

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

In the Matter of the Accusation Against:

**ARROW-MED RX INC. DBA JANA HEALTHCARE PHARMACY,
ALEXANDR AKOPNIK,
Pharmacy Permit Number PHY 50759,
Compounding Permit Number LSC 100684;**

and

**DEMAR LEWIS, III
Pharmacist License Number RPH 37541,**

Respondents.

Agency Case No. 6904

OAH No. 2021060182

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, except

that, pursuant to the provisions of Government Code section 11517, subdivision (c)(2)(C), the following technical changes are made to:

- Page 1 Case Number "CI 2018 81487" should read as "6904"
- Page 31, Term #6, paragraph 1 OAH case number "202106" should read as "2021060182"

The technical changes made above do not affect the factual or legal basis of the Proposed Decision, which shall become effective at 5:00 p.m. on April 13, 2022.

It is so ORDERED on March 14, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" being the most prominent parts.

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the First Amended Accusation Against:

**ARROW-MED RX INC., d.b.a. JANA HEALTHCARE
PHARMACY, ALEXANDR AKOPNIK, OWNER, MIRA ZEFFREN,**

Pharmacy Permit No. PHY 50759,

Compounding Permit No. LSC 100684

and

DEMAR LEWIS, III,

Pharmacist License No. RPH 37541

Respondents

Case No. CI 2018 81487

OAH No. 2021060182

PROPOSED DECISION

Abraham M. Levy, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter by telephone/video conference on January 18, 2022, due to the COVID-19 pandemic.

Leslie A. Walden, Deputy Attorney General, represented complainant, Anne Sodergren, Executive Officer of the Board of Pharmacy (board), Department of Consumer Affairs.

Demar Lewis III, respondent, represented himself.

The matter is proceeding under the First Amended Accusation only against respondent Lewis. On October 5, 2021, respondents Arrow-Med Rx Inc., d.b.a. Jana Healthcare Pharmacy, Alexandr Akopnik, and their attorney signed a Stipulated Surrender of License and Order regarding respondent's compounding permit and a Stipulated Settlement and Disciplinary Order as to respondent's pharmacy permit. That stipulation is now before the board for consideration. Complainant asked that the matter be taken off calendar as to these respondents.

The matter was submitted for decision on January 18, 2022.

SUMMARY

Complainant seeks to discipline respondent's¹ pharmacist license because he committed unprofessional conduct in his role as PIC at a compounding pharmacy

¹ In this decision "respondent" refers to Demar Lewis except as otherwise noted.

where he worked for a six-month period. Respondent does not dispute that he committed unprofessional conduct and that his license is subject to discipline due to his failure to ensure the pharmacy's compliance with applicable laws and regulations. Based on the record as a whole, respondent violated laws and regulations governing the practice of pharmacy. Through his testimony he offered facts and circumstances to mitigate the degree of discipline; as a result, a term of probation with terms and conditions will ensure public protection.

FACTUAL FINDINGS

Background and Procedural History

1. On February 9, 1983, the board issued Pharmacist License Number RPH 37541 to respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2022, unless renewed. Respondent does not have a history of discipline.

2. On October 4, 2011, the board issued Permit Number PHY 50759 to respondent Arrow-Med Rx Inc., d.b.a. Jana Healthcare Pharmacy with Alexandr Akopnik as President and 100 percent Shareholder. Respondent was the PIC from August 15, 2018, to May 20, 2019. The Permit was in full force and effect at all times relevant to the charges in this matter.

3. On December 30, 2014, the board issued Sterile Compounding Permit Number LSC 100684 to respondent Jana Healthcare. The Permit was in full force and effect at all times relevant to the charges brought herein. The Permit was cancelled on July 19, 2019.

4. On September 26, 1987, the board issued Pharmacist License Number RPH 41239 to respondent Mira J. Zeffren. The board revoked her Pharmacist License on November 6, 2015, in the matter captioned *In the Matter of the First Amended Accusation against Mira J Zeffren*, Case Number AC 5070. As alleged in the first amended accusation filed in that matter, respondent Zeffren acted as an undisclosed officer, associate and/or person with management or control of respondent Arrow-Med Rx Inc., d.b.a. Jana Healthcare Pharmacy.

Violations Alleged in the First Amended Accusation, Respondent's Stipulation to the Truth of the Alleged Facts and Violations, and Evidence of Record in Support of the Allegations

5. On January 19, 2021, complainant filed and served the First Amended Accusation against respondents. The allegations in the pleading are based on the investigations board investigators Suzy Patell, Pharm.D. and Anna Yamada, Pharm. D. performed. Inspector Patell inspected the pharmacy as part of the pharmacy's renewal of its sterile compounding license. Inspector Yamada conducted an inspection in response to a consumer complaint. Reports of both inspectors were received as evidence.

There are thirteen causes for discipline, but only causes of action one through four and seven apply to respondent. These are addressed in this decision. Complainant also seeks reimbursement of the costs of the investigation and prosecution of this matter.

6. At the start of the hearing, respondent stipulated to the truth and accuracy of the factual allegations in the causes of action applicable to him. He further agreed the factual allegations constitute violations of the laws and regulations

governing the pharmacy and a PIC. With the understanding that his license may be subject to board discipline due to these violations, respondent sought to present mitigating factors in his defense.

7. The charges against respondent in the first amended accusation and the evidence of record supporting these charges are summarized as follows:

8. As alleged in the First Cause for Discipline, respondent failed to comply with Health and Safety Code section 11165, subdivision (d), and violated laws and regulations applicable to the pharmacy pursuant to the Business and Professions Code section 4301, subdivision (o), because respondents did not report within seven days of dispensing controlled substances to patients information regarding the controlled substances to the Department of Justice (DOJ) in its Controlled Substance Utilization Review and Evaluation System (CURES).

9. Respondents confirmed they violated Health and Safety Code section 11165, subdivision (d), in a January 31, 2019, cumulative report the pharmacy sent to Inspector Yamada. This report detailed the timelines for when the prescriptions of controlled substances were dispensed and when the pharmacy reported them to the DOJ CURES unit. Respondents failed to timely report the following number of controlled substances during the following months:

- 75 controlled substance prescriptions in June 2018
- 245 controlled substance prescriptions in July 2018
- 254 controlled substance prescriptions in August 2018
- 286 controlled substance prescriptions in September 2018

- 307 controlled substance prescriptions in October 2018
- 279 controlled substance prescriptions in November 2018
- 308 controlled substance prescriptions in December 2018
- 263 controlled substance prescriptions in January 2019

10. Under the Second Cause for Discipline, respondent is charged pursuant to Business and Professions Code sections 4301, subdivision (o), with violating applicable laws and regulations governing the pharmacy's operation because the pharmacy permitted a pharmacy technician to process new prescriptions and refill prescriptions while she worked remotely from her home when respondent was PIC.

