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

In the Matter of the Accusation Against:

Case No. 5694

LAURA MICHELLE DAWLEY, Pharmacist License No. RPH 55947

OAH No. 2017051408

Respondent.

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on March 28, 2018.

It is so ORDERED on February 26, 2018.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

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

In the Matter of the Accusation Against:

LAURA MICHELLE DAWLY, Pharmacist License No. RPH 55947,

Respondent.

Case No. 5694

OAH No. 2017051408

PROPOSED DECISION

Howard W. Cohen, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard this matter on November 20, 2017, in Los Angeles.

Sheronda L. Edwards, Deputy Attorney General, represented complainant Virginia K. Herold, Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Fenton Law Group, LLP, represented respondent Laura Michelle Dawly, who was present.

The parties agreed to redact all documents offered in evidence to protect the privacy rights of third parties in lieu of requesting a protective sealing order. The ALJ ordered the court reporter to replace any reference to a patient's name in the transcript with the patient's initials.

Oral and documentary evidence was received. The record was held open to allow the parties to submit simultaneous closing briefs by December 13, 2017, and to allow complainant to file a reply closing brief by December 20, 2017. Complainant and respondent timely filed closing briefs, which were marked for identification as exhibits 46 and E, respectively. Complainant filed no reply closing brief.

The record was closed and the matter was submitted on December 20, 2017.

SUMMARY

Complainant seeks to revoke or suspend respondent's pharmacist license for errors in prescription practices, alleging she incorrectly processed and verified prescriptions, dispensed a dangerous drug in an incorrectly labeled container, failed to complete quality assurance reports for all medication errors, dispensed a post-dated prescription, and incorrectly dispensed methylphenidate tablets that had been returned to the pharmacy by a patient. Respondent admitted the errors and offered evidence of mitigation and rehabilitation. As discussed below, there is cause to revoke respondent's license, suspend the revocation, and place respondent's license on probation for three years on certain terms and conditions.

FACTUAL FINDINGS

Jurisdiction and Parties

- 1. Complainant filed the Accusation in her official capacity. Respondent timely filed a notice of defense.
- 2. The Board issued Pharmacist License number RPH 55947 to respondent on August 5, 2004. The license is scheduled to expire on December 31, 2019.
- 3. From March 8, 2011 to January 14, 2015, and from May 21, 2015, to the present, respondent has been the pharmacist-in-charge (PIC) of Rite Aid Pharmacy #6514 in Victorville. She was PIC at that pharmacy at all times relevant to the charging allegations.

Board Investigation

- 4. On May 12, 2014, the Board received a complaint from Marisa Rodriguez, a pharmacy technician employed by Rite Aid #6514, claiming that she observed respondent fail to report medication errors, reuse returned medications, and fill postdated prescriptions. Rodriguez testified at hearing to substantiate her observations and reaffirm her complaint. She admitted that, though she was aware of the mistakes when they were made, she did not call the mistakes to respondent's attention, or to anyone else's attention. She testified that she was willing to allow incorrectly filled prescriptions to be distributed to patients even though she knew they were filled in error, because she was not the pharmacist and it was not her responsibility to take any corrective action. Rodriguez's admission that she chose to engage in what appears to be unethical behavior potentially harmful to patients lends support to respondent's claim of Rodriguez's animus toward her; it does not, however, call into question the basis for the substantive charges against respondent in light of other evidence on the record.
- 5. On January 6, 2015, Board Inspector Anna Yamada, accompanied by another inspector, inspected Rite Aid Pharmacy #6514. Yamada discovered evidence of multiple violations, including variations from prescriptions; dispensing a prescription with incorrect dosage instructions; failing to complete quality assurance reports for multiple medication errors;

filling and dispensing postdated prescriptions for morphine; and dispensing adulterated methylphenidate.

6. Yamada interviewed Rodriguez and Samy Farag, a licensed pharmacist who works for Rite Aid, filling in at different pharmacies as a "floater." She inspected the pharmacy and obtained witness statements.

