude pharmacists from their required duties. Those violations subjected the public to the potential of harm and actually resulted in harm to some patients. While it is true that Respondent IV Solutions has no prior disciplinary record with the Board, it had only been licensed for about six years when it began engaging in misconduct and it had received three citations. Moreover, the violations established in this case were various, consistent and pervasive, spanning from 2008 through 2011 (about the time that the initial accusation was brought). Some mitigating facts were presented, mainly that Respondent IV Solutions cooperated with the Board's investigations and some of the violations were inadvertent. However, the mitigating facts are counter-balanced by aggravating facts, and substantially outweighed by the level of intentional and calculated misconduct. Most glaring is the absence of rehabilitation evidence. Given the breadth and span of the misconduct established, it was incumbent on Respondent IV Solutions to demonstrate some level of acceptance, contrition and dedication to preventing such misconduct in the future. The record is bereft of any hint that Mr. Vara believes he has done much if anything wrong and that similar misconduct in the future will be avoided. Finally, although the prices charged to J.M. and R.M. were not illegal or the basis for discipline, they certainly were unsavory. Since revocation is the maximum discipline recommended for a Category III violation, and Respondent IV Solutions has done little to show that the public will be adequately protected by being placed on probation, revocation is warranted in this case. (Factual Findings 1-148 and Legal Conclusions 1-30.)

32. Respondent Sadow. It was established that less discipline than revocation of Respondent Sadow's license is warranted. It is true that Respondent Sadow facilitated much of IV Solutions' misconduct by serving as its PIC during the events in question and failing to exercise her discretion and oversight in important areas of the pharmacy. However, all of the involved misconduct was spearheaded by Mr. Vara. It must also be remembered that Respondent Sadow was not involved in the misconduct discovered during the 2008 inspections of the pharmacy. Since Respondent Sadow essentially abdicated her role as PIC during the relevant times, the most appropriate discipline should be to prevent her from serving in that capacity again while on probation. Respondent Sadow otherwise has proven to be a competent pharmacist and no sanctions are warranted to protect the public from her performance of clinical duties. She had a spotless record with the Board in a career spanning almost 40 years before becoming involved with IV Solutions, a fact that also should not be ignored. Since the gravamen of the violations were in Category III, Respondent Sadow's probation should extend four years, which is slightly less than the minimum recommended. Although a suspension is warranted as a reminder to her of the need to uphold her duties as a licensed pharmacist, a period of suspension greater than two weeks would be punitive and unwarranted. Aside from prohibiting her from serving as a PIC or owning or operating a pharmacy while on probation, none of the other optional terms are warranted. (Factual Findings 1-151.)

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Other Considerations

33. Section 4307, subdivision (a), provides, in pertinent part, that any person whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee. Mr. Vara is the owner/operator of Respondent IV Solutions. No evidence was presented indicating that IV Solutions has any other locations. However, based on the discipline imposed on him through Respondent IV Solutions, an order against Mr. Vara under section 4307 is warranted. Respondent Sadow is not currently working as a PIC. Based on her less serious level of misconduct, an order under section 4307 against her is not warranted per se. However, in order to protect the public, conditions of her probation shall include that Respondent Sadow not be allowed to act as a PIC for any licensee while on probation, nor own or operate a pharmacy.

Costs

34. Section 125.3 provides that an administrative law judge may order a licentiate who has violated a licensing law to pay the reasonable costs of the investigation and enforcement of the case. Respondents violated provisions of the Pharmacy Law. It was established that the Board incurred reasonable costs in the amount of $119,242.25. Respondent IV Solutions is responsible for all of the violations established in this case. However, Respondent Sadow's culpability in this case was more passive, i.e., failing to exercise her oversight as the PIC. Under these circumstances, Respondent Sadow should be responsible for 10 percent of the overall costs, or $11,924.22. Respondent IV Solutions should be responsible for the remainder of the costs. (Factual Findings 152-157.)

ORDER

A. Original Pharmacy Permit Number PHY 45885, issued to Respondent IV Solutions, Inc., is revoked.

B. Respondent IV Solutions, Inc., shall pay the Board of Pharmacy reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3, in the amount of $107,318.03.

C. Respondent IV Solutions, Inc., and Alex Vara, are prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a Board licensee.

D. Pharmacist License No. RPH 27398, issued to Respondent Renee Sadow, is revoked. However, revocation of her license is stayed for four years under the following terms:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

* an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

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

* a conviction of any crime; or

* discipline, citation, or other administrative action filed by any state and federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

2. Reporting to the Board

Respondent shall report to the Board quarterly. The report shall be made either in person or in writing, as directed. Respondent shall state under penalty of perjury whether there has been compliance with all the terms and conditions of probation. If the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable notice, Respondent shall appear in person for interviews with the Board upon request at various intervals at a location to be determined by the Board. Failure to appear for a scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

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4. Cooperation with Board Staff

Respondent shall cooperate with the Board's inspectional program and in the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation. Failure to comply 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 3606 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 her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3606, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify her 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 3606 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 her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 3606 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

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"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. Supervision of Interns, Serving as 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. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

Respondent shall pay to the Board costs in the amount of $11,924.22. Respondent shall make monthly payments according to a schedule approved by the Board. There shall be no deviation from that 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.

Whether the filing of bankruptcy by Respondent relieves Respondent of her responsibility to reimburse the Board its costs of investigation and prosecution is a legal matter to be decided by a court of competent jurisdiction.

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.

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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 her license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

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

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

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

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

13. Tolling of Probation

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 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 80 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 80 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 80 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. Actual Suspension

As part of probation, Respondent is suspended from the practice of pharmacy for 14 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 devices or controlled substances.

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.

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

17. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the Board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

DATED: March 5, 2015

ERIC SAWYER
Administrative Law Judge
Office of Administrative Hearings

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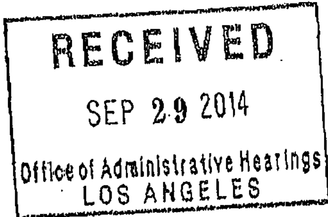

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Third Amended Accusation Against:

**IV SOLUTIONS INC.
Alireza Varastehpour-President
3384 Motor Avenue
Los Angeles, CA 90034
Original Pharmacy Permit No. PHY 45885**

And

**RENEE SADOW
24 Union Jack St., #3
Marina del Rey, CA 90292-8600
Pharmacist License No. RPH 27398**

Respondents.

Case No. 3606

OAH No. L-~~2010080069~~ 2011050988

THIRD AMENDED ACCUSATION

Complainant alleges:

PARTIES

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

2. On or about May 9, 2002, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 45885 to IV Solutions Inc. with Alireza Varastehpour aka Alex Vara as President (Respondent IV Solutions). The Original Pharmacy Permit was in full force and effect at all

times relevant to the charges brought herein and will expire on May 1, 2010, unless renewed. Board records show that Jeannie Kim was the Pharmacist-in-Charge (PIC) from November 25, 2008 to February 16, 2009 and Renee Sadow has been the PIC from February 16, 2009 to the present.

3. On or about April 25, 1971, the Board of Pharmacy issued Original Pharmacist License Number RPH 27398 to Renee Sadow (Respondent PIC Sadow). The license was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2011, 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 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

6. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

(c) Gross negligence.

(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.

. . .

1 (j) The violation of any of the statutes of this state, or any other state, or of the United
2 States regulating controlled substances and dangerous drugs.
3 . . .
4 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
5 violation of or conspiring to violate any provision or term of this chapter or of the applicable
6 federal and state laws and regulations governing pharmacy, including regulations established by
7 the board or by any other state or federal regulatory agency.
8 (p) Actions or conduct that would have warranted denial of a license.
9 (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the
10 board."
11 7. Section 4051 of the Code states:
12 "(a) Except as otherwise provided in this chapter, it is unlawful for any person to
13 manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to
14 dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she
15 is a pharmacist under this chapter.
16 (b) Notwithstanding any other law, a pharmacist may authorize the initiation of a
17 prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or
18 patient consultation if all of the following conditions are met:
19 (1) The clinical advice or information or patient consultation is provided to a health care
20 professional or to a patient.
21 (2) The pharmacist has access to prescription, patient profile, or other relevant medical
22 information for purposes of patient and clinical consultation and advice.
23 (3) Access to the information described in paragraph (2) is secure from unauthorized access
24 and use."
25 8. Section 4078 (a)(1) of the code provides that "no person shall place a false or
26 misleading label or description". Subsection (a) (2) further provides that "no prescriber shall
27 direct that prescription be labeled with any information that is false or misleading".
28

9. Section 4076 (a) (6) provides, in pertinent part, that a pharmacist about dispense a prescription except container that meets the requirement of state and federal law and is **correctly** labeled with the name and address of the pharmacy.