11. Inspector Yamada, during her inspection of the pharmacy on January 24, 2019, learned that pharmacy technician TT was processing and filling prescriptions remotely from her home. During her review of the licenses of the persons at the pharmacy, respondent told Inspector Yamada that pharmacy technician TT worked remotely, and to do this work, she was given access to the pharmacy's database. Respondent told Inspector Yamada TT usually worked after 6:00 p.m., when she was not working her primary job as a pharmacy technician at a hospital. Respondent further told Inspector Yamada that TT processed new and refilled prescriptions from her home, but the labels were generated and printed in the pharmacy. He believed TT had such remote access starting about August 2018. Inspector Yamada advised respondent and the owner of the pharmacy, Mr. Akopnik, that accessing the pharmacy database and processing prescriptions was a "pharmacy function" and was required to occur in a pharmacy, and not in TT's home. Inspector Yamada obtained a list of the prescriptions TT generated and filled, which was admitted and made part of the record.

12. Under the Third Cause for Discipline, respondent is charged with failing to comply with laws governing the operation of a pharmacy under Business and Professions Code section 4301, subdivision (o), because on or before September 18, 2018, the pharmacy provided drug take-back services to a skilled nursing facility it serviced without prior registration with the Drug Enforcement Agency as a collector, in violation of California Code of Regulations, title 16, sections 1776, 1776.1, subdivision (h), and 1776.4, subdivision (b).

13. Inspector Yamada learned that the pharmacy was taking back medications despite not having the required registration to do so during her inspection when she found medication bubble cards, inside boxes labeled "expired meds," and returned patient bubble cards inside the boxes. Respondent was with Inspector Yamada when she discovered these returned medications. He told her the pharmacy was not supposed to accept returned medications, and he had no idea the returned drugs were in the pharmacy. Inspector Yamada continued her inspection and found more returned drugs from a skilled nursing facility, and a drug return log from a skilled nursing facility. Mr. Akopnik then joined respondent and Inspector Yamada and said that the pharmacy accepted the returned drugs from the skilled nursing facility to send to RX Reverse Distributors for destruction. Respondent again confirmed to Inspector Yamada that the pharmacy was not registered to provide take back services. Copies of the log of the medications taken back from the skilled nursing facility and photographs of the medications taken back were admitted as evidence.

14. As alleged in the Fourth Cause for Discipline, respondent's license is subject to discipline under Business and Professions Code sections 4116, subdivision (a), and California Code of Regulations, title 16, section 1714, subdivisions (b), (e) and (d), because on October 28, 2018, and on or about December 13, 2018, respondent

Zeffren, who worked, in effect, as an operations manager at the pharmacy, possessed a key to the pharmacy even though she was not a licensed pharmacist. Ms. Zeffren used the key to open the pharmacy and allowed two technicians to access and enter the pharmacy drug area where dangerous drugs and devices, including controlled substances, were maintained, without a pharmacist being present.

15. The evidentiary basis supporting this allegation is found in Inspector Yamada's report which indicates the following: Respondent disclosed to Inspector Yamada on May 19, 2019, the date he left the pharmacy, that Ms. Zeffren had a key to the pharmacy, but he did not give one to her. He provided Ms. Yamada with two videos he had which showed that on October 28, 2018, and December 13, 2018, Ms. Zeffren was in the pharmacy when respondent arrived. On October 28, 2018, the video showed (as Ms. Yamada described it) respondent enter the pharmacy, and Ms. Zeffren was already there and greeted him. Respondent entered the pharmacy drug dispensing area which was already open. He asked her if one of the technicians was there and whether she had let the technician into the pharmacy. She asked, "Is that okay? As long as I am here and [another technician is here]?" She then said, "They would have both left. That's why I figured you'd be okay with it until you got here."

On December 13, 2018, as recorded in a video respondent made available to Ms. Yamada, Ms. Zeffren used her key to enter the pharmacy before respondent was at the pharmacy, and she let two technicians into the pharmacy. According to Inspector Yamada's description of the video, the video showed Ms. Zeffren walk out of the pharmacy drug area as respondent just arrived, and Ms. Zeffren and two technicians were already in the pharmacy.

16. As charged in the Seventh Cause for Discipline, respondent's license is subject to discipline because he failed to follow laws and regulations governing the

pharmacy's operation under Business and Professions Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.4, subdivision (j). Section 1751.4, subdivision (j), requires air and surface sampling of a compounding pharmacy's clean room, and if the results are positive for pathogens, to follow up to investigate and clean the area.

17. Inspector Patell documented this violation in her report noting that Clean Room Services (CRS) conducted viable air and surface sample of the pharmacy's compounding clean room on December 21, 2018. The results obtained from these samples yielded out of specification results that identified colony forming units (cfus) of highly pathogenic microorganisms. CRS informed respondent of these results in two emails on February 7, 2019, and February 21, 2019.

18. Despite these results, respondent did not investigate and perform remediation and resampling, seek to eliminate the contamination source, and clean and re-sample. Instead of conducting this investigation or taking steps to eliminate the pathogens, respondent informed CRS that the pharmacy was not ready to resample and sent the CRS technician who was at the pharmacy back to CRS. Further, and despite out of compliance results, on February 7, 2019, respondent compounded two bags of Meropenam, a medication used to treat bacterial infections.

19. In his testimony to explain why neither he, nor the pharmacy, took any action to remediate the presence of pathogens in the clean room, respondent said that the pharmacy was not able to pay CRS the \$2,500 fee to conduct this second test. During her inspection, respondent told Inspector Patell that the pharmacy was unable to pay its invoices to CRS.

20. Inspector Patell found no records regarding the pharmacy's action (or inaction) regarding CRS.

Respondent's Testimony

21. Respondent testified and submitted a statement which has been considered. His testimony is summarized as follows: As noted earlier, he does not dispute the facts alleged in the first amended accusation, or that they constitute violations of laws and regulations governing pharmacies and pharmacists. He said he worked at the pharmacy for a ten-month period and was under a lot of stress because he was not getting paid for his work there. The situation caused turmoil with his wife, his daughter was graduating from college, and he was working multiple jobs to make ends meet. In hindsight, respondent recognizes he should have been more diligent to solve the problems at the pharmacy and inform the board of these problems.

Regarding the specific violations alleged in the first amended accusation, respondent said he did not know about the medications that were taken back from the skilled nursing facility. He said he informed Ms. Zeffren that the pharmacy was not registered to take back medications, but she did it anyway. He said she just made the unilateral decision to take back the medications. He said she did not follow any regulations. At the same time, he recognized as the PIC he was responsible for the pharmacy's compliance with applicable laws and regulations.

With respect to the pathogens in the clean room found during sampling, respondent said he had no option to remedy it because the company had no money to take care of the problem.