Deviations from Prescriptions

- 7. At hearing, respondent admitted that, on January 30, 2014, she incorrectly processed and verified a prescription as methylphenidate 5mg Rx #320772 to patient MD, instead of the prescribed methylphenidate ER 54mg, without the prior consent of the prescribing physician.¹
- a. On February 5, 2014, the patient appeared at the pharmacy to complain about the incorrect prescription. Farag, who was filling in for respondent, corrected the error and dispensed methylphenidate ER 54mg Rx #323796 to patient MD. He wrote "patient return" on the label of the returned medication and placed the bottle in the designated area for expired or damaged items in a cabinet containing controlled substances. He also telephoned respondent and notified her of the error.
- b. Respondent subsequently admitted to Yamada that she filled the methylphenidate prescription in error. She said she did not recall speaking with Farag on February 5, 2014, while she was out of the state, or the details of the medication error. Respondent was distraught because she received an emergency call from her sister in Arkansas on January 30, 2014, before filling the prescription, stating her mother had a heart attack and was scheduled to have quadruple bypass heart surgery. Respondent planned immediately to fly to Arkansas, and informed Rite Aid management so another pharmacist could take her place.
- 8. On February 17, 2014, respondent incorrectly dispensed a prescription for erythromycin 250mg Rx #326326 for patient TF instead of the prescribed patient, her son EF, without the prior consent of the prescribing physician.
- a. The following day, on February 18, 2014, another pharmacist at the pharmacy corrected the error and dispensed erythromycin 250mg Rx #326641 for patient EF.
- b. Rodriguez had prepared the incorrect label for the bottle but had not called the error to respondent's attention. Respondent told Yamada that she did not recall the prescription error, but remembered staff informing her that a customer was upset about her son's medication being incorrectly dispensed.

¹ The prescription was for the extended release version of the medication, at a higher dose than that actually dispensed to the patient.

Labeling Errors

9. Respondent admitted to Yamada and at hearing that, on April 5, 2013, when respondent dispensed triamterene/HCTZ 37.5/25 as Rx #262434 to patient RB, she incorrectly labeled the bottle with directions to "take one capsule by mouth once daily one capsule by mouth twice daily," instead of the prescribing doctor's directions to "take one capsule daily." On April 19, 2013, three weeks later, respondent corrected the error and processed and verified patient RB's prescription, with the correct labeling, under a new prescription number, Rx #270129.

Quality Assurance Program Errors

- 10. During her January 6, 2015, inspection, Yamada found that the pharmacy did not complete quality assurance reports for all reported medication errors.
- a. On March 8 and April 5, 2013, patient RB's triamterene/HCTZ 37.5/25 Rx #262434 was dispensed with the incorrect directions. On April 19, 2013, the error was corrected, but there was no quality assurance report of this medication error available when requested on January 6, 2015.
- b. On January 30, 2014, patient MD's methylphenidate ER 54mg prescription was incorrectly dispensed as methylphenidate 5mg Rx #320772. On February 5, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- c. On February 17, 2014, patient EF's erythromycin 250mg was incorrectly dispensed to TF as erythromycin 250mg Rx #326326. On February 18, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- 11. When Farag corrected the methylphenidate error on February 5, 2014, he was not aware that he was required to prepare a quality assurance report. He testified, and told Yamada during her inspection, that he did not learn of this requirement until the date of the inspection. Farag telephoned respondent on February 5 to inform her about the medication error; he testified she told him she would report the error upon her return. Respondent does not recall the conversation, and disputes that she would have made such a statement, as it is Rite Aid policy that the pharmacist on duty must complete a quality assurance review within two days of discovering an error, and the policy is posted throughout the pharmacy. Rite Aid had not trained

² The monthly prescription had previously been mislabeled when dispensed to the patient a month earlier, on March 8, 2018; at that time, respondent had by hand corrected the label instructions before the medication was provided to the patient. The timing of the April refill suggests that the patient took the correct dose.

