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

In the Matter of the Petition for Early Termination of Probation of:

Case No. 4907

COMPLETE INFUSION CARE, CIC, INC., Pharmacy Permit No. PHY 53829, Sterile Compounding License No. LSC 100883,

OAH No. 2018120123

Petitioner.

In the Matter of the Petition for Early Termination of Probation of:

Case No. 4907

ALI POURMOLA.

OAH No. 2018120124

Pharmacist License No. RPH 48035,

Petitioner.

### **DECISION**

A quorum of the Board of Pharmacy (Board) heard these matters on December 14, 2018, in Irvine, California. Administrative Law Judge Howard W. Cohen of the Office of Administrative Hearings presided.

Desiree Tulleners, Deputy Attorney General, represented the Attorney General under Business and Professions Code section 4309 and Government Code section 11522.

Michael Houske, Attorney at Law, General Counsel and Executive Vice President of Complete Infusion Care, CIC, Inc., (CIC) represented petitioners CIC and Ali Pourmola, who was present. The parties stipulated that both petitions should be heard together and a single decision should issue.

Evidence was received, the record was closed, and the matters were submitted for decision on December 14, 2018, following which the Board met in executive session and decided the matters on the day of hearing.

### **FACTUAL FINDINGS**

### Parties and Jurisdiction

- 1. The Board issued Pharmacy Permit number PHY 46839 to petitioner CIC on September 22, 2004. The permit expired on March 4, 2016. The Board issued Sterile Compounding License number LSC 99250 to petitioner CIC on November 15, 2004. The license expired on March 7, 2016. The Board issued petitioner CIC its current Pharmacy Permit, number PHY 53829, on March 4, 2016; the permit is scheduled to expire on March 1, 2019. The Board issued petitioner CIC its current Sterile Compounding License, number LSC 100883, on March 7, 2016; the license is scheduled to expire on March 1, 2019. The original pharmacy permit and sterile compounding license were subject to discipline in Case No. 4907; in exchange for issuing CIC a new permit and license for a new pharmacy location, petitioner agreed that Pharmacy Permit number PHY 53829 and Sterile Compounding License number LSC 100883 would be subject to the disciplinary order issued with respect to the original permit and license in Case No. 4907. (See Factual Finding 4.)
- 2. The Board issued Pharmacist License number RPH 48035 to petitioner Pourmola on August 8, 1995. The license is scheduled to expire on October 31, 2020.
- 3. On July 5, 2018, CIC filed a Petition for Early Termination of Probation with the Board. On October 12, 2018, petitioner Pourmola filed a Petition for Early Termination with the Board.

### Disciplinary History

- 4. On May 18, 2016, the Board issued a Decision and Order in Case No. 4907, effective June 17, 2016, adopting a Stipulated Settlement and Disciplinary Order as to Complete Infusion Care and Ali Pourmola. The Decision and Order revoked petitioner CIC's retail pharmacy permit and sterile compounding license, stayed the revocation, and placed petitioner CIC on four years' probation on certain terms and conditions, including that petitioner CIC pay the Board \$10,333 for costs of investigation and prosecution and \$10,000 as an administrative penalty, stipulate to the Board's continuing jurisdiction over a new permit and license to be issued at petitioner CIC's request as a result of a change in location, comply with all laws governing the practice of pharmacy, pay monitoring costs, and cooperate with Board-requested inspections.
- 5. On September 23, 2016, the Board issued a Decision and Order in Case No. 4907, effective October 24, 2016, adopting a Stipulated Settlement and Disciplinary Order as to Ali Pourmola. The Decision and Order revoked petitioner Pourmola's pharmacist license, stayed the revocation, and placed petitioner Pourmola on four years' probation on certain terms and conditions, including that petitioner Pourmola pay the Board \$10,333 for costs of investigation and prosecution and \$10,000 as an administrative penalty, stipulate to the Board's continuing jurisdiction, comply with all laws governing the practice of pharmacy, cooperate with Board-requested inspections, complete at least 10 hours of remedial education relating to

compounding and enroll in an ethics program, and engage in the supervised practice of pharmacy for 50 percent of the work week.