10. Section 4081 of the code states:

"(a) All records of manufacture and sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours (section by authorized officers of the law, it shall be preserved for at least three years from the date of making. A current inventory shall be kept by every wholesaler [and] pharmacy holding a currently valid and unrevoked certificate, license, [or] permit..."

(b) The owner, officer, and partner of any pharmacy or wholesaler...shall be jointly responsible with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory."

11. Section 4113 (b) of the Code provides that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Section 4125 (a) provides that "[e]very pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel".

13. Section 4305 of the Code states:

"(a) Any person, who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a pharmacy, who willfully fails to notify the board of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a

pharmacist, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action."

14. Section 4306.5 (a) provides that unprofessional conduct for a pharmacist includes acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

15. Section 4322 of the Code states that:

"Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars ($5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment."

16. Title 16, California Code of Regulations (hereinafter "CCR") section 1709.1, provides in part, that a pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

17. CCR section 1711(d) provides that each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

18. CCR section 1716 provides that pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

19. CCR Section 1751.6, subsection (a) states that consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

20. CCR Section 1793.1 states that "[o]nly a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment."

21. Section 4307(a) of the Code provides that any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

22. 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.

DRUG DEVICE CLASSIFICATION(S)

23. "Lovenox" is a prescription anticoagulant that prevents the formation of blood clots and is a dangerous drug per Business and Professions Code Section 4022.

24. The "Curlin 4000 CMS Pump" is an ambulatory infusion pump and a dangerous device which can only be obtained by prescription from a licensed practitioner.

FIRST CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

25. Respondents IV Solutions, PIC Sadow, and Respondent Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivision (f), which prohibits 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. The circumstances are as follows:

Patient J.M.

26. From about November 6, 2009 to September 1, 2010, Respondent IV Solutions furnished several prescription dispensings and sent excessively high bills to J.M.'s insurance plan provider in the amount of $2,031,446.10 in drug treatments while Respondent IV Solutions only incurred an acquisition cost of approximately $34,187.87.

Respondent IV Solutions claimed that its charges in the total amount of $2,031,446.10 are "usual and customary", however, J.M.'s wife researched price comparisons of the average wholesale price of an in-network pharmacy and retail cash price (Walgreens) and Respondent IV Solutions price of the same medications charged to J.M. which revealed that Respondent's charges were grossly excessive as follows:

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Drug: Pegasys 180mcg/0.5ml syringe; one kit=4 doses (syringes)	
Average wholesale price (AWP)	$2764.76 per kit
In-network pharmacy's cash price (Walgreens)	$2764.76 per kit
IVS charged price	$117,824.00 per kit

Drug: ribavirin 200mg; one bottle=84 capsules	
Average wholesale price (AWP)	$525.00 per bottle
In-network pharmacy's cash price (Walgreens)	$607.99 per bottle
IVS charged price	$12,780.00 per bottle

Drug: Procrit 40,000 units/ml; one vial	
Average wholesale price (AWP)	$777.60 per vial
In-network pharmacy's cash price (Walgreens)	$812.00 per vial
IVS charged price	$34,425.00 per vial

Drug: Neupogen 300mcg/ml; one vial	
Average wholesale price (AWP)	$327.99 per vial
In-network pharmacy's cash price (Walgreens)	$355.00 per vial
IVS charged price	$13,143.00 per vial

The prescriptions were transmitted by the physician to Respondent IV Solutions, which was an out-of-network pharmacy. Neither the physician nor Respondent IV Solutions ever revealed to J.M. or his wife that the pharmacy was out of network *and failed to disclose the cost of care to the patient in advance of rendering services, the anticipated charges to the insurer and the co-insurance amount before services commenced.* Moreover, Respondent IV Solutions failed to provide J.M. with billing for over a year. The bills were only sent to the insurance company.

The total amount paid by insurance (paid directly to the patient) is $899,577.76. In addition to leaving a remaining balance to the patient in the amount of $1,131.868.34, the overcharging of the drugs affects J.M.'s lifetime coverage cap. J.M. and his wife retained an attorney who demanded documentation from Respondent IV Solutions. Respondent IV Solutions, through its attorney, produced a forged copy of an agreement and consent form that was purportedly signed by J.M. J.M. and his wife ~~denies~~ deny ever signing this document.

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Patient R.M.

27. From about April 22, 2011 to May 28, 2011, Respondent IV Solutions furnished several dispensings of Cubicin and billed R.M.'s insurance plan in the amount of $12,755 for each day's drug treatment while Respondent only incurred an acquisition cost of approximately $177.27 for each day. ~~Other pharmacy services such as home health care and nursing care were billed to insurance in amounts totaling over $59,000~~. Patient R.M. was referred to Respondent IV Solutions by the health care provider. Neither the health care provider nor Respondent IV Solutions informed Patient R.M. that it was an out of network provider. Respondent IV Solutions *failed to disclose the cost of care to the patient in advance of rendering services, the anticipated charges to the insurer and the co-insurance amount before services commenced.* Patient R.M.'s insurance paid out a total of $514,769.43 to Respondent for drugs. Respondent incurred a total cost of $7,309.04 for the drugs.

SECOND CAUSE FOR DISCIPLINE

(Obtaining a Dangerous Device from an Unlicensed Wholesaler)

28. Respondents IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code section 4169(a)(1) which states that a person or entity may not purchase, trade, sell, or transfer dangerous drugs and devices at wholesale with a person or entity that is not licensed with the Board as a wholesaler or pharmacy. Respondents violated section 4169(a)(l) in that from about January 1, 2009 to about January 1, 2012, Respondent IV Solutions obtained *Curlin* 4000 CMS pumps from an unlicensed wholesaler located in Cincinnati, Ohio.

THIRD CAUSE FOR DISCIPLINE

(Performing the Duties of a Pharmacist without a License)

29. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in

conjunction with California Code of Regulations 1793.1 subsection (b) which states that only a pharmacist may consult with a patient or his agent regarding a prescription and subsection (e) which states that only a pharmacist may consult with any prescriber, nurse or other health care professional or authorized agent. The circumstances are that from about April 17, 2010 to April 19, 2010, as President of Respondent IV Solutions Inc. located at 3384 Motor Avenue in Los Angeles, Respondent Vara, a non-pharmacist, performed the duties of a registered pharmacist without being licensed, by having calls delivered to him and/or responding to calls delivered to the pharmacy for the following reasons:

a. ~~4/17/10 at 9:17 am-from Becky (reason-need the RPH) delivered to Alex;~~
b. ~~4/17/10 at 9:55 am-from L. Buted for pt. E. E. (reason-need the RPH) delivered to Alex;~~
c. ~~4/17/10 at 11:17 am-from L. Kerr for pt. T. (reason-need the RPH) delivered to Alex;~~
d. 4/17/10 at 11:32 am-from Kevin Gilbreth for pt. D.K. (reason-nursing) delivered to Alex;
e. ~~4/17/10 at 12:49 am from C. Serna at Genus Home Care for pt. D.K. (reason-office) delivered to Alex;~~
f. 4/17/10 at 2:39 pm from Donna Gilbreth for pt. D.K. (reason-need the RPH) delivered to OC Pharmacist; message- family member called stating pump is programmed incorrectly;
g. 4/17/10 at 3:25 pm from Donna Gilbreth for D.K. (reason-delivery issue) message- returning call from Alex;
h. 4/17/10 at 3:36 pm from Kevin Gilbreth for D.K. (reason-need the RPH) delivered to OC Pharmacist; message "If there is something wrong with the pump can I get one that works/its Sat and I need this done before Sunday";
i. ~~4/17/10 at 5:20 pm from Rachel @ Genus Home Care for D.K. (reason-need the RPH) delivered to Alex;~~
j. ~~4/17/10 at 7:16 pm from Connie Li (reason-need the RPH) delivered to Alex;~~
k. ~~4/18/10 at 3:15 pm from Cheryl @Tri City Hospital for pt. J.R. (reason-need the RPH) delivered to Alex;~~
l. ~~4/19/10 at 7:55 pm from Dr. Solsky (reason- need the RPH) delivered to OC Pharmacist; message ***Requesting to speak to Alex***.~~

FOURTH CAUSE FOR DISCIPLINE

(Performing the Duties of a Pharmacist without a License)

30. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (f), (j), (o), and (p) in conjunction with California Code of Regulations 1793.1 subsection (g) which states that only a pharmacist may perform all functions which require professional judgment. The circumstances are as follows:

On April 17, 2010, Respondent Vara responded to calls from caregivers D. Gilbreth and K. Gilbreth that were delivered to the pharmacy for the following reason: Need the Pharmacist. Respondent Vara represented himself to be a pharmacist. The caregivers informed Respondent Vara that the Curlin IV pump #115698 rented from their pharmacy malfunctioned and that the settings did not match the order/label which resulted in D.K. receiving 13.5gm of Zosyn IV continuously instead of 3.375gm every six (6) hours intermittently. Respondent Vara performed the duties of a pharmacist without being licensed when he determined that the Curlin IV pump #115698 was functioning properly and refused to replace the pump as requested by the patient's caregivers. Moreover, when D. Gilbreth requested to speak to a pharmacist, Respondent stated "you can speak to me". Despite her repeated requests, no pharmacist from Respondent IV Solutions ever returned D. Gilbreth's call nor did a pharmacist ever contact any of the caregivers, patient, prescriber, nurse, or other health care professional regarding the aforementioned IV pump issue.