Farag to understand he was required to prepare a quality assurance report in respondent's absence.

- 12. Respondent wrote, in a statement provided to Yamada, that she was not aware there was a problem with the erythromycin prescription. "If I was made aware of a medication error; I would have immediately reported it as per Rite Aid policy." (Ex. 38.) At the hearing, however, respondent admitted to having some knowledge of the erythromycin error because she either heard of the aftermath of the customer's complaint or she personally resolved the matter with the customer. Respondent did not prepare or cause to be prepared a quality assurance report.
- 13. Pharmacies must retain quality assurance reports for at least one year from the date of correction. There is insufficient evidence on the record to demonstrate that reports of the March 8, 2013 and April 5, 2013 errors were not prepared. Yamada's inspection took place more than a year after the alleged incidents occurred, and complainant offered no evidence as to how long quality assurance reports were kept in Rite Aid's files. There is, however, sufficient evidence to demonstrate that the reports for January 30 and February 17, 2014, were not prepared.

Postdating Prescription

- 14. On September 26, 2013, the pharmacy received a postdated prescription, dated September 29, 2013, for morphine sulfate ER 60mg and morphine sulfate IR 30mg for patient WK. As she admitted at hearing, on September 26, 2013, respondent dispensed both morphine sulfate ER 60mg Rx #298354 and morphine sulfate IR 30mg Rx #298355 to patient WK.
- 15. At the hearing, respondent did not deny she filled and dispensed the morphine prescriptions early, but claimed she had committed an inadvertent oversight. Though morphine is a highly regulated Schedule II controlled substance, and pharmacists are trained to look very closely at the dates of prescriptions for Schedule II controlled substances and the doctor's signature, on the whole the evidence does not establish that the mistake was other than inadvertent.

Dispensing Adulterated Medication

- 16. On January 30, 2014, patient MD's methylphenidate 5mg Rx #320772 was incorrectly dispensed, and the patient returned the bottle, now containing 84 of the 90 dispensed tablets, to the pharmacy on February 5, 2014. (See Factual Finding 7a.) The methylphenidate bottle was commingled with the pharmacy's active drug stock and the contents of the returned medication bottle of methylphenidate 5mg were dispensed to another patient. On May 12, 2014, 60 of patient MD's returned methylphenidate 5mg tablets were used to dispense a prescription for methylphenidate 5mg Rx #344319 to patient MH.
- 17. Respondent testified that when the incorrectly dispensed methylphenidate prescription container was returned to the pharmacy, she placed it on the bottom shelf of the locked Schedule II controlled substance cabinet, in a red basket clearly marked for destruction.

Her testimony was corroborated by that of Farag. Respondent speculated to Yamada that somewhere along the line the methylphenidate prescription bottle must have been removed from the red return basket designated for receiving returned medications and placed into the regular drug stock, stating it may have occurred during the monthly drug inventories. Respondent was responsible for counting the adulterated drug to list in the pharmacy's "perpetual active inventory" and for conducting a monthly inventory and, as PIC, respondent was responsible for the staff pharmacist's re-dispensing of the adulterated methylphenidate.

Mitigation and Rehabilitation

- 18. Respondent admitted her mistakes. Some she attributed to the stress attending her mother's heart condition; with respect to others, respondent offered no excuse. Her license has never before been disciplined. When she received the Accusation in this matter, she was distraught, never having been in trouble before. She began taking continuing education courses related to the disciplinary charges brought against her, to improve her practical skills.
- 19. Respondent is respected by her professional peers and by patients using her pharmacy, as reflected in several character reference letters she submitted. William Zen, Pharm.D., wrote of her "sterling reputation," organization, commitment to excellence in treating customers and employees, her high ethical standards. (Ex. C.) Jill Sczech, M.S., Pharm.D., a Rite Aid floater, wrote that respondent's store "is one of the most organized and detail oriented stores that I have worked at." (*Id.*) She wrote of respondent's leadership skills, care for her patients, pharmaceutical knowledge, and integrity. Kathryn Chelekis Brown, R.Ph., a relief pharmacist at Rite Aid, wrote of respondent's attention to detail, organization, and professional skills. All were aware of the Accusation. Two patients wrote gratefully of respondent's attentiveness and care to them and their families.