22. In the letter respondent submitted in support of his testimony, he noted he has been a licensed pharmacist for 39 years, and he never encountered a pharmacy

owner that had no regard for pharmacy regulations or employees. He said he was not equipped to be the PIC at the pharmacy due to the financial constraints and philosophy of the pharmacy's owner. He said the whole experience has been distressing to him. Respondent added that he wants to work only as a pharmacist and not as a PIC.

Costs

23. Complainant requests reimbursement for costs incurred by the board in connection with the investigation and prosecution of this matter, in the total amount of \$42,698.75, calculated at \$21,211.25 for legal worked billed by the Attorney General's Office and \$21,487.50 for the actual costs to the board for its investigation. Complainant however is seeking 20 percent of these total costs against respondent, which would be \$8,539.75.

24. The costs were certified in the manner provided by Business and Professions Code section 125.3, subdivision (c), in the Certification of Prosecution Costs and Declaration by Deputy Attorney General Walden, and the certifications signed by complainant, Inspector Yamada, Inspector Patell, and Supervising Inspector Janice Dang. Consistent with criteria to assess the reasonableness of costs under California Code of Regulations, title 1, section 1042, subdivision (b), the costs are deemed reasonable.

25. Respondent testified that he does not have the ability to pay these costs. He is working intermittently as a pharmacist and also works as an Uber driver to pay his bills.

Parties' Arguments

26. In closing, complainant said there is sufficient evidence to revoke respondent's license based on the violations. At the same time, complainant referenced the board's disciplinary guidelines for purposes of setting the degree of discipline, and based on the violations, asked if revocation is not deemed the appropriate remedy, that respondent not be permitted to serve as a PIC, and that he be heavily monitored.

27. Respondent, in his closing comments, agreed he was ultimately responsible for what happened in the pharmacy. He said right now he does not have the "bandwidth" to act as a PIC. He understands in the future he needs to be more proactive and work with a pharmacy's management team, and if this cannot be done, then he must bring the matter to the board's attention.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. The standard of proof in an administrative disciplinary action seeking the suspension or revocation of a professional license is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Administrative proceedings to impose discipline on a licensee are noncriminal and non-penal; they are not intended to punish the licensee, but to protect the public. (*Sulla v. Bd. of Registered Nursing* (2012) 205 Cal.App.4th 1195, 1206.)

2. "Clear and convincing evidence" requires a high probability of the existence of the disputed fact, greater than proof by a preponderance of the evidence.

Evidence of a charge is clear and convincing as long as there is a high probability that the charge is true. (*People v. Mabini* (2001) 92 Cal.App.4th 654, 662.) Complainant must meet this burden of proof for each cause for discipline alleged in the Accusation.

Applicable Laws and Regulations

3. Business and Professions Code section 4301, subdivision (o), provides as follows:

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

[¶] . . . [¶]

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

4. Business and Professions Code section 4113 provides as follows:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) 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.

(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board. . . .

5. Business and Professions Code section 4110, subdivision (a), provides as follows:

(a) No person shall conduct a pharmacy in the State of California unless they have obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be

required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The license shall not be renewed unless the applicant includes necessary matters identified by the board in the renewal application, including, but not limited to, notification to the board regarding compounding practices, including compounded human drug preparations distributed outside of the state. The board may, by regulation, determine the circumstances under which a license may be transferred.

6. Business and Professions Code section 4115, subdivision (a), provides that a pharmacy technician may perform packaging or other nondiscretionary tasks only while assisting and while under the direct supervision of a pharmacist.

7. Business and Professions Code section 4116, subdivision (a), provides as follows:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing

clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

8. Business and Professions Code section 4307 provides as follows:

(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, partner, or any other person with management or control of any partnership, corporation, trust, 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, partner, or any other person with management or control 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, partner, or in any other position with management or control 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, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such 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.

11. Business and Professions Code section 4329 provides as follows:

Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

12. Health and Safety Code, section 11165, subdivision (d), provides that a dispensing pharmacy shall report to the Department of Justice within seven days of dispensing each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance.

13. California Code of Regulations title 16, section 1707.4, subdivision (a), states:

(a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:

(1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.

(2) The prescription container:

(A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of

the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;

(B) the name of the pharmacy refilling the prescription; and

(C) the name of the pharmacy that received the refill request.

(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.

14. California Code of Regulations, title 16, section 1714, subdivisions (b), (d), and (e) ["Operational Standards and Security"] state in pertinent part:

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

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

15. California Code of Regulations section 1717.1, subdivision (a), states:

(a) For dangerous drugs other than controlled substances:
Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

16. California Code of Regulations title 16 section 1793.3, subdivision (a), states:

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

17. California Code of Regulations title 16 section 1776.1, subdivision (h), states:

(h) A pharmacy must be registered with the federal DEA as a collector for purposes of maintaining a prescription drug

take-back collection receptacle. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

18. California Code of Regulations title 16, section 1776.4, subdivision (b), states:

(b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:

(1) Be registered and maintain registration with the DEA as a collector.

(2) Notify the board in writing within 30 days of establishing a collection receptacle.

(3) Notify the board in writing within 30 days when they cease to maintain the collection receptacle.

(4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.

(5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.

19. California Code of Regulations, title 16, section 1716 states:

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

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

20. California Code of Regulations, title 16, section 1751.4, subdivision (j), states:

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the

environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

Cause Exists to Impose Discipline Against Respondent's License

21. Complainant established by clear and convincing evidence, as set forth in the First Cause for Discipline, that respondent engaged in unprofessional conduct under Business and Professions Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11165, subdivision (d). As found above, information relating to controlled substances dispensed to patients was not provided to the DOJ within seven days of dispensing the drugs. By this failure to provide this information to DOJ, respondent, as pharmacist in charge, did not ensure the pharmacy's compliance with state laws and regulations pertaining to the practice of pharmacy.

22. Complainant established by clear and convincing evidence, as set forth in the Second Cause for Discipline, that respondent engaged in unprofessional conduct under Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4110, subdivision (a), and California Code of Regulations, title 16, sections 1707.4, subdivision (a), 1717.1, subdivision (a), 1714, subdivisions (b) and (d). As found above, pharmacy technician TT was permitted to process and fill prescriptions remotely from her home by accessing the pharmacy's database. In effect, she did work for the pharmacy in her home outside the designated and licensed location of the pharmacy and outside the control and direct supervision of a licensed pharmacist. (See Bus. & Prof., § 4115, subd. (a).) By permitting this

conduct as the PIC, respondent failed to ensure the pharmacy's compliance with state laws and regulations pertaining to the practice of pharmacy.

23. Complainant established by clear and convincing evidence that respondent engaged in unprofessional conduct under the Third Cause for Discipline, pursuant to Business and Professions Code section 4301, subdivision (o), because on or before September 18, 2018, the pharmacy provided drug take-back services to a skilled nursing facility it serviced without prior registration with the Drug Enforcement Agency as a collector, in violation of California Code of Regulations, title 16, sections 1776, 1776.1, subdivision (h), and 1776.4, subdivision (b). By this violation, respondent, in his capacity as pharmacist in charge, failed to ensure the pharmacy's compliance with state laws and regulations pertaining to the practice of pharmacy.