- 6. Both the CIC and the Pourmola Decision and Orders recited that the petitioner in each matter admitted that the charges and allegations in the Fourth Amended Accusation (Accusation) filed in the case, if proven at a hearing, would constitute cause for license discipline, that the complainant could establish a factual basis for the charges, that petitioner waived its right to contest those charges, and that its permit and license was subject to discipline.
- 7. The Accusation was based on an October 2012 inspection that revealed various violations. The Accusation stated, against petitioner CIC, three causes for discipline for unprofessional conduct (staff training in injectable compounding, compounding limitations and requirements, and recordkeeping of compounded drug products), and five additional causes for discipline, for sale of drugs lacking quality of strength, erroneous or uncertain prescription, labeling requirements, sterile injectable labeling requirements, and records of compounding products. Only the fifth cause for discipline, for erroneous or uncertain prescription, was also stated against petitioner Pourmola.

### Petition for Reinstatement

- 8. Both petitioners are in full compliance with their terms of probation. Petitioners CIC and Pourmola have paid the Board's costs in full. Petitioner CIC has been paying monitoring costs as required. Petitioner Pourmola has completed the ethics course and the continuing education courses required by the terms of his probation.
- 9. Collective rehabilitative efforts since the 2012 violations demonstrate significant changes in the pharmacy's operations, including such areas as training, sterile compounding procedures, oversight, labeling, and recordkeeping. Since Dr. Avedis Kojayan became Pharmacist-in-Charge (PIC) in January 2, 2013, petitioner CIC has not been cited for any violations.
- 10. Petitioner Pourmola testified that, with respect to the Fourth Amended Accusation, he was entirely responsible for failing to document his correction of an incorrect prescription dose, and that he recognizes the importance of accurate documentation. Changes have been made to pharmacy policies and procedures to ensure accurate documentation.
- 11. The Board has considered all evidence petitioners CIC and Pourmola presented in support of the Petitions. Petitioners established, by clear and convincing evidence, rehabilitation sufficient to warrant early termination of probation. They have implemented safety measures and redundant systems and have passed nine inspections. The current PIC at CIC understands the issues leading to the Accusation and has taken all necessary remedial actions. Petitioner Pourmola has accepted full responsibility for his actions and is in full compliance with the terms of his probation. Neither petitioner poses a clear risk to public safety.

### LEGAL CONCLUSIONS

- 1. A petitioner must prove rehabilitation and that probation should be terminated early by clear and convincing evidence. (See, e.g., *Flanzer v. Board of Dental Examiners* (1990) 220 Cal.App.3d 1392, 1398; *Hippard v. State Bar* (1989) 49 Cal.3d 1084, 1091-1092.) The showing of rehabilitation must be sufficient to overcome the Board's former adverse determination. (See, e.g., *Housman v. Board of Medical Examiners* (1948) 84 Cal.App.2d 308, 315-316.) In deciding whether to grant a petition for early termination of probation, the Board may consider, among other factors, petitioner's activities since discipline was imposed, petitioner's offense, and petitioner's documented rehabilitative efforts. (Bus. & Prof. Code, § 4309, subd. (d).)
- 2. Based on its factual findings, the Board concludes that cause exists to grant the Petitions for Early Termination of Probation under Government Code section 11522 and Business and Professions Code section 4309.

### **ORDER**

The Petition for Early Termination of Probation of Pharmacy Permit number 53829 (originally imposed on permit number 46839) and Sterile Compounding License number 100883 (originally imposed on license number 99250), issued to petitioner Complete Infusion Care, CIC, Inc., is granted.

The Petition for Early Termination of Probation of Pharmacist License number RPH 48035, issued to petitioner Ali Pourmola, is granted.

