

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

In the Matter of the Accusation Against:

RAYMOND CHOW, dba RIVERA PHARMACY

Pharmacy Permit No. PHY 55692,

and

RAYMOND CHOW,

Registered Pharmacist License No. RPH 23215

Respondents.

Agency Case No. 6848

OAH No. 2020040706

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 December 23, 2020.

It is so ORDERED on November 23, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe
Board President

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PROPOSED DECISION

Matthew Goldsby, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter by videoconference on September 1, 2020, in Los Angeles, California.

Mario Cuahutle, Deputy Attorney General, appeared and represented complainant Anne Sodergren, Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Attorney at Law, appeared and represented respondent Raymond Chow, doing business as Rivera Pharmacy under Pharmacy Permit number PHY 55692 (Rivera Pharmacy), and individually under Registered Pharmacist License number RPH 23215.

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on September 1, 2020.

FACTUAL FINDINGS

Jurisdictional Matters

1. On May 18, 2017, the Board issued respondent Original Pharmacy Permit number PHY 55692 to do business as Rivera Pharmacy. The permit is in full force and effect and is scheduled to expire on May 1, 2021.

2. On July 22, 1963, the Board issued respondent Original Pharmacist License number RPH 23215. The license is in full force and effect and is scheduled to expire on April 30, 2022.

3. Respondent is the designated pharmacist-in-charge of Rivera Pharmacy.

4. On February 28, 2020, while acting in her official capacity, complainant brought an Accusation against respondent.

5. On March 20, 2020, respondent timely submitted a Notice of Defense.

Consumer Complaint

6. On May 16, 2018, the Board received a complaint from Prime Therapeutics LLC (Prime), a Pharmacy Benefit Manager. The complaint alleged that an onsite audit revealed that Rivera Pharmacy was submitting claims indicative of fraud, waste, or abuse.

7. On July 18, 2019, a Board Inspector appeared at Rivera Pharmacy to investigate the complaint. The Board Inspector interviewed respondent and a pharmacy technician who were both cooperative and responded to questions. While inspecting the premises, the Board Inspector generally observed that the site was very disorganized. Throughout the facility, the inspector observed expired medications and empty vials.

8. On September 11, 2019, the Board Inspector issued a notice to respondent that Rivera Pharmacy was not complying with the laws governing the practice of pharmacy and the rules and regulations of the Board. As the pharmacist-in-charge of Rivera pharmacy, respondent was found to be in violation of many of the same rules and regulations. As described in further detail below, the Board Inspector concluded respondent was violating laws and regulations relating to compounding facilities and equipment, labeling of compounded drug preparations, recordkeeping of compounded drug preparations, self-assessment, misbranded and adulterated drugs, unprofessional conduct, failure to maintain a current inventory, and furnishing dangerous drugs without a prescription.

Compounding Equipment

9. The Board Inspector examined the interior of a refrigerator onsite. She observed that respondent stored food along with compounded medications. Respondent did not maintain a daily log daily of refrigerator and freezer temperatures where compounded drugs were made and stored.

10. Respondent demonstrated to the Board Inspector how he measures and weighs compounded medications. Respondent did not have records to show whether the scales were regularly calibrated.

11. The Board inspector observed that the workspace where respondent compounded medications was dirty. Photographs show that, at the time of inspection, a compounding work area had papers and prescription bags scattered on the surface of the work area. A sink area was cluttered with empty pill bottles and compounding tools as well as other things unrelated to compounding medications, including a container of M&M's, a bag of Milano cookies, a mango, dishwashing liquid, a bottle of bubble bath, and cannisters of hair spray and shave cream.

12. Pursuant to regulations adopted by the Board, each licensed pharmacy is required to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. (Cal. Code Regs., tit. 16, § 1714, subd. (b).) Any pharmacy engaged in compounding is required to maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations, including records of maintenance and cleaning of the facilities and equipment. (Cal. Code Regs., tit. 16, § 1735.6, subd. (a).) Any equipment used to compound drug preparations must be stored, used, maintained, and cleaned in accordance with manufacturers'

specifications. (Cal. Code Regs., tit. 16, § 1735.6, subd. (b).) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate must be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration must be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy. (Cal. Code Regs., tit. 16, § 1735.6, subd. (c).)

13. Respondent did not have a written compounding policy and procedure in place. Any pharmacy engaged in compounding is required to maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (Cal. Code Regs., tit. 16, § 1735.5, subd. (a).) The policies and procedures must be reviewed on an annual basis by the pharmacist-in-charge and each review must be documented. The policies and procedures must be updated whenever changes in policies and procedures are implemented. (Cal. Code Regs., tit. 16, § 1735.5, subd. (b).) At minimum, the policies and procedures must include specific provisions enumerated by the regulations. (Cal. Code Regs., tit. 16, § 1735.5, subd. (c).)

14. The Board Inspector concluded that respondent was violating Board regulations by failing to maintain and document daily the refrigerator and freezer temperatures where compounded drugs were stored, for not having any compounding policy and procedure, and for having a dirty compounding space.