24. Complainant established by clear and convincing evidence under the Fourth Cause for Discipline that respondent's license is subject to discipline under Business and Professions Code sections 4116, subdivision (a), and 4301, subdivision (o), because, as found above, on October 28, 2018, and on December 13, 2018, Ms. Zeffren, who worked, in effect, as an operations manager at the pharmacy, possessed a key to the pharmacy and gained entry to it. By this violation, respondent failed to ensure the pharmacy's compliance with state laws and regulations pertaining to the practice of pharmacy.

25. Complainant established by clear and convincing evidence under the Seventh Cause for Discipline that respondent's license is subject to discipline under Business and Professions Code sections 4301, subdivision (o), relating to his response or lack of response to results of air and surface sampling that showed highly pathogenic organisms in the pharmacy's compounding clean room. As found above, in violation of California Code of Regulations title 16 section 1751.4, subdivision (j),

respondent failed to inspect clean, remediate, or resample the room after he was notified that air and surface sampling of the pharmacy's clean room yielded out of specification results that identified cfus of highly pathogenic microorganisms. Respondent thus failed in his capacity as pharmacist in charge to ensure the pharmacy's compliance with state laws and regulations.

Imposition of Discipline

26. With causes of discipline having been found, the issue now is the degree of discipline to impose. To make this assessment the board has published disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 2/2017) (Guidelines) that are to be used in reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.). Deviation from these guidelines "is appropriate where the Board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems." (Cal. Code Regs., tit. 16, § 1760.)

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following factors are considered, in relevant part: the actual or potential harm to the public; prior disciplinary record, including level of compliance with disciplinary order(s); prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s); number and/or variety of current violations; nature and severity of the act(s), offense(s) or crime(s) under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the act(s) or offense(s); whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another; whether the respondent had

knowledge of or knowingly participated in such conduct; and the financial benefit to the respondent from the misconduct. (Bus. & Prof. Code section § 4300.)

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one. A respondent is permitted to present mitigating circumstances at a hearing and has the burden to show any rehabilitation or corrective measures he or she has taken.

The Guidelines contain four categories of violations and recommended penalties. For the violations of the Business and Professions Code at issue here, the level of discipline is appropriately classified as "Category II" because, consistent with the board's Guidelines, the violations posed a serious potential for harm, and respondent's conduct involved the disregard of pharmacy law and public safety, and reflected on his competency and ability to take care. Under this classification, the minimum range of discipline is revocation, revocation stayed, three years' probation with standard terms and conditions and optional terms as appropriate. The maximum range is revocation.

27. After giving due consideration to the board's criteria and the evidence of record as a whole, it is determined that a three-year period of probation with standard terms and restrictions and appropriate optional conditions are in the public interest consistent with the need for public protection.

This conclusion is reached for these reasons: Respondent turned a blind eye to the pharmacy owner and management team's refusal to follow the laws and regulations regarding the operation of the pharmacy and its sterile compounding unit. He did not object when Ms. Zeffren had a key to the pharmacy and on two occasions opened the pharmacy. He also did not object to a pharmacy technician working

outside the pharmacy and outside a pharmacist's supervision who was processing and refilling prescriptions. And respondent did not object to the pharmacy continuing to compound medications in the clean room when pathogens were found by sampling. In fact, respondent compounded a medication after the sampling results were revealed. He also failed to ensure information regarding controlled substances was timely submitted to the DOJ. In short, respondent completely failed in his duties as PIC.

With this noted, respondent faced a situation at the pharmacy he had not encountered before where the owner and management team refused to comply with the laws governing the operation of the pharmacy and, on top of that, they also lacked the financial means to safely operate a sterile compounding pharmacy. Respondent has otherwise been a licensed pharmacist without discipline for 39 years. Further he has taken responsibility for his failure to ensure the pharmacy operated according to law. As the California Supreme Court stated in *Seide v. Committee of Bar Examiners* (1989) 49 Cal.3d 933, 940, "[f]ully acknowledging the wrongfulness of [one's] actions is an essential step towards rehabilitation."

Costs

28. As found above, it is determined that the reasonable costs relating to the investigation and prosecution of this matter are \$42,698.75, of which complainant seeks recovery of 20 percent of this sum, or \$8,539.75, against respondent.

The factors to be considered in determining the reasonableness of costs pursuant to statutory provisions like Business and Professions Code section 125.3 are identified in *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45. The factors include whether the licensee has been successful at hearing in getting charges dismissed or reduced; the licensee's subjective good faith belief in the merits

of his or her position; whether the licensee has raised a colorable challenge to the proposed discipline; the financial ability of the licensee to pay; and whether the scope of the investigation was appropriate to the alleged misconduct.

After giving due consideration to these factors, it is determined that a reduction to \$2,000 from \$8,539.75 is appropriate for these reasons: Respondent does not have the financial ability to pay the full amount of costs, he was not paid for much of his work at the pharmacy given the financial issues present there, he has his child's college tuition to pay, he is driving Uber to make ends meet, he has a 39-year unblemished record and he was successful in obtaining a disposition less than revocation of his license. He is also being ordered to pay for an Ethics course and prohibited from serving as a PIC, so his income will be limited. Making him pay more would financially overburden him, be unduly punitive, and quite likely make it impossible for him to successfully complete probation. The purpose of discipline is not to punish, but to protect the public by eliminating practitioners who are dishonest, immoral, disreputable or incompetent. (*Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.)

ORDER

Registered Pharmacist License Number RPH 37541 issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for three years upon the following terms and conditions:

1. **Obey All Laws:** Respondent shall obey all state and federal laws and regulations. Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

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

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

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

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

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

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

6. **Notice to Employers:** During the period of probation, respondent shall notify all present and prospective employers of the decision in OAH case number 202106 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment while on probation) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in OAH case number 2021060182, and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or 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 his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in OAH case number 2021060182 in advance of respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or 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 OAH case number 2021060182 and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

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

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant:
During the period of probation, respondent shall not supervise any intern pharmacist,

be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs:** As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$2,000. Respondent shall make said payments as follows: within three years of the effective date of this Decision, pursuant to a reasonable payment plan agreed to by the Board.

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

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

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

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

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

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

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

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment:** Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within

ten (10) days of a change in name, residence address, mailing address, or phone number.

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

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

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

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

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

month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

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

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

16. **No Supervision of Ancillary Personnel:** During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the Board. Failure to comply with this provision shall be considered a violation of probation.

17. **Practice Requirement – Extension of Probation:** Except during periods of suspension, respondent shall, at all times while on probation, be employed as a registered pharmacist in California for a minimum of thirty (30) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the Board or its designee.