FIFTH CAUSE FOR DISCIPLINE

(False Representation of Licensure)

31. Respondent Vara is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301, subdivisions (f), (j), (o), and (p) and Code Section 4322 for falsely representing himself as a pharmacist. Specifically, on April 17, 2010, Respondent Vara represented himself as a pharmacist to Genus Home Care and J. Haywood, Administrator for Genus Home Care.

SIXTH CAUSE FOR DISCIPLINE

(False and Misleading Label on Prescription)

32. Respondents IV Solutions, and PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (f), (j), (o), and (p) in conjunction with Business and Professions Code Section 4078(a)(1) which states that no person shall place a false or misleading label on a prescription. Moreover, Respondent violated

Code Section 4076(a)(6) which states, in pertinent part, that a pharmacist shall not dispense a prescription except in a container that is **correctly** labeled with the name and address of the pharmacy. Specifically, on April 2, 2010 and April 7, 2010, Respondent PIC Sadow used prescription labels on RX 1813 and RX1837 that falsely represented the name of the pharmacy as "IV Solutions Clinical Pharmacy" an unknown, unlicensed pharmacy instead of "IV Solutions Inc." which is identified on their pharmacy's license PHY 45885.

SEVENTH CAUSE FOR DISCIPLINE

(Records of Dangerous Drugs and Devices Kept Open for Inspection)

33. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code Section 4081(a) and (b) by failing to make all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices available for inspection by the Board as requested.

Specifically, on April 2, 2010, Respondent IV Solutions, generated a Delivery Ticket to D.K. and sent wound care supplies including 3x1000ml Sodium Chloride Irrig.; 72 ABD Pads 7.5x8inches; 10 adhesive remover; 1 admission packet; 200 Alcohol Prep Pads; 15 Alcohol Swabtx3; 50 Gauze soft sponge 2x2 6Ply; 100 Gauze sponge 4x4 8Ply; 12 Gauze Fluff Roll 4.5in.x 4.1Yd; 100 Gloves powder free latex (medium); 10 Povie Swabstix 3s; 10 Syringe with Catheter Tip; and 3 Tape Paper 2" that were not ordered by the prescriber.

Respondents failed to provide the list of dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous drugs sent to D.K. as requested by the Board on August 11, 2010 and September 16, 2010.

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EIGHTH CAUSE FOR DISCIPLINE

(Medication Error)

34. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with California Code of Regulations 1716 as follows:

On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment as required. On April 17, 2010, D.K.'s family discovered that the total 24 hour dose of 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every six (6) hours.

NINTH CAUSE FOR DISCIPLINE

(Quality Assurance Review Not Initiated)

35. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code section 4125(a) which requires a pharmacy to establish a Quality Assurance Program to review medication errors and California Code of Regulation, title 16, section 1711(d) which requires all medication errors discovered are subject to a quality assurance review with an investigation to commence within two (2) business days from the date of discovery. The circumstances are as follows:

On April 17, 2010, Respondent PIC Sadow failed to conduct a quality assurance review within two days after discovering that the Curlin pump #115698 continuously infused the total 24 hours dose of 13.5gm of IV Zosyn into D.K. instead of intermittently as prescribed.

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TENTH CAUSE FOR DISCIPLINE

(Subvert or Attempt to Subvert an Investigation)

36. Respondent IV Solutions, Vara, and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code section 4301(q) for engaging in conduct that subverted or attempted to subvert an investigation of the Board. Specifically, Respondents failed to provide the list of dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous drugs sent to D.K. as requested by the Board on August 11, 2010 and September 16, 2010.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Misuse of Education)

37. Respondent PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code Section 4306.5(a) for her inappropriate exercise of her education, training or experience as a pharmacist. On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment as required. On April 17, 2010, D.K.'s family discovered that the total 24 hour dose of 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every six (6) hours.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to have Consultation Available)

38. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with California Code of Regulations 1751.6 subsection (a) which states that consultation shall be available to the patient and/or primary caregiver concerning proper use of

sterile injectable products and related supplies furnished by the pharmacy. The circumstances are as follows:

On October 8, 2010, Respondent IV Solutions dispensed and delivered a Curlin infusion pump along with sterile injectable products and *related* supplies to C.R., who had been discharged from the hospital the previous day after her foot surgery. When the pharmacy delivered the pump, no consultation was provided to C.R. or any caregiver for C.R. The employee who delivered the pump left a receipt for the delivered items.

On or about October 9, 2010, a home health care nurse visited C.R., to administer intravenous morphine via the Curlin infusion pump. The nurse was unfamiliar with the Curlin pump and called all of the phone numbers known to her for IV Solutions, but was unable to reach anyone because the phone calls would not roll over to the on-call service. The Director of the home health care service and C.R. also tried to call as well without success. Consequently, the nurse and C.R. decided to forego the morphine and C.R. had to rely upon less effective medication to address her pain. During the Board investigation, Respondent Vara admitted that Respondent IV Solutions does not provide in-service consultations to home health care agency nurses who experience trouble using the pump for their patients as he considers it to be a nursing issue.

THIRTEENTH CAUSE FOR DISCIPLINE

(The Thirteenth Cause for Discipline has been withdrawn)

FOURTEENTH CAUSE FOR DISCIPLINE

(Making of False Documents)

39. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4301 subdivision (f) and (g) in that Respondent IV Solutions, through its owner, Respondent Vara, falsely represented an unlicensed facility, Stat Clinic Pharmacy, as a pharmacy and provided pharmacy services to approximately 25 patients, which included creating and

receiving pharmacy-related documentation with patients and/or their physicians such as contracts and agreements, medical forms, confidential medical records, and prescriptions.

FIFTEENTH CAUSE FOR DISCIPLINE

(Violation of State Law Governing Pharmacy/Receiving and Holding Misbranded Dangerous Drugs)

40. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Health and Safety Code Section 111440 for importing 215 vials of Lovenox which are dangerous drugs, from Canada that were both misbranded and restricted to sales in Canada.

SIXTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Ordering and Delivery to an Unlicensed Facility)

41. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Code Section 4059.5(a) for ordering and delivering Lovenox, a dangerous drug, to an unlicensed premise.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Security)

42. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) for violation of Regulation 1714(d) and (e) in that its owner Respondent Vara was in possession of the pharmacy key on February 29, 2008 and April 7, 2008, and opened the pharmacy without a pharmacist present.

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EIGHTEENTH CAUSE FOR DISCIPLINE

(Pharmacy Operating without a Pharmacist Present)

43. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) and 4081 for violations of Code Sections 4113(b), 4305(b), 4305(b), and Regulation 1793.1, in that owner Respondent Vara opened the pharmacy for business on February 29, 2008 without a pharmacist present. On April 7, 2008, Respondent Vara opened the pharmacy for business without a pharmacist present and a pharmacy technician was allowed to mix an IV Solution at the pharmacy while no pharmacist was present.

NINETEENTH CAUSE FOR DISCIPLINE

(Noncompliant Pharmacist Identification)

44. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) for violation of Regulation 1717(f) in that during a Board investigation on February 29, 2008, an investigator found that the pharmacy did not have a system to identify which pharmacist was responsible for the filling of a prescription. Moreover, on April 7, 2008, upon further investigation, the investigator found that the pharmacy still had not implemented a system after having been ordered to do so.

TWENTIETH CAUSE FOR DISCIPLINE

(Non-Pharmacist Filling Prescriptions)

45. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4051 subdivision (a) in that during a Board investigation, the pharmacy was found to have non-pharmacists filling multiple prescriptions for controlled substances and dangerous drugs from March 1, 2008 to March 20, 2008.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

(Noncompliant Refilling of Controlled Substance)

46. Respondent IV Solutions and Vara subject to disciplinary action under Code Section 4301 Subdivisions (j) and (o) in conjunction with Health and Safety Code Section 11200(c) for refilling a Schedule II controlled substance on March 14, 2008.