Cost of Enforcement

20. The Board incurred investigative costs for inspectors and a supervising inspector in the amount of \$6,578.75, and enforcement costs, in the form of Attorney General fees and costs, in the amount of \$11,777.50, for a total of \$18,356.25. Those costs are reasonable. Complainant anticipated that the Board would incur approximately \$1,020 in additional attorney's fees from November 17, 2017, to the commencement of hearing. (Ex. 46.) A good faith estimate of costs may be used "where actual costs are unavailable." (Bus. & Prof. Code, 125.3.) Complainant did not establish why she could not submit evidence of actual additional enforcement costs at hearing. Without such evidence, an award of anticipated costs must be, and is, disallowed.

³ All further statutory references are to the Business and Professions Code, unless otherwise stated.

LEGAL CONCLUSIONS

Applicable Authority

- 1. The Board may suspend or revoke a license for unprofessional conduct. (§§ 4300, 4301.) Unprofessional conduct includes violating any laws regulating controlled substances and dangerous drugs (§ 4301, subd. (j)), and violating any laws governing pharmacy (§ 4301, subd. (o)). The Board retains jurisdiction to discipline an expired license. (§§ 118, subd. (b), 4300.1.)
- 2. "Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions." (§ 4001.1.)
- 3. "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." (§ 4113, subd. (c).) "Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (§ 4036.5.)
- 4. "No person shall antedate or postdate a prescription." (Health and Saf. Code, § 11172.)
- 5. A person shall not sell dangerous drugs that the person knew or reasonably should have known were adulterated. (§ 4169, subd. (a)(2).) "Dangerous drugs" are those that may not be lawfully dispensed without prescription furnished under section 4006. (§ 4022.) The Board may adopt regulations restricting the sale of dangerous drugs. (§ 4006.) The Board may discipline a license "to prevent the sale of pharmaceutical preparations and drugs that do not conform to the [applicable] standard and tests as to quality and strength...." (§ 4342, subd. (a).) The Board may punish any knowing or willful violation of any regulation adopted under section 4006 by fine or imprisonment. (§ 4342, subd. (b).)
- 6. "A pharmacist shall not dispense any prescription except in a container... correctly labeled with... [t]he directions for the use of the drug." (§ 4076, subd. (a)(2).)
- 7. Every pharmacy must establish a quality assurance program that documents and assesses medication errors. (Cal. Code Regs. (CCR), tit. 16, § 1711, subd. (a)). Medication errors are variations from a prescription or drug order not authorized by the prescriber. (CCR, § 1711, subd. (b).) Each pharmacy must use its quality assurance program findings to develop systems and processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business

⁴ All further references to the CCR are to title 16.

days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review." (CCR, § 1711, subd. (d).) Every quality assurance review record "shall be immediately retrievable in the pharmacy for at least one year from the date the record was created." (CCR, § 1711, subd. (f).)

- 8. "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." (CCR, § 1716.)
- 9. The Board bears the burden of proof by clear and convincing evidence, because pharmacists hold a professional license. (See *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence requires proof that is so clear as to leave no substantial doubt and that is sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)

Cause for Discipline

- 10. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (*o*), in that she deviated from the requirements of a prescription without the prior consent of the prescriber in violation of CCR section 1716, as set forth in Factual Findings 7 and 8.
- 11. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (*o*), in that she dispensed a dangerous drug in an incorrectly labeled container in violation of CCR section 1716, as set forth in Factual Findings 9.
- 12. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (*o*), in that she failed to complete quality assurance reports for all reported medication errors in violation of CCR section 1711, subdivisions (d) and (f), as set forth in Factual Findings 10 through 13.
- 13. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (j), in that she dispensed a post-dated prescription in violation of Health and Safety Code section 11172, as set forth in Factual Findings 14 and 15.
- 14. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (*o*), in that she dispensed dangerous drugs she knew or reasonably should have known were adulterated in that they had been returned by a patient and could not be shown to satisfy statutory requirements for quality and strength, in violation of Business and Professions Code sections 4342 and 4169, subdivision (a)(2), as set forth in Factual Findings 16 and 17 and Legal Conclusion 5.