If respondent does not practice as a registered pharmacist in California for the minimum number of hours in any given calendar month, for any reason (including vacation), respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the Board in writing within ten (10) days following the next calendar month during which respondent practices as a registered pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

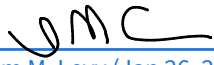
It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive

and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

18. **No Ownership or Management of Licensed Premises:** Respondent shall not own, have any legal or beneficial interest in, nor 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 interests or provide documentation thereof shall be considered a violation of probation.

19. **Completion of Probation:** Upon written notice by the Board or its designee indicating successful completion of probation, respondent's license will be fully restored.

DATE: January 26, 2022


Abraham M. Levy (Jan 26, 2022 11:57 PST)
ABRAHAM M. LEVY
Administrative Law Judge
Office of Administrative Hearings

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

12 In the Matter of the First Amended Accusation
13 Against:

14 **ARROW-MED RX INC. DBA JANA**
15 **HEALTHCARE PHARMACY,**
ALEXANDR AKOPNIK, OWNER
16 **MIRA ZEFFREN**

5233 Melrose Avenue
17 Los Angeles, CA 90038

18 Pharmacy Permit No. PHY 50759,
Compounding Permit No. LSC 100684

19 and

20 **DEMAR LEWIS III**

21 6121 Shoup Ave. #6
Woodland Hills, CA 91367

22 Pharmacist License No. RPH 37541

23 Respondents.
24

Case No. 6904

FIRST AMENDED ACCUSATION

1 **PARTIES**

2 1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her
3 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
4 Affairs.

5 2. On or about October 4, 2011, the Board of Pharmacy issued Permit Number PHY
6 50759 to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy with Alexandr Akopnik as President
7 and 100% Shareholder (Respondent Jana Healthcare). Demar Lewis III was the Pharmacist in
8 Charge from August 15, 2018 to May 20, 2019. The Permit was in full force and effect at all
9 times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

10 3. On or about December 30, 2014, the Board of Pharmacy issued Sterile Compounding
11 Permit Number LSC 100684 to Respondent Jana Healthcare. Demar Lewis III was the
12 Pharmacist in Charge from August 15, 2018 to May 20, 2019. The Permit was in full force and
13 effect at all times relevant to the charges brought herein and expired on July 19, 2019.

14 4. On or about February 9, 1983, the Board of Pharmacy issued Pharmacist License
15 Number RPH 37541 to Demar Lewis III (Respondent Lewis). The Pharmacist License was in
16 full force and effect at all times relevant to the charges brought herein and will expire on June 30,
17 2022, unless renewed.

18 5. On or about September 26, 1987, the Board of Pharmacy issued Pharmacist License
19 Number RPH 41239 to Mira J. Zeffren. The Pharmacist License was revoked on November 6,
20 2015 *In the Matter of the First Amended Accusation against Mira J. Zeffren*, Board of Pharmacy,
21 Case Number AC 5070. Respondent acted as an undisclosed officer, associate and/or person with
22 management or control of Respondent Pharmacy.

23 **JURISDICTION**

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

27 7. Section 4113 of the Code states in pertinent part:

28

1 “(d) Every pharmacy shall notify the board in writing, on a form designed by the board,
2 within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge,
3 and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge.
4 The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If
5 disapproved, the pharmacy shall propose another replacement within 15 days of the date of
6 disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is
7 approved by the board.

8 (e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30
9 days a permanent replacement pharmacist-in-charge to propose to the board on the notification
10 form, the pharmacy may instead provide on that form the name of any pharmacist who is an
11 employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who
12 is actively involved in the management of the pharmacy on a daily basis, to act as the interim
13 pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns
14 the pharmacy, shall be prepared during normal business hours to provide a representative of the
15 board with the name of the interim pharmacist-in-charge with documentation of the active
16 involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and
17 with documentation of the pharmacy’s good faith efforts prior to naming the interim pharmacist-
18 in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the
19 identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the
20 name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent
21 pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall
22 propose another replacement within 15 days of the date of disapproval, and shall continue to
23 name proposed replacements until a pharmacist-in-charge is approved by the board.”

24 8. Section 4110 of the Code subdivision (a) states:

25 “(a) No person shall conduct a pharmacy in the State of California unless he or she has
26 obtained a license from the board. A license shall be required for each pharmacy owned or
27 operated by a specific person. A separate license shall be required for each of the premises of any
28 person operating a pharmacy in more than one location. The license shall be renewed annually.

1 The board may, by regulation, determine the circumstances under which a license may be
2 transferred.”

3 9. Section 4116 of the Code subdivision (a) states in pertinent part:

4 “(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the
5 law, or a person authorized to prescribe shall be permitted in that area, place, or premises
6 described in the license issued by the board wherein controlled substances or dangerous drugs or
7 dangerous devices are stored, possessed, prepared, manufactured, derived, compounded,
8 dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who
9 enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing
10 clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to
11 the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized
12 individual is present.”

13 10. Section 4301 of the Code states:

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

17

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

22 11. Section 4037 subdivision (a) of the Code states in pertinent part:

23 “Pharmacy” means an area, place, or premises licensed by the board in which the
24 profession of pharmacy is practiced and where prescriptions are compounded. “Pharmacy”
25 includes, but is not limited to, any area, place, or premises described in a license issued by the
26 board wherein controlled substances, dangerous drugs, or dangerous devices are stored,
27 possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the
28

1 controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at
2 retail.

3 12. Section 4305 of the Code states in pertinent part:

4 “(a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act
5 as the pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that
6 a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in
7 Sections 4101 and 4113 shall constitute grounds for disciplinary action.

8 (b) Operation of a pharmacy for more than 30 days without supervision or management by
9 a pharmacist-in-charge shall constitute grounds for disciplinary action.”

10 13. Section 4307 of the Code states in pertinent part:

11 (a) Any person who has been denied a license or whose license has been revoked or is
12 under suspension, or who has failed to renew his or her license while it was under suspension, or
13 who has been a manager, administrator, owner, member, officer, director, associate, partner, or
14 any other person with management or control of any partnership, corporation, trust, firm, or
15 association whose application for a license has been denied or revoked, is under suspension or has
16 been placed on probation, and while acting as the manager, administrator, owner, member,
17 officer, director, associate, partner, or any other person with management or control had
18 knowledge of or knowingly participated in any conduct for which the license was denied,
19 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,
20 administrator, owner, member, officer, director, associate, partner, or in any other position with
21 management or control of a licensee as follows:

22 (1) Where a probationary license is issued or where an existing license is placed on
23 probation, this prohibition shall remain in effect for a period not to exceed five years.

24 (2) Where the license is denied or revoked, the prohibition shall continue until the license is
25 issued or reinstated.