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 Original Pharmacy Permit Number PHY 45885 issued to IV Solutions, Inc.

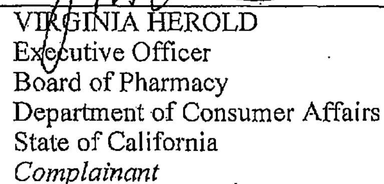
2. Revoking or suspending Pharmacist License No. RPH 27398 issued to Renee Sadow.

3. Ordering Respondent IV Solutions, Inc. and PIC Sadow to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Preventing Respondents IV Solutions, Inc., PIC Sadow, and Vara from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee.

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

DATED: 9/2/14



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

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

In the Matter of the Second Amended Accusation Against: **IV SOLUTIONS INC.** **Alireza Varastehpour-President** **3384 Motor Avenue** **Los Angeles, CA 90034** **Original Pharmacy Permit No. PHY 45885** **And** **RENEE SADOW** **24 Union Jack St., #3** **Marina del Rey, CA 90292-8600** **Pharmacist License No. RPH 27398** Respondents.	Case No. 3606 OAH No. L-2010080069 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about May 9, 2002, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 45885 to IV Solutions Inc. with Alireza Varastehpour aka Alex Vara as President (Respondent IV Solutions). The Original Pharmacy Permit was in full force and effect at all

times relevant to the charges brought herein and will expire on May 1, 2010, unless renewed. Board records show that Jeannie Kim was the Pharmacist-in-Charge (PIC) from November 25, 2008 to February 16, 2009 and Renee Sadow has been the PIC from February 16, 2009 to the present.

3. On or about April 25, 1971, the Board of Pharmacy issued Original Pharmacist License Number RPH 27398 to Renee Sadow (Respondent PIC Sadow). The license was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2011, 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 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

6. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

"(c) Gross negligence.

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

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

. . . .

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

. . . .

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

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

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

7. Section 4051 of the Code states:

"(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

"(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

"(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

"(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

"(3) Access to the information described in paragraph (2) is secure from unauthorized access and use."

8. Section 4078 (a)(1) of the code provides that "no person shall place a false or misleading label or description". Subsection (a) (2) further provides that "no prescriber shall direct that prescription be labeled with any information that is false or misleading".

9. Section 4076 (a) (6) provides, in pertinent part, that a pharmacist about dispense a prescription except container that meets the requirement of state and federal law and is **correctly** labeled with the name and address of the pharmacy.

10. Section 4081 of the code states:

"(a) All records of manufacture and sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours (section by authorized officers of the law, it shall be preserved for at least three years from the date of making. A current inventory shall be kept by every wholesaler [and] pharmacy holding a currently valid and unrevoked certificate, license, [or] permit....."

"(b) The owner, officer, and partner of any pharmacy or wholesaler...shall be jointly responsible with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory."

11. Section 4113 (b) of the Code provides that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Section 4125 (a) provides that "[e]very pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel".

13. Section 4305 of the Code states:

"(a) Any person, who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

"(b) Any person who has obtained a license to conduct a pharmacy, who willfully fails to notify the board of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

"(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of

termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action."

14. Section 4306.5 (a) provides that unprofessional conduct for a pharmacist includes acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

15. Section 4322 of the Code states that:

"Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars ($5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment."

16. Title 16, California Code of Regulations (hereinafter "CCR") section 1709.1, provides in part, that a pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

17. CCR section 1711(d) provides that each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

18. CCR section 1716 provides that pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

19. CCR Section 1751.6, subsection (a) states that consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

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20. CCR Section 1793.1 states that "[o]nly a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment."

21. Section 4307(a) of the Code provides that any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

22. 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.

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DRUG DEVICE CLASSIFICATION(S)

23. "Lovenox" is a prescription anticoagulant that prevents the formation of blood clots and is a dangerous drug per Business and Professions Code Section 4022.

24. The "Curlin 4000 CMS Pump" is an ambulatory infusion pump and a dangerous device which can only be obtained by prescription from a licensed practitioner.

FIRST CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

25. Respondents IV Solutions, PIC Sadow, and Respondent Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivision (f), which prohibits 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. The circumstances are as follows:

Patient JM

26. From about November 6, 2009 to September 1, 2010, Respondent IV Solutions furnished several prescription dispensings and sent excessively high bills to JM's insurance plan provider in the amount of $2,031.446.10 in drug treatments while Respondent IV Solutions only incurred an acquisition cost of approximately $34,187.87.

Respondent IV Solutions claimed that its charges in the total amount of $2,031,446.10 are "usual and customary", however, JM's wife researched price comparisons of the average wholesale price of an in-network pharmacy and retail cash price (Walgreens) and Respondent IV Solutions price of the same medications charged to JM which revealed that Respondent's charges were grossly excessive as follows:

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Drug: Pegasys 180mcg/0.5ml syringe; one kit=4 doses (syringes)	
Average wholesale price (AWP)	$2764.76 per kit
In-network pharmacy's cash price (Walgreens)	$2764.76 per kit
IVS charged price	$117,824.00 per kit

Drug: ribavirin 200mg; one bottle=84 capsules	
Average wholesale price (AWP)	$525.00 per bottle
In-network pharmacy's cash price (Walgreens)	$607.99 per bottle
IVS charged price	$12,780.00 per bottle

Drug: Procrit 40,000 units/ml; one vial	
Average wholesale price (AWP)	$777.60 per vial
In-network pharmacy's cash price (Walgreens)	$812.00 per vial
IVS charged price	$34,425.00 per vial

Drug: Neupogen 300mcg/ml; one vial	
Average wholesale price (AWP)	$327.99 per vial
In-network pharmacy's cash price (Walgreens)	$355.00 per vial
IVS charged price	$13,143.00 per vial

The prescriptions were transmitted by the physician to Respondent IV Solutions, which was an out-of-network pharmacy. Neither the physician nor Respondent IV Solutions ever revealed to JM or his wife that the pharmacy was out of network. Moreover, Respondent IV Solutions failed to provide JM with billing for over a year. The bills were only sent to the insurance company.

The total amount paid by insurance (paid directly to the patient) is $899,577.76. In addition to leaving a remaining balance to the patient in the amount of $1,131,868.34, the overcharging of the drugs affects JM's lifetime coverage cap. JM and his wife retained an attorney who demanded documentation from Respondent IV Solutions. Respondent IV Solutions, through its attorney, produced a forged copy of an agreement and consent form that was purportedly signed by JM. JM and his wife denies ever signing this document.

Patient RM

27. From about April 22, 2011 to May 28, 2011, Respondent IV Solutions furnished several dispensings of Cubicin and billed RM's insurance plan in the amount of $12,755 for each day's drug treatment while Respondent only incurred an acquisition cost of approximately $177.27 for each day. Other pharmacy services such as home health care and nursing care were

billed to insurance in amounts totaling over $59,000. Patient RM was referred to Respondent IV Solutions by the health care provider. Neither the health care provider nor Respondent IV Solutions informed Patient RM that it was an out of network provider. Patient RM's insurance paid out a total of $514,769.43 to Respondent for drugs. Respondent incurred a total cost of $7,309.04 for the drugs.

SECOND CAUSE FOR DISCIPLINE

(Obtaining a Dangerous Device from an Unlicensed Wholesaler)

28. Respondents IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code section 4169(a)(1) which states that a person or entity may not purchase, trade, sell, or transfer dangerous drugs and devices at wholesale with a person or entity that is not licensed with the Board as a wholesaler or pharmacy. Respondents violated section 4169(a)(l) in that from about January 1, 2009 to about January 1, 2012, Respondent IV Solutions obtained Curling 4000 CMS pumps from an unlicensed wholesaler located in Cincinnati, Ohio.