- 15. The Board shall consider its Disciplinary Guidelines (rev. 10/2007) (Guidelines) when determining whether and how to discipline a license. (CCR, § 1774.) The Disciplinary Guidelines establish four categories for evaluating violations and determining discipline.
- 16. Category I violations are "potentially harmful" but "relatively minor" violations and repeated violations of a "relatively minor nature." (Guidelines at p. 6.) Category II violations are those that (1) exhibit a "serious potential for harm," (2) show "greater disregard" for public safety or Pharmacy Law, (3) reflect adversely on the licensee's ethics, care, or competence, or (4) result in a criminal conviction not involving controlled substances, their use, or their possession." (Id.) Category III violations include (1) drug related criminal convictions, (2) knowing or willful violations of the Pharmacy Law or the Uniform Controlled Substances Act, and (3) license-related acts of fraud. (Id. at p. 15.) Category IV violations are the most severe; they are not relevant here, and include such violations as possession and transportation of a controlled substance for sale.
- 17. For Category I violations, the Guidelines recommend revocation or stayed revocation with one year of probation. For Category II offenses, the Guidelines recommend revocation or stayed revocation with three years' minimum probation. For Category III violations, the Guidelines prescribe revocation or stayed revocation with 90 days' actual suspension and three to five years of probation. For multiple category violations, the Guidelines recommend imposing penalties for the highest category in which the licensee's conduct falls.
- 18. The following factors are also relevant when determining what discipline to impose on a license: actual or potential harm to the public, actual or potential harm to any consumer, prior disciplinary record, number and variety of current violations, nature and severity of the crimes under consideration, aggravating evidence, mitigating evidence, rehabilitation evidence, compliance with terms of any criminal sentence or probation, overall criminal record, evidence of expungement under Penal Code section 1203.4, time passed since the acts or offenses, whether the conduct was intentional or negligent or demonstrated incompetence, and financial benefit to the respondent from the misconduct. (Guidelines (p. 3); Code, § 4300.)
- 19. All of respondent's violations are Category I or II violations, except the violation of section 4169, subdivision (a)(2) (selling dangerous drugs that the person knew or reasonably should have known were adulterated). Respondent committed multiple violations, some entailing potential harm to patients. Applying all the relevant factors, however, and considering that respondent was not shown to act out of any improper motive, has never before been disciplined, and has taken steps to educate herself to prevent any further violations, the record in this case supports the conclusion that revocation stayed, with three years' probation on appropriate terms and conditions, should suffice to protect the public. The statutes relating to the licensing of professions generally are not designed to punish, but to protect the public from dishonest, untruthful, and disreputable licensees. (*Arneson v. Fox* (1980) 28 Cal.3d 440, 451.)

Cost Recovery

20. Complainant is entitled to the recover reasonable costs of investigation and prosecution of this matter in the amount of \$18,356.25, under Code section 125.3, as set forth in Factual Finding 20.

ORDER

Pharmacist license number RPH 55947, issued to respondent Laura Michelle Dawly, is revoked. The revocation is stayed, however, and respondent's license is placed on probation for three years on 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:

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

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

2. Report to the Board

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

be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board

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

4. Cooperate with Board Staff

Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of 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 case number 5694 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5694 and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 5694 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy

employment service, respondent shall cause her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 5694 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

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

"Employment" within the meaning of this provision shall include any full-time, parttime, 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 \$18,356.25. Respondent shall make said payments on a schedule to be determined 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.

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.