26 (b) Manager, administrator, owner, member, officer, director, associate, partner, or any
27 other person with management or control of a license as used in this section and Section 4308,
28 may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

1 (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to
2 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.
3 However, no order may be issued in that case except as to a person who is named in the caption,
4 as to whom the pleading alleges the applicability of this section, and where the person has been
5 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part
6 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision
7 shall be in addition to the board's authority to proceed under Section 4339 or any other provision
8 of law.

9 14. Section 4329 of the Code states in pertinent part:

10 "Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-
11 charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous
12 drugs except as otherwise provided in this chapter, is guilty of a misdemeanor."

13 15. Section 4105 of the Code states in pertinent part:

14 "(a) All records or other documentation of the acquisition and disposition of dangerous
15 drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed
16 premises in a readily retrievable form.

17"

18 **HEALTH AND SAFETY CODE**

19 16. Section 11165 subdivision (d) of the Health and Safety Code states:

20 "(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
21 substance, as defined in the controlled substances schedules in federal law and regulations,
22 specifically Sections 1308.12, 1308.13, and 1308.14, and respectively, of Title 21 of the Code of
23 Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
24 information to the Department of Justice as soon as reasonably possible, but not more than seven
25 days after the date a controlled substance is dispensed, in a format specified by the Department of
26 Justice:

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

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

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

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

11 (5) Quantity of the controlled substance dispensed.

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

14 (7) Number of refills ordered.

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

16 (9) Date of origin of the prescription.

17 (10) Date of dispensing of the prescription.

18 (11) The serial number for the corresponding prescription form, if applicable."

19 **REGULATIONS**

20 17. California Code of Regulations, title 16, section 1707.4 subdivision (a) states in
21 pertinent part:

22 "A pharmacy licensed by the board may process a request for refill of a prescription
23 received by a pharmacy within this state, provided:..."

24 18. California Code of Regulations, title 16, section 1717.1 subdivision (a) states:

25 "(a) For dangerous drugs other than controlled substances: Two or more pharmacies may
26 establish and use a common electronic file to maintain required dispensing information.
27 Pharmacies using such a common file are not required to transfer prescriptions or information for
28

1 dispensing purposes between or among pharmacies participating in the same common
2 prescription file.”

3 19. California Code of Regulations, title 16, section 1714 states in pertinent part:

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

8

9 (d) Each pharmacist while on duty shall be responsible for the security of the prescription
10 department, including provisions for effective control against theft or diversion of dangerous
11 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
12 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.”

13 (e) The pharmacy owner, the building owner or manager, or a family member of a
14 pharmacist owner (but not more than one of the aforementioned) may possess a key to the
15 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key
16 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire,
17 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that
18 the pharmacist may readily determine whether the key has been removed from the container.

19 20. California Code of Regulations, title 16, section 1776 states:

20 “Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors
21 licensed by the board may offer, under the requirements in this article, specified prescription drug
22 take-back services through collection receptacles and/or mail back envelopes or packages to
23 provide options for the public to discard unwanted, unused or outdated prescription drugs. Each
24 entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and
25 this article.

26 Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug
27 distributors (licensed wholesalers and third-party logistics providers) who are registered with the
28

1 DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-
2 back receptacle as authorized under this article.”

3 21. California Code of Regulations, title 16, section 1776.1 subdivision (h) states:

4 “(h) A pharmacy must be registered with the federal DEA as a collector for purposes of
5 maintaining a prescription drug take-back collection receptacle. Such pharmacies cannot employ
6 anyone convicted of a felony related to controlled substances, or anyone who has had a DEA
7 permit denied, surrendered or revoked.”

8 22. California Code of Regulations, title 16, section 1776.4 subdivision (b) states in
9 pertinent part:

10 “(b) Only pharmacies and hospitals/clinics with onsite pharmacies may establish collection
11 receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted
12 prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a
13 collection receptacle in a skilled nursing facility shall:

14 (1) Be registered and maintain registration with the DEA as a collector.

15 (2) Notify the board in writing within 30 days of establishing a collection receptacle.

16 (3) Notify the board in writing within 30 days when they cease to maintain the collection
17 receptacle.

18 (4) Notify the board in writing within 14 days of any tampering of the collection receptacle
19 or theft of deposited drugs.

20 (5) Notify the board in writing within 14 days of any tampering, damage or theft of a
21 removed liner.

22 (6) List all collection receptacles it maintains annually at the time of renewal of the
23 pharmacy license.”

24 23. California Code of Regulations, title 16, section 1793.3 states in pertinent part:

25 “(a) In addition to employing a pharmacy technician to perform the tasks specified in
26 section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or
27 otherwise enter prescription information into a computer record system, but the responsibility for
28 the accuracy of the prescription information and the prescription as dispensed lies with the

1 registered pharmacist who initials the prescription or prescription record. At the direction of the
2 registered pharmacist, a non-licensed person may also request and receive refill authorization.”

3 24. California Code of Regulations, title 16, section 1751.5 states in pertinent part:

4 “(a) When compounding sterile drug preparations the following standards must be met:

5 ...

6 (5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl
7 alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by
8 the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely
9 disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and
10 after contact with non-sterile objects. Gloves shall also be routinely inspected for holes,
11 punctures, or tears and replaced immediately if such are detected.

12”

13 25. California Code of Regulations, title 16, section 1735.5 states in pertinent part:

14 “(a) Any pharmacy engaged in compounding shall maintain written policies and procedures
15 for compounding that establishes procurement procedures, methodologies for the formulation and
16 compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other
17 standard operating procedures related to compounding. Any material failure to follow the
18 pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

19 (b) The policies and procedures shall be reviewed and such review shall be documented on
20 an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated
21 whenever changes in policies and procedures are implemented.

22 26. California Code of Regulations, title 16, section 1751.1 states in pertinent part:

23 “(a) In addition to the records required by section 1735.3, any pharmacy engaged in any
24 compounding of sterile drug preparations shall maintain the following records, which must be
25 readily retrievable, within the pharmacy:

26 (1) Documents evidencing training and competency evaluations of employees in
27 sterile drug preparation policies and procedures.

28 ...

1 (3) Results of assessments of personnel for aseptic techniques including results of
2 media-fill tests and gloved fingertip testing performed in association with media-fill tests.

3 ...

4 (9) Other facility quality control records specific to the pharmacy's policies and
5 procedures (e.g., cleaning logs for facilities and equipment).

6”

7 27. California Code of Regulations, title 16, section 1751.4 states in pertinent part:

8 ...”

9 (j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile
10 compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall
11 be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000
12 liters) at each location and shall be done at least once every six months. Viable surface and viable
13 air sampling shall be performed by a qualified individual who is familiar with the methods and
14 procedures for surface testing and air sampling. Viable air sampling is to be performed under
15 dynamic conditions that simulate actual production. Viable surface sampling is to be performed
16 under dynamic conditions of actual compounding. When the environmental monitoring action
17 levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to
18 conducting an investigation pursuant to its policies and procedures. Remediation shall include, at
19 minimum, an immediate investigation of cleaning and compounding operations and facility
20 management.