THIRD CAUSE FOR DISCIPLINE

(Performing the Duties of a Pharmacist without a License)

29. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with California Code of Regulations 1793.1 subsection (b) which states that only a pharmacist may consult with a patient or his agent regarding a prescription and subsection (e) which states that only a pharmacist may consult with any prescriber, nurse or other health care professional or authorized agent. The circumstances are that from about April 17, 2010 to April 19, 2010, as President of Respondent IV Solutions Inc located at 3384 Motor Avenue in Los Angeles, Respondent Vara, a non-pharmacist, performed the duties of a registered pharmacist without being licensed, by having calls delivered to him and/or responding to calls delivered to the pharmacy for the following reasons:

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a. 4/17/10 at 9:17 am-from Becky (reason-need the RPH) delivered to Alex;
b. 4/17/10 at 9:55 am-from L. Buted for pt. E. E. (reason-need the RPH) delivered to Alex;
c. 4/17/10 at 11:17 am-from L. Kerr for pt. T. (reason-need the RPH) delivered to Alex;
d. 4/17/10 at 11:32 am-from Kevin Gilbreth for pt. D. Kordyak (reason-nursing) delivered to Alex;
e. 4/17/10 at 12:49 am from C. Serna at Genus Home Care for pt. D. Kordyak (reason-office) delivered to Alex;
f. 4/17/10 at 2:39 pm from Donna Gilbreth for pt. D. Kordyak (reason-need the RPH) delivered to OC Pharmacist; message- family member called stating pump is programmed incorrectly;
g. 4/17/10 at 3:25 pm from Donna Gilbreth for D. Kordyak (reason-delivery issue) message-returning call from Alex;
h. 4/17/10 at 3:36 pm from Kevin Gilbreth for D. Kordyak (reason-need the RPH) delivered to OC Pharmacist; message "If there is something wrong with the pump can I get one that works/its Sat and I need this done before Sunday";
i. 4/17/10 at 5:20 pm from Rachel @ Genus Home Care for D. Kordyak (reason-need the RPH) delivered to Alex;
j. 4/17/10 at 7:16 pm from Connie Li (reason-need the RPH) delivered to Alex;
k. 4/18/10 at 3:15 pm from Cheryl @Tri City Hospital for pt. J.R. (reason-need the RPH) delivered to Alex;
l. 4/19/10 at 7:55 pm from Dr. Solsky (reason- need the RPH) delivered to OC Pharmacist; message-***Requesting to speak to Alex***.

FOURTH CAUSE FOR DISCIPLINE

(Performing the Duties of a Pharmacist without a License)

30. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (f), (j), (o), and (p) in conjunction with California Code of Regulations 1793.1 subsection (g) which states that only a pharmacist may perform all functions which require professional judgment. The circumstances are as follows:

On April 17, 2010, Respondent Vara responded to calls from caregivers D. Gilbreth and K. Gilbreth that were delivered to the pharmacy for the following reason: Need the Pharmacist. Respondent Vara represented himself to be a pharmacist. The caregivers informed Respondent Vara that the Curlin IV pump #115698 rented from their pharmacy malfunctioned and that the settings did not match the order/label which resulted in D. Kordyak receiving 13.5gm of Zosyn IV continuously instead of 3.375gm every six (6) hours intermittently. Respondent Vara performed the duties of a pharmacist without being licensed when he determined that the Curlin IV pump #115698 was functioning properly and refused to replace the pump as requested by the patient's caregivers. Moreover, when D. Gilbreth requested to speak to a pharmacist,

Respondent stated "you can speak to me". Despite her repeated requests, no pharmacist from Respondent IV Solutions ever returned D. Gilbreth's call nor did a pharmacist ever contact any of the caregivers, patient, prescriber, nurse, or other health care professional regarding the aforementioned IV pump issue.

FIFTH CAUSE FOR DISCIPLINE

(False Representation of Licensure)

31. Respondent Vara is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301, subdivisions (f), (j), (o), and (p) and Code Section 4322 for falsely representing himself as a pharmacist. Specifically, on April 17, 2010, Respondent Vara represented himself as a pharmacist to Genus Home Care and J. Haywood, Administrator for Genus Home Care.

SIXTH CAUSE FOR DISCIPLINE

(False and Misleading Label on Prescription)

32. Respondents IV Solutions, and PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (f), (j), (o), and (p) in conjunction with Business and Professions Code Section 4078(a)(1) which states that no person shall place a false or misleading label on a prescription. Moreover, Respondent violated Code Section 4076(a)(6) which states, in pertinent part, that a pharmacist shall not dispense a prescription except in a container that is **correctly** labeled with the name and address of the pharmacy. Specifically, on April 2, 2010 and April 7, 2010, Respondent PIC Sadow used prescription labels on RX 1813 and RX1837 that falsely represented the name of the pharmacy as "IV Solutions Clinical Pharmacy" an unknown, unlicensed pharmacy instead of "IV Solutions Inc" which is identified on their pharmacy's license PHY 45885.

SEVENTH CAUSE FOR DISCIPLINE

(Records of Dangerous Drugs and Devices Kept Open for Inspection)

33. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code Section 4081(a) and (b) by failing to make all

1 records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous
2 devices available for inspection by the Board as requested.

3 Specifically, on April 2, 2010, Respondent IV Solutions, generated a Delivery Ticket to D.
4 Kordyak and sent wound care supplies including 3x1000ml Sodium Chloride Irrig.; 72 ABD Pads
5 7.5x8inches; 10 adhesive remover; 1 admission packet; 200 Alcohol Prep Pads; 15 Alcohol
6 Swabtx3; 50 Gauze soft sponge 2x2 6Ply; 100 Gauze sponge 4x4 8Ply; 12 Gauze Fluff Roll
7 4.5in.x 4.1Yd; 100 Gloves powder free latex (medium); 10 Povie Swabstix 3s; 10 Syringe with
8 Catheter Tip; and 3 Tape Paper 2" that were not ordered by the prescriber.

9 Respondents failed to provide the list of dangerous drugs, supplies, including wound care
10 supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous
11 drugs sent to D. Kordyak as requested by the Board on August 11, 2010 and September 16, 2010.

12 **EIGHTH CAUSE FOR DISCIPLINE**

13 **(Medication Error)**

14 34. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for
15 unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in
16 conjunction with California Code of Regulations 1716 as follows:

17 On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the
18 intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment
19 as required. On April 17, 2010, D. Kordyak's family discovered that the total 24 hour dose of
20 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the
21 continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every
22 six (6) hours.

23 **NINTH CAUSE FOR DISCIPLINE**

24 **(Quality Assurance Review Not Initiated)**

25 35. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for
26 unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in
27 conjunction with Business and Professions Code section 4125(a) which requires a pharmacy to
28 establish a Quality Assurance Program to review medication errors and California Code of

Regulation, title 16, section 1711(d) which requires all medication errors discovered are subject to a quality assurance review with an investigation to commence within two (2) business days from the date of discovery. The circumstances are as follows:

On April 17, 2010, Respondent PIC Sadow failed to conduct a quality assurance review within two days after discovering that the Curlin pump #115698 continuously infused the total 24 hours dose of 13.5gm of IV Zosyn into D. Kordyak instead of intermittently as prescribed.

TENTH CAUSE FOR DISCIPLINE

(Subvert or Attempt to Subvert an Investigation)

36. Respondent IV Solutions, Vara, and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code section 4301(q) for engaging in conduct that subverted or attempted to subvert an investigation of the Board. Specifically, Respondents failed to provide the list of dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous drugs sent to D. Kordyak as requested by the Board on August 11, 2010 and September 16, 2010.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Misuse of Education)

37. Respondent PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code Section 4306.5(a) for her inappropriate exercise of her education, training or experience as a pharmacist. On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment as required. On April 17, 2010, D. Kordyak's family discovered that the total 24 hour dose of 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every six (6) hours.

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1 **TWELFTH CAUSE FOR DISCIPLINE**

2 **(Failure to have Consultation Available)**

3 38. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for
4 unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in
5 conjunction with California Code of Regulations 1751.6 subsection (a) which states that
6 consultation shall be available to the patient and/or primary caregiver concerning proper use of
7 sterile injectable products and related supplies furnished by the pharmacy. The circumstances are
8 as follows:

9 On October 8, 2010, Respondent IV Solutions dispensed and delivered a curlin infusion
10 pump along with sterile injectable products and relatel supplies to C.R., who had been discharged
11 from the hospital the previous day after her foot surgery. When the pharmacy delivered the
12 pump, no consultation was provided to C.R. or any caregiver for C.R. The employee who
13 delivered the pump left a receipt for the delivered items.

14 On or about October 9, 2010, a home health care nurse visited C.R., to administer
15 intravenous morphine via the Curlin infusion pump. The nurse was unfamiliar with the Curlin
16 pump and called all of the phone numbers known to her for IV Solutions, but was unable to reach
17 anyone because the phone calls would not roll over to the on-call service. The Director of the
18 home health care service and C.R. also tried to call as well without success. Consequently, the
19 nurse and C.R. decided to forego the morphine and C.R. had to rely upon less effective
20 medication to address her pain.

21 During the Board investigation, Respondent Vara admitted that Respondent IV Solutions
22 does not provide in-service consultations to home health care agency nurses who experience
23 trouble using the pump for their patients as he considers it to be a nursing issue.