This Decision shall be effective	March 7, 2019.
DATED:	Vullan
	Victor Law, R.Ph., President
	Board of Pharmacy
	State of California

- 3. The existing permit (Original Permit No. PHY 46839 and Sterile Compounding Permit No. LSC 99250) is currently the subject of a disciplinary order issued effective June 17, 2016, by the Board in the disciplinary matter entitled *In The Matter of Accusation Against Complete Infusion Care, et al.*, Board of Pharmacy Case No. 4907. A true and correct copy of the decision and order in this matter is attached hereto as **Exhibit A** and incorporated by this reference.
- 4. In exchange for processing and issuance of the new permit pursuant to the change in location, applicant understands and agrees that the Board shall have continuing jurisdiction over the new permit issued to applicant such that the disciplinary order issued by the Board in Case No. 4907, including any terms and conditions and remaining tenure of probation, shall carry forward and be applicable to the new permit issued to applicant. The Board hereby waives any right it may have had to deny issuance of the new permit.
- 5. A portable document format (PDF) or facsimile signature on this document shall be binding as an original signature. Parties agree to use of PDF or facsimile signatures in lieu of original signatures for all purposes relevant to enforcement of this Stipulation.

Dated: 5/17/17

VIRGINIA HEROLD

Exacutive Officer

California Board of Pharmacy

Dated: 12/12/16

ALI POURMOLA

President

Complete Infusion Care CIC Inc.

## Exhibit A

Final Decision and Order Pharmacy Board Disciplinary Case No. 5907

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

In the Matter of the Fourth Amended Accusation Against:

Case No. 4907

COMPLETE INFUSION CARE; ALI POURMOLA 8588 Venice Blvd. Los Angeles, CA 90034 Pharmacy Permit No. PHY 46839 Sterile Compounding License No. LSC 99250, OAH No. 2015020271

POURMOLA ONLY

And

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO COMPLETE INFUSION CARE; ALI

ALI POURMOLA P.O. Box 49251 Los Angeles, CA 90049 Pharmacist License No. RPH 48035,

Respondents.

### **DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is here by adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on June 17, 2016.

It is so ORDERED on May 18, 2016.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6 7	Kamala D. Harris Attorney General of California Marc D. Greenbaum Supervising Deputy Attorney General Leslie A. Walden Deputy Attorney General State Bar No. 196882 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-3465 Facsimile: (213) 897-2804 Attorneys for Complainant  BEFORE THE	
8 9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
10 11	In the Matter of the Fourth Amended Accusation Against:  Case No. 4907	
12 13 14	COMPLETE INFUSION CARE; ALI POURMOLA 8588 Venice Blvd. Los Angeles, CA 90034 Pharmacy Permit No. PHY 46839 Sterile Compounding License No. LSC  OAH No. 2015020271  STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO COMPLETE INFUSION CARE; ALI POURMOLA	
15 16 17	99250, And	
18 19 20	ALI POURMOLA P.O. Box 49251 Los Angeles, CA 90049 Pharmacist License No. RPH 48035,	
21 22	Respondents.	
23		
24	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-	
25	entitled proceedings that the following matters are true:	
26	<u>PARTIES</u>	
27	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.	
28	She brought this action solely in her official capacity and is represented in this matter by Kamala	

- D. Harris, Attorney General of the State of California, by Leslie A. Walden, Deputy Attorney General.
- 2. Respondent Complete Infusion Care; Ali Pourmola ("Respondent") is represented in this proceeding by attorney Michael Houske, whose address is: Complete Infusion Care 8588 Venice, California 90034.
- 3. On or about September 22, 2004, the Board of Pharmacy issued Pharmacy Permit No. PHY 46839 to Respondent. The Pharmacy Permit expires on September 1, 2016.
- 4. On or about November 15, 2004, the Board of Pharmacy issued Sterile Compounding License No. LSC 99250 to Respondent. The Sterile Compounding License expires on September 1, 2016.

### **JURISDICTION**

- 5. Accusation No. 4907 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The original Accusation and all other statutorily required documents were properly served on Respondent on September 5, 2014. Respondent timely filed his Notice of Defense contesting the Accusation. The Accusation was subsequently amended and the operative Accusation in the matter is the Fourth Amended Accusation, which was served on February 2, 2016.
- 6. A copy of the Fourth Amended Accusation No. 4907 is attached as exhibit A and incorporated herein by reference.