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

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

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

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

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

13. Tolling of Probation

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

Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 30 hours per calendar month in California, respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

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

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 30 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 30 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

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

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

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15. Completion of Probation

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

DATED: January 19, 2018

-- DocuSigned by:

Howard W. Cohen

HOWARD W. COHEN

Administrative Law Judge Office of Administrative Hearings

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8							
9	BEFORE THE						
10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS						
11	STATE OF CALIFORNIA						
12	In the Matter of the Accusation Against:	Case No. 5694					
13	LAURA MICHELLE DAWLY						
14	17152 Century Plant Rd. Apple Valley, CA 92307	ACCUSATION					
15	Pharmacist License No. RPH 55947						
16	Respondent.						
17							
18	Complainant alleges:						
19	<u>PARTIES</u>						
20	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity						
21	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.						
22	2. On or about August 5, 2004, the Board of Pharmacy issued Pharmacist License						
23	Number RPH 55947 to Laura Michelle Dawly (Respondent). From on or about March 8, 2011 to						
24	on or about January 14, 2015, and from on or about May 21, 2015, to the present, Respondent has						
25	been the pharmacist-in-charge of Rite Aid Pharmacy #6514, located at 16120 Bear Valley Road,						
26	Victorville, CA 92395 ("Rite Aid Pharmacy"). T	he Pharmacist License was in full force and					
27	effect at all times relevant to the charges brought	herein and will expire on December 31, 2017,					
28	unless renewed.						
- 11	1						

JURISDICTION

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

STATUTORY PROVISIONS

- 4. Section 4300 states, in part, that "[e]very license issued may be suspended or revoked."
 - 5. Section 4300.1 of the Code states:

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

6. Section 4301 of the Code states, in part, that:

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

. . .

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

. . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter [the Pharmacy Law, Bus. & Prof. Code, § 4000, et seq.) 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."

1	7. Section 4022 of the Code states, in part, that:
2	"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in
3	humans or animals, and includes the following:
4	"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without
5	prescription," "Rx only," or words of similar import.
6	•••
7	"(c) Any other drug or device that by federal or state law can be lawfully dispensed only o
8	prescription or furnished pursuant to Section 4006."

- on
 - 8. Section 4076 of the Code states, in part, that:
- "(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
 - (2) The directions for the use of the drug."
 - Section 4169 of the Code states, in part, that: 9.
 - "(a) A person or entity shall not do any of the following:
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."
 - Section 4342 of the Code states: 10.
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).
- (b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336,"

HEALTH AND SAFETY CODE

11. Health and Safety Code 11172 states: "No person shall antedate or postdate a prescription."

REGULATORY PROVISIONS

- 12. California Code of Regulations, title 16, section 1711, states, in part, that:
- "(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- "(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

 Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created."
 - 13. California Code of Regulations, title 16, section 1716, states, in part, that:
- "Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code."

COST RECOVERY

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

15. DRUG CLASSIFICATIONS

Brand Name	Generic Name	Dangerous Drugs	Controlled	Indications For
		Per Bus. & Prof.	Substance Per	Use
		Code, § 4022	Health & Safety	i
			Code (HSC)	
Ritalin	Methylphenidate	Yes	Yes	ADHD
			HSC §	
			11055(d)(6)	1.
Concerta	Methylphenidate	Yes	Yes	ADHD
	ER		HSC §	
			11055(d)(6)	
Erythrocin	Erythromycin	Yes	No	Antibiotic
Dyazide	Triamterene/HCTZ	Yes	No	Hypertension

FIRST CAUSE FOR DISCIPLINE

(Variation from Prescription)

- 16. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, section 1716, in that Respondent deviated from the requirements of a prescription without the prior consent of the prescriber. The circumstances are as follows:
- 17. On or about January 30, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly processed and verified a prescription as methylphenidate 5mg Rx #320772 to patient MD, instead of the prescribed methylphenidate ER 54mg. On or about February 5, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed methylphenidate ER 54mg Rx #323796 to patient MD.

18. On or about February 17, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly dispensed a prescription for erythromycin 250mg Rx #326326 for patient TF instead of the prescribed patient EF. On or about February 18, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed erythromycin 250mg Rx #326641 for patient EF.