24 **THIRTEENTH CAUSE FOR DISCIPLINE**

25 **Making Up False Document)**

26 Respondent is further subject to disciplinary action for unprofessional conduct under Code
27 Section 4301 subdivision (f) and (g) for creating a false document. Complainant realleges
28 paragraph 38 as though fully set forth herein. On Monday, October 11, 2010, C.R. felt that she

no longer needed the above-rerenewal unused morphine and contacted the pharmacy to request a refund. She was told that someone would get back to her, however, she received no response. The unused pump, supplies and morphine were picked up by the pharmacy on October 12, 2010 and Respondent IV Solutions left a receipt. The receipt reflects that three (3) bags of morphine were charged to C.R. for a total of $210.00, when in fact, she only received one bag of morphine as indicated on her initial delivery ticket.

FOURTEENTH CAUSE FOR DISCIPLINE

(Making of False Documents)

39. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4301 subdivision (f) and (g) in that Respondent IV Solutions, through its owner, Respondent Vara, falsely represented an unlicensed facility, Stat Clinic Pharmacy, as a pharmacy and provided pharmacy services to approximately 25 patients, which included creating and receiving pharmacy-related documentation with patients and/or their physicians such as contracts and agreements, medical forms, confidential medical records, and prescriptions.

FIFTEENTH CAUSE FOR DISCIPLINE

(Violation of State Law Governing Pharmacy/Receiving and Holding Misbranded Dangerous Drugs)

40. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Health and Safety Code Section 111440 for importing 215 vials of Lovenox which are dangerous drugs, from Canada that were both misbranded and restricted to sales in Canada.

SIXTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Ordering and Delivery to an Unlicensed Facility)

41. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Code Section 4059.5(a) for ordering and delivering Lovenox, a dangerous drug, to an unlicensed premise.

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SEVENTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Security)

42. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) for violation of Regulation 1714(d) and (e) in that its owner Respondent Vara was in possession of the pharmacy key on February 29, 2008 and April 7, 2008, and opened the pharmacy without a pharmacist present.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Pharmacy Operating without a Pharmacist Present)

43. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) and 4081 for violations of Code Sections 4113(b), 4305(b), 4305(b), and Regulation 1793.1, in that owner Respondent Vara opened the pharmacy for business on February 29, 2008 without a pharmacist present. On April 17, 2008, Respondent Vara opened the pharmacy for business without a pharmacist present and a pharmacy technician was allowed to mix an IV Solution at the pharmacy while no pharmacist was present.

NINETEENTH CAUSE FOR DISCIPLINE

(Noncompliant Pharmacist Identification)

44. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) for violation of Regulation 1717(f) in that during a Board investigation on February 29, 2008, an investigator found that the pharmacy did not have a system to identify which pharmacist was responsible for the filling of a prescription. Moreover, on April 7, 2008, upon further investigation, the investigator found that the pharmacy still had not implemented a system after having been ordered to do so.

TWENTIETH CAUSE FOR DISCIPLINE

(Non-Pharmacist Filling Prescriptions)

45. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4051 subdivision (a) in that during a Board investigation, the pharmacy was found to

have non-pharmacists filling multiple prescriptions for controlled substances and dangerous drugs from March 1, 2008 to March 20, 2008.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Noncompliant Refilling of Controlled Substance)

46. Respondent IV Solutions and Vara subject to disciplinary action under Code Section 4301 Subdivisions (j) and (o) in conjunction with Health and Safety Code Section 11200(c) for refilling a Schedule II controlled substance on March 14, 2008.

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 Original Pharmacy Permit Number PHY 45885 issued to IV Solutions, Inc.

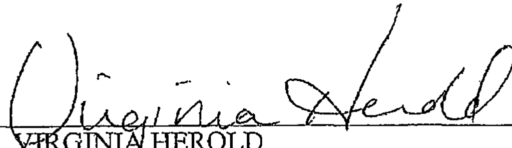
2. Revoking or suspending Pharmacist License No. RPH 27398 issued to Renee Sadow.

3. Ordering Respondent IV Solutions, Inc. and PIC Sadow to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Preventing Respondents IV Solutions, Inc., PIC Sadow, and Vara from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee.

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

DATED: 1/17/13



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

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

In the Matter of the Accusation Against: **IV SOLUTIONS INC. Alireza Varastehpour-President 3384 Motor Avenue Los Angeles, CA 90034 Original Pharmacy Permit No. PHY 45885** **And** **RENEE SADOW 24 Union Jack St., #3 Marina del Rey, CA 90292-8600 Pharmacist License No. RPH 27398** Respondents.	Case No. 3606 OAH No. L-2010080069 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about May 9, 2002, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 45885 to IV Solutions Inc. with Alireza Varastehpour aka Alex Vara as President (Respondent IV Solutions). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2010, unless renewed.

1 Board records show that Jeannie Kim was the Pharmacist-in-Charge (PIC) from November 25,
2 2008 to February 16, 2009 and Renee Sadow has been the PIC from February 16, 2009 to the
3 present.

4 3. On or about April 25, 1971, the Board of Pharmacy issued Original Pharmacist
5 License Number RPH 27398 to Renee Sadow (Respondent PIC Sadow). The license was in full
6 force and effect at all times relevant to the charges brought herein and will expire on June 30,
7 2011, unless renewed.

8 JURISDICTION

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

12 5. Section 4300 provides, in pertinent part, that every license issued by the Board is
13 subject to discipline, including suspension or revocation.

14 6. Section 4301 of the Code states:

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

18 . . . .

19 "(c) Gross negligence.

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

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

25 . . . .

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

28 . . . .

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

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

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

7. Section 4051 of the Code states:

"(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

"(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

"(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

"(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

"(3) Access to the information described in paragraph (2) is secure from unauthorized access and use."

8. Section 4078 (a)(1) of the code provides that "no person shall place a false or misleading label or description". Subsection (a) (2) further provides that "no prescriber shall direct that prescription be labeled with any information that is false or misleading".

9. Section 4076 (a) (6) provides, in pertinent part, that a pharmacist about dispense a prescription except container that meets the requirement of state and federal law and is **correctly** labeled with the name and address of the pharmacy.

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10. Section 4081 of the code states:

"(a) All records of manufacture and sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours (section by authorized officers of the law, it shall be preserved for at least three years from the date of making. A current inventory shall be kept by every wholesaler [and] pharmacy holding a currently valid and unrevoked certificate, license, [or] permit....."

"(b) The owner, officer, and partner of any pharmacy or wholesaler...shall be jointly responsible with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory."

11. Section 4113 (b) of the Code provides that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Section 4125 (a) provides that "[e]very pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel".

13. Section 4305 of the Code states:

"(a) Any person, who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

"(b) Any person who has obtained a license to conduct a pharmacy, who willfully fails to notify the board of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

"(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of

termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action."

14. Section 4306.5 (a) provides that unprofessional conduct for a pharmacist includes acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

15. Section 4322 of the Code states that:

"Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars ($5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment."

16. Title 16, California Code of Regulations (hereinafter "CCR") section 1709.1, provides in part, that a pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

17. CCR section 1711(d) provides that each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

18. CCR section 1716 provides that pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

19. CCR Section 1793.1 states that "[o]nly a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment."

20. Section 4307(a) of the Code provides that any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

21. 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.

DRUG CLASSIFICATION(S)

22. "Lovenox" is a prescription anticoagulant that prevents the formation of blood clots and is a dangerous drug per Business and Professions Code Section 4022.