### ADVISEMENT AND WAIVERS

- 7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4907. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel

the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

### CULPABILITY

- 10. Respondent understands and agrees that the charges and allegations in Accusation No. 4907, if proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit No. PHY 46839 and Sterile Compounding License No. LCS 99250.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.
- 12. Respondent agrees that its Pharmacy Permit is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

### CONTINGENCY

- 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw the agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

### **DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 46839 issued September 22, 3004 and Sterile Compounding License No. LSC 99250 issued November 15, 2004 to Respondent Complete Infusion Care; Ali Pourmola is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions.

### 1. Obey All Laws

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

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

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

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

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

### 2. Report to the Board

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

### 3. Interview with the Board

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

### 4. Cooperate with Board Staff

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

### 5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of \$10,339.00. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

### 

8. 

### .12

### 

### 6. Probation Monitoring Costs

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

### 7. Status of License<sup>1</sup>

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

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

### 8. License Surrender While on Probation/Suspension

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

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

<sup>&</sup>lt;sup>1</sup> License means license and/or pharmacy permit.

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

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

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

### 9. Notice to Employees

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

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or

hired at any time during probation.

22.

### 10. Owners and Officers: Knowledge of the Law

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

### 11. Posted Notice of Probation

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

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

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

### 12. Violation of Probation

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

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

probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in the Fourth Amended Accusation shall be deemed true and correct.

#### 13. Completion of Probation

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

### Separate File of Records

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

#### Administrative Penalty 15.

As a condition precedent to successful completion of probation, Respondent Pharmacy shall pay to the Board an administrative penalty in the amount of \$10,000.00. Respondent shall make said payments on a payment plan approved by the Board. Respondent Pourmola and Respondent Pharmacy shall be jointly and severally liable for the administrative penalty. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay the administrative penalty by the deadline(s) as directed shall be considered a violation of probation.

1111.

11//

25

26

27

28

### **ACCEPTANCE**

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Michael Houske. I understand the stipulation and the effect it will have on my Pharmacy Permit, and Sterile Compounding License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

Respondent

I have read and fully discussed with Respondent Complete Infusion Care; Ali Pourmola the terms and conditions and other matters contained in the above Stipulaged Settlement and

Disciplinary Order. I approve its form and content,

Michael Houske Attorney for Respondent

16

2

3

4

5

8

9

10

11

12

. 13

14

1.5

17

18

19

20

Dated:

21 22

23

24

25 26

27

28

LA2013510143 51963153.doc

### ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Respectfully submitted,

KAMALA D. HARRIS Attorney General of California MARC D. GREENBAUM

Supervising Deputy Attorney General

Deputy Attorney General Attorneys for Complainant

### Exhibit A

Fourth Amended Accusation No. 4907

1	KAMALA D. HARRIS	
2	Attorney General of California MARC D. GREENBAUM	·
3	Supervising Deputy Attorney General LESLIE A. WALDEN	
4	Deputy Attorney General State Bar No. 196882	
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013	
6	Los Angeles, CA 90013 Telephone: (213) 897-3465 Facsimile: (213) 897-2804	
7	Attorneys for Complainant	
- 8	BEFOR' BOARD OF P	
9	DEPARTMENT OF CO STATE OF CA	ONSUMER AFFAIRS
10		
11	In the Matter of the Fourth Amended Accusation Against:	Case No. 4907
12	1	FOURTH AMENDED ACCUSATION
13	POURMOLA 8588 Venice Blvd.	
14	Los Angeles, CA 90034 Pharmacy Permit No. PHY 46839	
15	Sterile Compounding License No. LCS 99250,	
16	and	
17		
18	ALI POURMOLA P.O. Box 49251	
19	Los Angeles, CA 90049 Pharmacist License No. RPH 48035,	
20		
21	Respondents.	
22		
23	Complainant alleges:	
24	PART	TIES
25	1. Virginia Herold (Complainant) brings this Fourth Amended Accusation solely in her	
26	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer	
27	Affairs.	A CONTRACT OF CONTROL
28		
		·

Ί

2

3

4

5

6

7

9

11

12

13

15

16

17

18

19

20

21

22

23

24

25

26

27

28

8. Section 4300.1 of the Code states:

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

- 9. Section 4076 of the Code states:
- "(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

66 99

(9) The expiration date of the effectiveness of the drug dispensed.