SECOND CAUSE FOR DISCIPLINE

(Dispensing Dangerous Drug in Incorrectly Labeled Container)

- 19. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating section 4076, subdivision (a)(2) of the Code, and California Code of Regulations, title 16, section 1716, for dispensing a dangerous drug in an incorrectly labeled container. The circumstances are as follows:
- 20. On or about April 5, 2013, while working at Rite Aid Pharmacy, Respondent dispensed triamterene/HCTZ 37.5/25 as Rx #262434 to patient RB, which was incorrectly labeled with directions to "take one capsule by mouth once daily one capsule by mouth twice daily," instead of the prescribed directions to "take one capsule daily." On or about April 19, 2013, Respondent corrected the error and processed and verified patient RB's prescription under a new prescription number of Rx #270129.

THIRD CAUSE FOR DISCIPLINE

(Quality Assurance Program)

- 21. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, 1711, subdivisions (d) and (f), for failure to complete quality assurance reports for all reported medication errors. The circumstances are as follows:
- 22. On or about January 6, 2015, a Board inspection of Rite Aid Pharmacy revealed that, while Respondent was the pharmacist-in-charge, Rite Aid Pharmacy did not complete quality assurance reports for all reported medication errors, as follows:
- a. On or about March 8, 2013, and on or about April 5, 2013, patient RB's triamterene/ HCTZ 37.5/25 Rx #262434 was dispensed with the incorrect directions. On or about April 19,

2013, the error was corrected, but there was no quality assurance report of this medication error available when requested on January 6, 2015.

- b. On or about January 30, 2014, patient MD's methylphenidate ER 54mg prescription was incorrectly dispensed as methylphenidate 5mg Rx #320772. On or about February 5, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- c. On or about February 17, 2014, patient EF's erythromycin 250mg was incorrectly dispensed to TF as erythromycin 250mg Rx #326326. On or about February 18, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.

Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 through 20 above, as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Postdating Prescription Prohibited)

- 23. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), of the Code, for violating Health and Safety Code 11172, in that on or about September 26, 2013, Respondent dispensed a post-dated prescription. The circumstances are as follows:
- 24. On September 26, 2013, Rite Aid Pharmacy received a postdated prescription, dated September 29, 2013, for morphine sulfate ER 60mg and morphine sulfate IR 30mg for patient WK. On September 26, 2013, while working at Rite Aid Pharmacy, Respondent dispensed both morphine sulfate ER 60mg Rx #298354 and morphine sulfate IR 30mg Rx #298355 to patient WK.

FIFTH CAUSE FOR DISCIPLINE

(Sales of Preparations or Drugs Lacking Quality or Strength)

25. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating sections 4342 and 4169, subdivision (a)(2), of the Code, for dispensing dangerous drugs that she knew or reasonably should have known were adulterated. The circumstances are as follows:

26. On or about January 30, 2014, while Respondent was the pharmacist-in-charge, patient MD's methylphenidate 5mg Rx #320772 was incorrectly dispensed, and methylphenidate 5mg Rx #320772 medication bottle containing 84 of the 90 dispensed tablets was returned to the pharmacy on February 5, 2014. The methylphenidate 5mg Rx #320772 medication bottle was commingled with the pharmacy's active drug stock and the contents of the returned medication bottle of methylphenidate 5mg were dispensed to another patient. Specifically, on or about May 12, 2014, while Respondent was the pharmacist-in-charge, 60 of patient MD's returned methylphenidate 5mg tablets were used to dispense a prescription for methylphenidate 5mg Rx #344319 to patient MH.

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:

- Revoking or suspending Pharmacist License Number RPH 55947, issued to Laura Michelle Dawly;
- 2. Ordering Laura Michelle Dawly to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
 - 3. Taking such other and further action as deemed necessary and proper.

DATED: _/0/10/16

VIRGINIA HEROLD
Executive Officer

Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

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