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FIRST CAUSE FOR DISCIPLINE

(Performing the Duties of a Pharmacist without a license)

23. Respondents IV Solutions, PIC Sadow, and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with California Code of Regulations 1793.1 subsection (b) which states that only a pharmacist may consult with a patient or his agent regarding a prescription and subsection (e) which states that only a pharmacist may consult with any prescriber, nurse or other health care professional or authorized agent. The circumstances are that from about April 17, 2010 to April 19, 2010, as President of Respondent IV Solutions Inc located at 3384 Motor Avenue in Los Angeles, Respondent Vara, a non-pharmacist, performed the duties of a registered pharmacist without being licensed, by having calls delivered to him and/or responding to calls delivered to the pharmacy for the following reasons:

a. 4/17/10 at 9:17 am-from Becky (reason-need the RPH) delivered to Alex;
b. 4/17/10 at 9:55 am-from L. Buted for pt. E. E. (reason-need the RPH) delivered to Alex;
c. 4/17/10 at 11:17 am-from L. Kerr for pt. T. (reason-need the RPH) delivered to Alex;
d. 4/17/10 at 11:32 am-from Kevin Gilbreth for pt. D. Kordyak (reason-nursing) delivered to Alex;
e. 4/17/10 at 12:49 am from C. Serna at Genus Home Care for pt. D. Kordyak (reason-office) delivered to Alex;
f. 4/17/10 at 2:39 pm from Donna Gilbreth for pt. D. Kordyak (reason-need the RPH) delivered to OC Pharmacist; message- family member called stating pump is programmed incorrectly;
g. 4/17/10 at 3:25 pm from Donna Gilbreth for D. Kordyak (reason-delivery issue) message-returning call from Alex;
h. 4/17/10 at 3:36 pm from Kevin Gilbreth for D. Kordyak (reason-need the RPH) delivered to OC Pharmacist; message "If there is something wrong with the pump can I get one that works/its Sat and I need this done before Sunday";
i. 4/17/10 at 5:20 pm from Rachel @ Genus Home Care for D. Kordyak (reason-need the RPH) delivered to Alex;
j. 4/17/10 at 7:16 pm from Connie Li (reason-need the RPH) delivered to Alex;
k. 4/18/10 at 3:15 pm from Cheryl @Tri City Hospital for pt. J.R. (reason-need the RPH) delivered to Alex;
l. 4/19/10 at 7:55 pm from Dr. Solsky (reason- need the RPH) delivered to OC Pharmacist; message-***Requesting to speak to Alex***.

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1 SECOND CAUSE FOR DISCIPLINE

2 (Performing the Duties of a Pharmacist without a License)

3 24. Respondents IV Solutions, PIC Sadow, and Vara are subject to
4 disciplinary action for unprofessional conduct within the meaning of Code Section 4301
5 subdivisions (j), (o), and (p) in conjunction with California Code of Regulations 1793.1
6 subsection (g) which states that only a pharmacist may perform all functions which require
7 professional judgment. The circumstances are as follows:

8 On April 17, 2010, Respondent Vara responded to calls from caregivers D. Gilbreth and K.
9 Gilbreth that were delivered to the pharmacy for the following reason: Need the Pharmacist.
10 RespondentVara represented himself to be a pharmacist. The caregivers informed Respondent
11 Vara that the Curlin IV pump #115698 rented from their pharmacy malfunctioned and that the
12 settings did not match the order/label which resulted in D. Kordyak receiving 13.5gm of Zosyn
13 IV continuously instead of 3.375gm every six (6) hours intermittently. Respondent Vara
14 performed the duties of a pharmacist without being licensed when he determined that the Curlin
15 IV pump #115698 was functioning properly and refused to replace the pump as requested by the
16 patient's caregivers. Moreover, when D. Gilbreth requested to speak to a pharmacist,
17 Respondent stated "you can speak to me". Despite her repeated requests, no pharmacist from
18 Respondent IV Solutions ever returned D. Gilbreth's call nor did a pharmacist ever contact any of
19 the caregivers, patient, prescriber, nurse, or other health care professional regarding the
20 aforementioned IV pump issue.

21 THIRD CAUSE FOR DISCIPLINE

22 (False Representation of Licensure)

23 25. Respondent Vara is subject to disciplinary action for unprofessional conduct within
24 the meaning of Code Section 4301, subdivisions (j), (o), and (p) and Code Section 4322 for
25 falsely representing himself as a pharmacist. Specifically, on April 17, 2010, Respondent Vara
26 represented himself as a pharmacist to Genus Home Care and J. Haywood, Administrator for
27 Genus Home Care.

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FOURTH CAUSE FOR DISCIPLINE

(False and Misleading Label on Prescription)

26. Respondents IV Solutions, and PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code Section 4078(a)(1) which states that no person shall place a false or misleading label on a prescription. Moreover, Respondent violated Code Section 4076(a)(6) which states, in pertinent part, that a pharmacist shall not dispense a prescription except in a container that is **correctly** labeled with the name and address of the pharmacy. Specifically, on April 2, 2010 and April 7, 2010, Respondent PIC Sadow used prescription labels on RX 1813 and RX1837 that falsely represented the name of the pharmacy as "IV Solutions Clinical Pharmacy" an unknown, unlicensed pharmacy instead of "IV Solutions Inc" which is identified on their pharmacy's license PHY 45885.

FIFTH CAUSE FOR DISCIPLINE

(Records of Dangerous Drugs and Devices Kept Open for Inspection)

27. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in conjunction with Business and Professions Code Section 4081(a) and (b) by failing to make all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices available for inspection by the Board as requested.

Specifically, on April 2, 2010, Respondent IV Solutions, generated a Delivery Ticket to D. Kordyak and sent wound care supplies including 3x1000ml Sodium Chloride Irrig.; 72 ABD Pads 7.5x8inches; 10 adhesive remover; 1 admission packet; 200 Alcohol Prep Pads; 15 Alcohol Swabtx3; 50 Gauze soft sponge 2x2 6Ply; 100 Gauze sponge 4x4 8Ply; 12 Gauze Fluff Roll 4.5in.x 4.1Yd; 100 Gloves powder free latex (medium); 10 Povie Swabstix 3s; 10 Syringe with Catheter Tip; and 3 Tape Paper 2" that were not ordered by the prescriber.

Respondents failed to provide the list of dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous drugs sent to D. Kordyak as requested by the Board on August 11, 2010 and September 16, 2010.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Medication Error)**

3 28. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for
4 unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in
5 conjunction with California Code of Regulations 1716 as follows:

6 On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the
7 intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment
8 as required. On April 17, 2010, D. Kordyak's family discovered that the total 24 hour dose of
9 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the
10 continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every
11 six (6) hours.

12 **SEVENTH CAUSE FOR DISCIPLINE**

13 **(Quality Assurance Review Not Initiated)**

14 29. Respondent IV Solutions and PIC Sadow are subject to disciplinary action for
15 unprofessional conduct within the meaning of Code Section 4301 subdivisions (j), (o), and (p) in
16 conjunction with Business and Professions Code section 4125(a) which requires a pharmacy to
17 establish a Quality Assurance Program to review medication errors and California Code of
18 Regulation, title 16, section 1711(d) which requires all medication errors discovered are subject to
19 a quality assurance review with an investigation to commence within two (2) business days from
20 the date of discovery. The circumstances are as follows:

21 On April 17, 2010, Respondent PIC Sadow failed to conduct a quality assurance review
22 within two days after discovering that the Curlin pump #115698 continuously infused the total 24
23 hours dose of 13.5gm of IV Zosyn into D. Kordyak instead of intermittently as prescribed.

24 **EIGHTH CAUSE FOR DISCIPLINE**

25 **(Subvert or Attempt to Subvert an Investigation)**

26 30. Respondent IV Solutions, Vara, and PIC Sadow are subject to disciplinary action for
27 unprofessional conduct within the meaning of Business and Professions Code section 4301(q) for
28 engaging in conduct that subverted or attempted to subvert an investigation of the Board.

Specifically, Respondents failed to provide the list of dangerous drugs, supplies, including wound care supplies, and prescription records, billing records, or protocol for the supplies and/or dangerous drugs sent to D. Kordyak as requested by the Board on August 11, 2010 and September 16, 2010.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Misuse of Education)

31. Respondent PIC Sadow is subject to disciplinary action for unprofessional conduct within the meaning of Business and Professions Code Section 4306.5(a) for her inappropriate exercise of her education, training or experience as a pharmacist. On April 2, 2010, Respondent PIC Sadow programmed the Curlin pump #115698 using the intermittent setting but failed to lock down the settings to secure the prescribed dosing regiment as required. On April 17, 2010, D. Kordyak's family discovered that the total 24 hour dose of 13.5gm of Zosyn antibiotic was delivered to him by an unsecured Curlin pump #115698 on the continuous setting instead of the intermittent setting of four divided doses of 3.375gm/dose every six (6) hours.

TENTH CAUSE FOR DISCIPLINE

(Violation of State Law Governing Pharmacy/Receiving and Holding Misbranded Dangerous Drugs)

32. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Health and Safety Code Section 111440 for importing 215 vials of Lovenox which are dangerous drugs, from Canada that were both misbranded and restricted to sales in Canada.

ELEVENTH CAUSE FOR DISCIPLINE

(Noncompliant Ordering and Delivery to an Unlicensed Facility)

33. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Code Section 4059.5(a) for ordering and delivering Lovenox, a dangerous drug, to an unlicensed premise.

TWELTH CAUSE FOR DISCIPLINE

(Noncompliant Security)

34. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) for violation of Regulation 1714(d) and (e) in that its owner Respondent Vara was in possession of the pharmacy key on February 29, 2008 and April 7, 2008, and opened the pharmacy without a pharmacist present.