" ,,,,

- 10. Section 4342 of the Code states:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."
- "(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."
  - 11. Section 4169 of the Code states:
  - "(a)A person or entity may not do any of the following:

66 55

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

28 "...

### 12. Section 4307 of the Code states:

"Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities"

- "(a) 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 99 placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:
- "(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- "(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
- "(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.
- "(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

### REGULATIONS

3. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

- 14. California Code of Regulations, title 16, section 1751.6, subdivisions (a) (b) and (c) states:
- "(a) 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."
- "(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."
- "(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment."
  - 15. California Code of Regulations, title 16, section 1735.2 subdivision (d)(5), states:
- "(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:"

- "(5) Process and/or procedure used to prepare the drug."
- 16. California Code of Regulations, title 16, section 1735.3 subdivision (a)(7), states:
  - "(a) For each compounded drug product, the pharmacy records shall include:

66 33

- "(3) The identity of the pharmacy personnel who compounded the drug product."
- "(4) The identity of the pharmacist reviewing the final drug product."

"

"(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code."

66 33

### COSTS

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.

### DANGEROUS DRUGS AND CONTROLLED SUBSTANCES

- 22. <u>Heparin</u>: Heparin is a dangerous drug pursuant to Business and Professions Code section 4022, and is used as an anticoagulant in the prevention and treatment of thrombosis and embolism and is a dangerous drug pursuant to Business and Professions Code section 4022.
- 23. <u>Ceftriaxone</u>: Ceftriaxone is a dangerous drug pursuant to Business and Professions Code section 4022, and is used as a prescription antibiotic.
- 24. <u>Carimune</u>: Carimune is a dangerous drug pursuant to Business and Professions Code section 4022, and is used to treat immune deficiencies.

- 25. <u>Morphine</u>: Morphine is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1)(L) and a dangerous drug pursuant to Business and Professions Code section 4022, and is used to treat severe pain.
- 26. <u>Bupivacaine</u>: Bupivacaine is a dangerous drug pursuant to Business and Professions Code section 4022, and is used as a local anesthetic.

### FIRST CAUSE FOR DISCIPLINE

[Unprofessional Conduct (Staff Training of Injectable Compounding) - Complete Infusion Care]

- 27. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with California Code of Regulations, title 16, section 1751.6, subdivisions (b) and (c) in that Respondent failed to ensure all pharmacy personnel engaging in compounding sterile injectable drug products had training and had demonstrated competence in the safe handling and compounding of sterile injectable products, and that records of training were available for each individual for three years beyond employment. The circumstances are as follows:
- 28. On or about October 16, 2012 an onsite inspection by the Board of Pharmacy revealed that Complete Infusion Care did not have training records of demonstrated competencies for pharmacy personnel.

### SECOND CAUSE FOR DISCIPLINE

[Unprofessional Conduct (Compounding Limitations and Requirements) - Complete Infusion

Care]

- 29. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with California Code of Regulations, title 16, section 1735.2 subdivision (d)(5) where prior to compounding drug products, Respondent failed to prepare a written master formula record that included at least a process or procedure used to prepare the drug. The circumstances are as follows:
- 30. On or about October 16, 2012, an onsite inspection by the Board of Pharmacy revealed that at Complete Infusion Care, the compounding records dated January 23, 2012 for RX 6850 and June 7, 2012 for RX 8437 for patient C.B. did not have the process or procedure used to

prepare and compound the preservative free non-sterile to sterile morphine 50 mg/ml + bupivacaine 30 mg/ml compound on the Compound Sheet under "Mix Instructions".

### THIRD CAUSE FOR DISCIPLINE

[Unprofessional Conduct (Record Keeping of Compounded Drug Products) - Complete Infusion

Care]

- 31. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4301, subdivision (o) in conjunction with California Code of Regulations, title 16, section 1735.3 subdivision (a), which states (a) for each compounded drug product, the pharmacy records failed to include: (7) the equipment used in compounding the drug product. The circumstances are as follows:
- 32. On or about October 16, 2012, an onsite inspection by the Board of Pharmacy revealed that at Complete Infusion Care, the compounding records dated January 23, 2012 for RX 6850 and June 7, 2012 for RX 8437 for patient C.B. did not document the equipment used in the compounding of the preservative free non-sterile to sterile morphine 50 mg/ml + bupivacaine 30 mg/ml compound on the Compound Sheet.