21”

22 **COST RECOVERY**

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

27 ///

1 **FIRST CAUSE FOR DISCIPLINE**

2 (Failure to Timely File Reports to CURES)

3 29. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
4 Business and Professions Code section 4301, subdivision (o) in conjunction with Health and
5 Safety Code section 11165 subdivision (d) in that Respondents failed to timely report information
6 for each prescription for Schedule II, Schedule III, or Schedule IV controlled substances to the
7 Department of Justice for reporting in its Controlled Substance Utilization Review and Evaluation
8 System (CURES). The information was required to have been reported to the CURES program
9 within seven (7) days after the prescription is dispensed. The circumstances are as follows:

10 30. On or about January 31, 2019 Respondent Lewis provided confirmation that
11 Respondent Jana Healthcare Pharmacy sent a cumulative report to the CURES program where it
12 stated that it had dispensed controlled substances as follows::

13 75 controlled substance prescriptions in June 2018

14 245 controlled substance prescriptions in July 2018

15 254 controlled substance prescriptions in August 2018

16 286 controlled substance prescriptions in September 2018

17 307 controlled substance prescriptions in October 2018

18 279 controlled substance prescriptions in November 2018

19 308 controlled substance prescriptions in December 2018

20 263 controlled substance prescriptions in January 2019

21 **SECOND CAUSE FOR DISCIPLINE**

22 (Unprofessional Conduct – Unlicensed Pharmacy Activity)

23 31. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
24 Business and Professions Code section 4301 subdivision (o), 4037 subdivision (a) in conjunction
25 with title 16 of the California Code of Regulations sections 1707.4 subdivision (a), 1717.1
26 subdivision (a), 1714 subdivisions (b) and (d), 1793.3 subdivision (a), and section 4110 in that on
27
28

1 or before January 24, 2019, pharmacy technician TT¹, using remote access, processed new and
2 refill prescriptions from an unlicensed location (her residence).

3 **THIRD CAUSE FOR DISCIPLINE**

4 (Failure to Obtain Drug Take-Back Registration)

5 32. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
6 Business and Professions Code section 4301, subdivision (o) in conjunction with title 16 of the
7 California Code of Regulations sections 1776, 1776.1 subdivision (h) and 1776.4 subdivision (b)
8 in that on or before September 18, 2018, the pharmacy provided drug take-back services to a
9 skilled nursing facility it serviced without prior registration with the DEA as a collector.

10 **FOURTH CAUSE FOR DISCIPLINE**

11 (Pharmacy Security)

12 33. Respondents Jana Healthcare and Lewis are subject to disciplinary action under
13 Business and Professions Code sections 4116 subdivision (a), title 16 California Code of
14 Regulations section 1714 subdivisions (b), (e) and (d) in that on or about October 28, 2018, and
15 on or about December 13, 2018, MZ² who worked as an operations manager at Respondent Jana
16 Healthcare Pharmacy, was in possession of a key to Respondent Jana Healthcare Pharmacy,
17 however she was not a licensed pharmacist at the time. MZ used the key to open the pharmacy
18 and allow technicians SR and IS to access and enter the pharmacy drug area where dangerous
19 drugs and devices, including controlled substances, were maintained without a pharmacist
20 present.

21 **FIFTH CAUSE FOR DISCIPLINE**

22 (Pharmacist-in-Charge Notification to the Board)

23 34. Respondent Jana Healthcare is subject to disciplinary action under Business and
24 Professions Code sections 4113 subdivisions (d) and (e), and 4305 subdivision (a) and (b) in that
25 on or about on May 20, 2019, Respondent Lewis disassociated as the pharmacist-in charge of
26 Respondent Jana Pharmacy, however Respondent Jana Healthcare Pharmacy did not provide

27 ¹ Initials of non-parties are used in lieu of full names.

28 ² MZ was a licensed pharmacist; however her pharmacy license was revoked as of
November 6, 2015.

written notification of the disassociation to the Board within 30 days. Moreover, Respondent Jana Healthcare Pharmacy continued to operate without a pharmacist-in-charge or an interim pharmacist-in-charge until on or about August 15, 2019 when a new pharmacist-in-charge was proposed to the Board.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Non-pharmacist taking charge)

35. Respondent Jana Healthcare is subject to disciplinary action under Business and Professions Code sections 4301 subdivision (o) and 4329 in that MZ, an individual whose pharmacist license was revoked as of November 6, 2015 and was not subsequently licensed by the Board, took charge of or acted as a supervisor, manager, or pharmacist-in-charge for Respondent Jana Healthcare.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Facility and Equipment Standards for Sterile Compounding)

36. Respondents Jana Healthcare and Lewis are subject to disciplinary action under Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of California Code of Regulations section 1751.4 subsection (j) in that after viable sampling performed on or about December 21, 2018 and on or about June 26, 2019 yielded out of specification results, Respondents failed to conduct an investigation and to perform remediation and resampling pursuant to its policies and procedures which require an investigation into the source of the contamination, and once determined, elimination of the contamination source; and cleaning and re-sampling. The table below lists the highly pathogenic microorganisms identified during each instance of sampling.

Highly Pathogenic Microorganisms Identification:

Date of Sampling	Location of sampling	Total Microbial count	Highly Pathogenic Microorganism	Number of colony forming units
12/21/2018	Air in anteroom on rack	12 cfu	Non-sporulating hyaline fungus	2 cfu
12/21/2018	Surface of anteroom wall	<2 cfu	Chaetomium species	1 cfu

6/26/2019	Air in anteroom on rack	128 cfu	Non-sporulating hyaline fungus	4 cfu
			Scopulariopsis species	102 cfu
			Aspergillus species	2 cfu
6/26/2019	Air in IV room on metal table	2 cfu	Scopulariopsis species	2 cfu

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Compounding Attire)

37. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations section 1751.5 subsection (a)(5) in that during an inspection on or about July 31, 2019, Respondent Jana Healthcare failed to perform hand cleansing with a persistently active alcohol-based product followed by donning of sterile gloves; no persistently active alcohol-based product was available in the pharmacy; RPH YA and TCH SR were unfamiliar with the concept; and the hand hygiene and garbing policy and procedures did not provide for the use of a persistently active alcohol based product before donning sterile gloves.

NINTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Policies and Procedure)

38. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations section 1735.5 subsection (b) in that between on or about July 31, 2019 and on or about March 9, 2020, Respondent Jana Healthcare failed to provide a documentation of performance of an annual review of the compounding policies and procedures and the last documentation of review of policies and procedures by a pharmacist-in-charge was in 2017 by PIC PM.

TENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Sterile Compounding Recordkeeping Requirements)

39. Respondent Jana Healthcare failed to comply with Business and Professions Code sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations

1 section 1751.1 subsection (a)(1) in that during an inspection on or about July 31, 2019, and as of
2 or about August 13, 2020, Respondent Jana Healthcare Pharmacy failed to provide documents
3 evidencing training, i.e. records of competency on hand hygiene and garbing and on cleaning and
4 disinfection practices for the following:

5 a. RPH GC, who had compounded at least five compounded sterile preparations
6 for Meropenem 2gm/normal saline 100ml, Rx #826847, on or about February 6, 9 and 12, 2019;
7 and

8 b. PIC Demar Lewis, who had compounded at least two compounded sterile
9 preparations for Meropenem 2gm/normal saline 100ml, Rx# 826847, on or about February 7,
10 2019.

11 **ELEVENTH CAUSE FOR DISCIPLINE**

12 (Failure to Comply with Sterile Compounding Recordkeeping Requirements)

13 40. Respondent Jana Healthcare failed to comply with Business and Professions Code
14 sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations
15 section 1751.1 subsection (a)(3) in that during an inspection on or about July 31, 2019, and as of
16 on or about August 3, 2020, Respondent Jana Healthcare failed to provide records of media-fill
17 tests and gloved fingertip testing performed in association with media-fill tests for PIC Demar
18 Lewis, who had compounded at least two compounded sterile preparations for Meropenem
19 2gm/normal saline 100ml, Rx# 826847 on or about February 7, 2019.

20 **TWELFTH CAUSE FOR DISCIPLINE**

21 (Failure to Comply with Sterile Compounding Recordkeeping Requirements)

22 41. Respondent Jana Healthcare failed to comply with Business and Professions Code
23 sections 4301 subdivision (o) in conjunction with title 16 of the California Code of Regulations
24 section 1751.1 subsection (a)(9) in that during an inspection on or about July 31, 2019, and as of
25 on or about August 3, 2020, Respondent Jana Healthcare failed provide records of daily cleaning
26 of facilities and equipment for the months of January 2019, April 2019, June 2019 and July 2019
27 and provided only partial records for May 2019. Additionally, Respondent Jana Healthcare did
28

not document monthly cleaning of walls, ceilings, storage shelving, tables, using a sporicidal agent for the months of December 2018, February 2019, March 2019 and May 2019.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Retain/Maintain Records of Dangerous Drugs and Devices)

42. Respondent Jana Healthcare failed to comply with Business and Professions Code section 4105 subsection (a) in that Respondent Jana Healthcare Pharmacy failed upon initial request dated on or about July 31, 2019, and until or about August 13, 2020, to provide records of disposition of compounded sterile preparations dispensed between July 1, 2018 and July 1, 2019.

DISCIPLINE CONSIDERATIONS

43. To determine the degree of discipline, if any, to be imposed on Respondents Jana Healthcare Pharmacy and Lewis, Complainant alleges as follows:

a. On or about October 21, 2019, in a prior action, the Board of Pharmacy issued Citation Number CI 2019 85511 to Jana Healthcare Pharmacy, PHY 50759 based on violations of Bus. & Prof. Code § 4113(d) [Every pharmacy shall notify the board in writing within 30 (d) days of the date of a change in pharmacist-in-charge] and Bus. & Prof. Code § 4305(b) [Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.] That Citation has been paid and is now final and is incorporated by reference as if fully set forth.

b. On or about December 24, 2014, *In the Matter of the Accusation Against DEMAR LEWIS, III*, Case No. 4658 and OAH No. 2014020154, the Board of Pharmacy issued a Decision and Order adopting the Stipulated Settlement and Disciplinary Order wherein Pharmacist License No. RPH 37541 issued to Demar Lewis III, was issued a letter of public reproof and required to pay costs of \$2,180.05. The circumstances of the discipline were the out of state discipline described as follows:

i. On or about June 17, 2004, in the case entitled *In the Matter of Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado of Demar Lewis, R.PH., License NO 13773, Case No. RG PH DLRAU*, Respondent was found by the CBP to be in violation of Colorado pharmacy law for numerous violations of record keeping,

1 labeling and dispensing practices. The action taken by CBP resulted in the suspension of
2 Respondent's license for 14 days followed by three (3) years' probation. Respondent was further
3 restricted from serving as a pharmacist manager, supervisor or consultant at any Colorado outlet,
4 was required to take and pass jurisprudence and professional competency examinations, and
5 provide a complete copy of the disciplinary order to each pharmacy manager and immediate
6 pharmacy supervisor at each location that he practiced.

7 ii. On or about September 1, 2005, in the matter entitled *In the Matter of*
8 *Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado*
9 *of Demar Lewis, R.PH., License NO 13773, Case No. RG PH DLVBB*, Respondent was found by
10 the CBP to be in violation of the terms and conditions of his probation under the order taken on
11 June 17, 2004 in Case No. RG PH DLRAU. As a result, the CBP suspended his license for three
12 months, followed by five (5) years' probation with certain terms and conditions.

13 iii. On or about April 1, 2008, in the matter entitled *In the Matter of*
14 *Disciplinary Proceedings Regarding the License to Practice Pharmacy in the State of Colorado*
15 *of Demar Lewis III, R.PH., License NO 13773, Case No. PH 2007-0008*, Respondent was found
16 by the CBP to be in violation of the terms and conditions of his probation under the order taken
17 September 1, 2005 in Case No. RG PH DLVBB. As a result, through a Stipulation and Final
18 Agency Order, the CBP ordered Respondent's license relinquished and cancelled, which has the
19 same force and effect as a revocation ordered by the Board.

20 iv. On or about on July 18, 2018, Citation CI 2014 64366 was issued to Jana
21 Healthcare Pharmacy by the Board for violations of Code sections 4301(g) and (o), 111255 and
22 72371. The citation has been affirmed.

23 **OTHER MATTERS**

24 44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
25 Number PHY 50759 issued to Jana Healthcare Pharmacy while Demar Lewis III had been an
26 officer and owner and had knowledge of or knowingly participated in any conduct for which the
27 licensee was disciplined, Demar Lewis III shall be prohibited from serving as a manager,
28 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50759 issued to Jana Healthcare Pharmacy while Alexandr Akopnik had been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Alexandr Akopnik 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 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50759 issued to Jana Healthcare Pharmacy while Mira J. Zeffren had been an undisclosed officer, associate and/or person with management or control and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Mira J. Zeffren 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 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 50759, issued to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100684, issued to Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 37541 issued to Demar Lewis III;

4. Prohibiting Demar Lewis III from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit

Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

5. Prohibiting Alexandr Akopnik from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

6. Prohibiting Mira J. Zeffren from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50759 is placed on probation or until Pharmacy Permit Number PHY 50759 is reinstated if it is revoked;

7. Ordering Arrow-Med Rx Inc. dba Jana Healthcare Pharmacy, and Demar Lewis III, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 1/19/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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