THIRTEENTH CAUSE FOR DISCIPLINE

(Pharmacy Operating without a Pharmacist Present)

35. Respondent IV Solutions and Vara are subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) and 4081 for violations of Code Sections 4113(b), 4305(b), 4305(b), and Regulation 1793.1, in that owner Respondent Vara opened the pharmacy for business on February 29, 2008 without a pharmacist present. On April 17, 2008, Respondent Vara opened the pharmacy for business without a pharmacist present and a pharmacy technician was allowed to mix an IV Solution at the pharmacy while no pharmacist was present.

FOURTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Pharmacist Identification)

36. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) for violation of Regulation 1717(f) in that during a Board investigation on February 29, 2008, an investigator found that the pharmacy did not have a system to identify which pharmacist was responsible for the filling of a prescription. Moreover, on April 7, 2008, upon further investigation, the investigator found that the pharmacy still had not implemented a system after having been ordered to do so.

FIFTHTEENTH CAUSE FOR DISCIPLINE

(Non-Pharmacist Filling Prescriptions)

37. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4051 subdivision (a) in that during a Board investigation, the pharmacy was found to

have non-pharmacists filling multiple prescriptions for controlled substances and dangerous drugs from March 1, 2008 to March 20, 2008.

SIXTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Refilling of Controlled Substance)

38. Respondent IV Solutions and Vara subject to disciplinary action under Code Section 4301 Subdivisions (j) and (o) in conjunction with Health and Safety Code Section 11200(c) for refilling a Schedule II controlled substance on March 14, 2008.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Making of False Documents)

39. Respondent IV Solutions and Vara are subject to disciplinary action under Code Section 4301 subdivision (g) in that Respondent IV Solutions, through its owner, Respondent Vara, falsely represented an unlicensed facility, Stat Clinic Pharmacy, as a pharmacy and provided pharmacy services to approximately 25 patients, which included creating and receiving pharmacy-related documentation with patients and/or their physicians such as contracts and agreements, medical forms, confidential medical records, and prescriptions.

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 Original Pharmacy Permit Number PHY 45885 issued to IV Solutions, Inc.

2. Revoking or suspending Pharmacist License No. RPH 27398 issued to Renee Sadow.

3. Ordering Respondent IV Solutions, Inc. and PIC Sadow to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Preventing Respondents IV Solutions, Inc., PIC Sadow, and Vara from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee.

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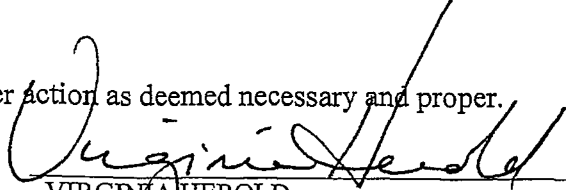
5. Taking such other and further action as deemed necessary and proper.

DATED: 7/25/11



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

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

In the Matter of the Accusation Against:	Case No. 3606
IV SOLUTIONS INC. **Alireza Varastehpour-President** **3384 Motor Avenue** **Los Angeles, CA 90034** **Original Pharmacy Permit No. PHY 45885**	OAH No. L-2010080069 **ACCUSATION**
Respondents.	

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 May 9, 2002, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 45885 to IV Solutions Inc. with Alireza Varastehpour aja Alex Vara as President (Respondent IV Solutions). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2010, unless renewed. Board records show that Jeannie Kim was the Pharmacist-in-Charge from November 25, 2008 to February 16, 2009.

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JURISDICTION

3. 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.

4. Section 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

5. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

"(c) Gross negligence.

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

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

. . . .

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

. . . .

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

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

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6. Section 4051 of the Code states:

"(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

"(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

"(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

"(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

"(3) Access to the information described in paragraph (2) is secure from unauthorized access and use."

7. Section 4081 also provides that the owner, officer and partner of any pharmacy or wholesaler shall be jointly responsible with the pharmacist-in-charge or exemptee for maintaining the records and inventory. A current inventory shall be kept by every pharmacy and wholesaler holding a currently valid and un-revoked license.

8. Section 4113 (b) of the Code provides that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

9. Section 4324 of the Code states:

"(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment in the state prison, or by imprisonment in the county jail for not more than one year.

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"(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment in the state prison, or by imprisonment in the county jail for not more than one year."

10. Section 4305 of the Code states:

"(a) Any person, who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

"(b) Any person who has obtained a license to conduct a pharmacy, who willfully fails to notify the board of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

"(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action."

11. Title 16, California Code of Regulations (hereinafter "CCR") section 1709.1, provides in part, that a pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

CCR Section 1793.1 provides, in part, that only a registered pharmacist, or an intern pharmacist acting under the supervision of a registered pharmacist, may:

"(a) receive a new prescription order orally from a prescriber or other person authorized by law...

(f) supervise the packaging of drugs and check the packaging procedure and product upon completion;

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(g) be responsible for all activities of pharmacy technician to ensure that all such activities are performed completely, safely and without risk of harm to patients;

(h) perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and

(i) perform all functions which require professional judgment".

12. 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.

13. "Lovenox" is a prescription anticoagulant that prevents the formation of blood clots and is a dangerous drug per Business and Professions Code Section 4022.

FIRST CAUSE FOR DISCIPLINE

(Violation of State Law Governing Pharmacy/Receiving and Holding Misbranded Dangerous Drugs)

14. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Health and Safety Code Section 111440 for importing 215 vials of Lovenox which are dangerous drugs, from Canada that were both misbranded and restricted to sales in Canada.

SECOND CAUSE FOR DISCIPLINE

(Noncompliant Ordering and Delivery to an Unlicensed Facility)

15. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 subdivisions (j) and (o) in conjunction with Code Section 4059.5(a) for ordering and delivering Lovenox, a dangerous drug, to an unlicensed premise.

THIRD CAUSE FOR DISCIPLINE

(Noncompliant Security)

16. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) for violation of Regulation

1714(d) and (e) in that its owner Alex Vara was in possession of the pharmacy key on February 29, 2008 and April 7, 2008, and opened the pharmacy without a pharmacist present.

FOURTH CAUSE FOR DISCIPLINE

(Pharmacy Operating without a Pharmacist Present)

17. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) and 4081 for violations of Code Sections 4113(b), 4305(b), 4305(b), and Regulation 1793.1, in that owner Alex Vara opened the pharmacy for business on February 29, 2008 without a pharmacist present. On April 17, 2008, Alex Vara opened the pharmacy for business without a pharmacist present and a pharmacy technician was allowed to mix an IV Solution at the pharmacy while no pharmacist was present.

FIFTH CAUSE FOR DISCIPLINE

(Noncompliant Pharmacist Identification)

18. Respondent IV Solutions is subject to disciplinary action for unprofessional conduct within the meaning of Code Section 4301 Subdivisions (j) and (o) for violation of Regulation 1717(f) in that during a Board investigation on February 29, 2008, an investigator found that the pharmacy did not have a system to identify which pharmacist was responsible for the filling of a prescription. Moreover, on April 7, 2008, upon further investigation, the investigator found that the pharmacy still had not implemented a system after having been ordered to do so.

SIXTH CAUSE FOR DISCIPLINE

(Non-Pharmacist Filling Prescriptions)

19. Respondent IV Solutions is subject to disciplinary action under Code Section 4051subdisivion (a) in that during a Board investigation, the pharmacy was found to have non-pharmacists filling multiple prescriptions for controlled substances and dangerous drugs from March 1, 2008 to March 20, 2008.

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SEVENTH CAUSE FOR DISCIPLINE

(Noncompliant Refilling of Controlled Substance)

20. Respondent IV Solutions is subject to disciplinary action under Code Section 4301 Subdivisions (j) and (o) in conjunction with Health and Safety Code Section 11200(c) for refilling a Schedule II controlled substance on March 14, 2008.

EIGHTH CAUSE FOR DISCIPLINE

(Making of False Documents)

21. Respondent IV Solutions is subject to disciplinary action under Code Section 4301 subdivison (g) in that Respondent IV Solutions, through its owner, Alex Vara, falsely represented an unlicensed facility, Stat Clinic Pharmacy, as a pharmacy and provided pharmacy services to approximately 25 patients, which included creating and receiving pharmacy-related documentation with patients and/or their physicians such as contracts and agreements, medical forms, confidential medical records, and prescriptions.

PRAYER

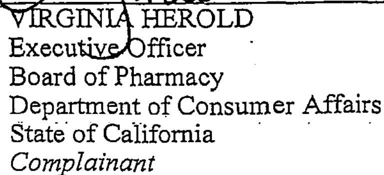
WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Pharmacy Permit Number PHY 45885, issued to IV Solutions, Inc.

2. Ordering IV Solutions, Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 2/25/11



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

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