### FOURTH CAUSE FOR DISCIPLINE

[Sale of Drugs Lacking Quality of Strength - Complete Infusion Care]

- 33. Respondents Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4342 and 4169 subdivision (a)(3) in that Respondent sold and/or transferred dangerous drugs that a reasonable person would know or reasonably should have known were misbranded. The circumstances are as follows:
- 34. On or about March 8, 2012, April 9, 2012, and May 25, 2012, Respondent dispensed sterile injectable compound Carimune 20gm RX Nos. 7267, 7673, and 8258 with labeled expiration dates of six (6) days, six (6) days and three (3) days, respectively, after preparation. The manufacturers beyond the use date for Carimune was within twenty-four hours of reconstitution of the drug. Complete Infusion Care conducted and obtained extended stability and

<sup>&</sup>lt;sup>1</sup> The patient's initials are used throughout this pleading in lieu of the patient name in order to protect patient privacy rights.

potency testing results for Carimune on April 25, 2014, but did not have extended stability and potency data at the time the Carimune was dispensed on March 8, 2012, April 9, 2012, and May 25, 2012.

### FIFTH CAUSE FOR DISCIPLINE

[Erroneous or Uncertain Prescription - Complete Infusion Care and Ali Pourmola]

- 35. Respondents Complete Infusion Care and Ali Pourmola are subject to disciplinary action under Business and Professions Code section 4300 in conjunction with California Code of Regulations, title 16, section 1761 subdivision (a) in that Respondents dispensed a prescription which contained significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations without contacting the prescriber for clarification. The circumstances are as follows:
- 36. On or about March 8, 2012, April 9, 2012, and May 22, 2012, Respondents dispensed uncertain and ambiguous prescriptions for Carimune 20gm RX, Nos. 7267, 7673, and 8258 to patient E.L.<sup>2</sup> without first clarifying the dose of the prescriptions with the prescriber. Specifically, E.L.'s Carimune prescriptions were written incorrectly for a daily dose of "0.4 mg/kg" for a calculated dose of 20mg per day and not the correct dose of "0.4gm/kg" for a calculated dose of 20gm per day. The prescriptions were dispensed by Respondents without first obtaining clarification of the correct ordered dose from the prescriber.

### SIXTH CAUSE FOR DISCIPLINE

[Labeling Requirements - Complete Infusion Care]

- 37. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4076 subdivision (a)(9) which precludes a pharmacist from dispensing any prescription unless in a container that is correctly labeled with the expiration dates of the effectiveness of the drug dispensed. The circumstances are as follows:
- 38. On or about May 25, 2012, Respondent dispensed five bags of Carimune RX# 8258 to patient E.L. labeled with the incorrect expiration date of May 28, 2012. Specifically, on or about May 25, 2012, Respondent dispensed a five (5) day course of Carimune 20gm RX # 8258

<sup>&</sup>lt;sup>2</sup> Patient initials are used in lieu of real names in order to protect the privacy rights of the individuals.

with a labeled expiration dated of May 28, 2012, which resulted in the last two (2) days of the five (5) day Carimune doses being labeled as expired at the time of use.

### SEVENTH CAUSE FOR DISCIPLINE

[Sterile Injectable Labeling Requirements - Complete Infusion Care]

- 39. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4076 in conjunction with California Code of Regulations, title 16, section 1751.2 and 1735.4, which requires a pharmacy that compounds sterile injectable products to include on the label the instructions for storage and handling. The circumstances are as follows:
- 40. On or about March 8, 2012 and April 9, 2012, Respondent dispensed Carimune 20gm RX Nos. 7267 and 7673 labeled with instructions to store medication at room temperature instead of being stored by the required method of refrigeration.

### EIGHTH CAUSE FOR DISCIPLINE

[Records of Compounding Products - Complete Infusion Care]

- 41. Respondent Complete Infusion Care is subject to disciplinary action under Business and Professions Code section 4300 in conjunction with California Code of Regulations, title 16, section 1735.3 subdivisions (a)(2), (3), (4), (6), and (10), which requires for each compounded product, that the pharmacy records include the date the drug was compounded, the identity of the pharmacy personnel who compounded the product, the identity of the pharmacist reviewing the final product, the manufacturer and a lot number of each component, and the quantity or amount of the drug compounded. The circumstances are as follows:
- 42. On or about March 8, 2012, April 9, 2012, and May 25, 2012, Respondent dispensed sterile injectable compound Carimune 20gm, RX nos. 7267, 7673 and 8258 without maintaining proper compounding records for each of the products dispensed.

### OTHER MATTERS

Permit Number PHY 46839 or Sterile Compounding License Number LSC 99250, issued to Complete Infusion Care, and Ali Pourmola (Pourmola) while acting as the manager,

administrator, owner, member, officer, director, associate, or partner of Complete Infusion Care had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 46939 or Sterile Compounding License Number LSC 99250, issued to Complete Infusion Care was revoked, suspended or placed on probation, Pourmola shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46839 or Sterile Compounding License Number LSC 99250, issued to Complete Infusion Care is placed on probation or until Pharmacy Permit Number PHY 46839 or Sterile Compounding License Number LSC 99250, issued to Complete Infusion Care is reinstated if it is revoked.

### DISCIPLINE CONSIDERATIONS

- 43. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges as follows:
- a) On or about October 15, 2009, in a prior action, the Board of Pharmacy issued Citation Number CI 2009 41466 to Respondent Ali Pourmola for violations of Business and Professions Code section 4059, subdivision (a) (furnishing dangerous drugs without prescription) and Health & Safety Code section 11200, subdivision (c) (no prescription for Schedule II substance may be refilled). Respondent was ordered to pay \$4000. On or about March 21, 2012, the Citation was modified and reduced. Respondent was ordered to pay \$1000. That Citation is now final and is incorporated by reference as if fully set forth.
- b) On or about October 15, 2009, in a prior action, the Board of Pharmacy issued Citation Number CI 2008 38864 to Respondent Complete Infusion Care for violations of Business and Professions Code section 4059, subdivision (a) (furnishing dangerous drugs without prescription) and Health & Safety Code section 11200, subdivision (c) (no prescription for Schedule II substance may be refilled). Respondent was ordered to pay \$4000. On or about April 20, 2012, the Citation was modified and reduced. Respondent was ordered to pay \$1500. That Citation is now final and is incorporated by reference as if fully set forth.

c) On or about July 1, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53606 to Respondent Complete Infusion Care for violations of Business and Professions Code Section 4115 subdivision (e) and California Code of Regulations section 1793.2 subdivision (b) (no person shall act as a pharmacy technician without being licensed by the Board) and ordered Respondent to pay \$1000. That Citation is now final and is incorporated by reference as if fully set forth.

### <u>PRAYER</u>

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

- 1. Revoking or suspending Pharmacy Permit Number PHY 46839, issued to Complete Infusion Care; Ali Pourmola
- 2. Revoking or suspending Sterile Compounding License Number LSC 99250, issued to Complete Infusion Care; Ali Pourmola;
- 3. Revoking or suspending Pharmacy License Number RPH 48035 issued to Ali Pourmola;
- 4. Prohibiting Ali Pourmola from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number 46839 or Sterile Compounding License Number LSC 99250 issued to Complete Infusion Care is placed on probation or until Pharmacy Permit Number 46839 or Sterile Compounding License Number LSC 99250 issued to Complete Infusion Care is reinstated if Pharmacy Permit Number 46839 or Sterile Compounding License Number LSC 99250 issued to Complete Infusion Care is sued is revoked;
- 5. Ordering Complete Infusion Care and Ali Pourmola 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; and

-////

1	6. Taking such other and further action as deemed necessary and proper.		
2			
3	DATED: 1/29/16 () Lies in Wester		
4	VIRGINIA MENOLD		
5	Executive Officer Board of Pharmacy Department of Consumer Affairs State of California		
6	Department of Consumer Affairs State of California		
7	Complainant		
8	LA2013510143 51963399.docx		
9	3.77032771400A		
10			
11			
12			
13			
14			
15			
16			
17   18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
.			