Improper Labeling of Compounded Drug Preparations

15. The regulations provide that each compounded drug preparation must be affixed with a container label prior to dispensing that contains at least: the name of the compounding pharmacy and dispensing pharmacy; the name (brand or generic) and strength, volume, or weight of each active ingredient; instructions for storage, handling, and administration; the beyond use date for the drug preparation; the date compounded; and the lot number or pharmacy reference number. (Cal. Code Regs., tit. 16, § 1735.4, subd. (a).)

16. The Board Inspector found that respondent failed to label prescription number 805056 with the name and strength, volume or weight of each active ingredient, the date compounded the lot number or pharmacy reference number, instructions for storage, handling and a statement that the drug had been compounded by Rivera pharmacy. Photographs show numerous unlabeled pill bottles throughout the premises which contained unknown pills. The Board Inspector also observed that, between December 1, 2017, and July 16, 2019, respondent compounded 22 prescriptions without proper labeling.

17. The Board Inspector concluded that respondent was violating the regulations based on her observations that respondent was not properly labeling compounding prescriptions.

Recordkeeping of Compounded Drug Preparation

18. Pursuant to regulations adopted by the Board, a drug preparation must not be compounded until the pharmacy has first prepared a written master formula document that includes at least eight elements required by the regulations. (Cal. Code

Regs., tit. 16, § 1735.2, subd. (e).) In addition, for each compounded drug preparation, pharmacy records are required to include the master formula document and a compounding log consisting of a single document containing 10 enumerated points of information, including but not limited to the name and strength of the compounded drug preparation, the date the drug preparation was compounded, and the quantity of each ingredient used in compounding the drug preparation. (Cal. Code Regs., tit. 16, § 1735.3, subd. (a).)

19. The Board Inspector concluded that respondent violated these regulations by compounding prescription number 805056 and the 22 prescriptions described at Factual Finding 16 without having a master formula or compounding log.

Self-Assessment

20. The regulations require the pharmacist-in-charge of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, § 1715.)

21. Also, prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge is required to complete a self-assessment for compounding pharmacies in the form and manner developed by the Board. (Cal. Code Regs., tit. 16, § 1725.2, subd. (k).)

22. The Board Inspector concluded that respondent was violating the regulations because respondent failed to complete the pharmacy and compounding self-assessments. When interviewed as the pharmacist-in-charge, respondent admitted that he was not familiar with the self-assessment requirements.

Misbranding

23. Board Inspector observed multiple expired medications, unlabeled or improperly labeled prescription vials in respondent's active stock area.

24. The law prohibits any person from purchasing, trading, selling, or transferring dangerous drugs that the person knew or reasonably should have known were adulterated. (Bus. & Prof. Code, § 4169, subd. (a)(2), Health & Saf. Code, § 111250 et seq.)

25. The Board Inspector concluded that respondent was violating the law by holding misbranded or adulterated drugs in its active drug stock.

Unprofessional Conduct

26. Unprofessional conduct includes the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not. (Bus. & Prof. Code, §4301, subd. (f).)

27. Unprofessional conduct also includes acts or omissions that involve, in whole or in part, the inappropriate exercise of a pharmacist's education, training, or experience, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a licensed pharmacy. (Bus. & Prof. Code, §4306.5, subd. (a).)

28. The Board Inspector identified 51 prescriptions that Rivera pharmacy had billed insurance companies from February 2019 through June 2019 that were not dispensed to any patient. The Board Inspector observed no evidence of a reversed

insurance claim for those prescriptions as of the date of the inspection on July 18, 2019. The Board Inspector determined that these practices violated Business and Professions Code sections 4301, subdivision (f), and 4306.5, subdivision (a).

29. At hearing, respondent presented evidence that reversals for the medications were processed and accepted on July 22, 2019. (Ex. D.)

Audit Results

30. In its complaint to the Board, Prime alleged that Rivera Pharmacy “did not purchase sufficient quantity to support the quantity billed” to Prime. (Ex. G.) Specifically, Prime alleged Rivera Pharmacy billed 270 tablets of Albutrol 2 mg and 1,920 tablets of Sucralfate 1 gm, and that an onsite audit conducted by Prime revealed that Rivera Pharmacy had not acquired these medications prior to billing Prime.

31. The Board Inspector performed an audit for the period from December 1, 2017 of July 16, 2019. The Board Inspector inquired with eight wholesalers and received records of purchases, returns, and credits from those that had any such records. (Ex. 5, pp. 76 and 255.) The Board Inspector determined that respondent had acquired no tablets of Albutrol 2 mg during the audit period, but disposed of 90 tablets, resulting in an overage. The Board Inspector also determined that Rivera Pharmacy had acquired 800 tablets of Sucralfate 1 gm during the audit period, and disposed of 1,942 such tablets during the audit period, also resulting in an overage.

32. At hearing, respondent presented invoices dated in 2016 to reflect purchases of both medications. However, the acquisition dates were not within the audit period and the evidence was insufficient to rebut the findings of the Board Inspector. Accordingly, the audit revealed respondent failed to maintain a current

inventory as required by the regulations. (Cal Code Regs., tit. 16, § 1718, Bus & Prof. Code, § 4081, subd. (a).)

33. The audit further revealed that respondent refilled and dispensed prescription number 721284 for patient MS for a higher quantity than the prescribed. The Board Inspector determined that, in doing so, respondent furnished a dangerous drug without a prescription from a physician in violation of Business and Professions Code section 4059, subdivision (a.) Respondent presented evidence that a physician who had not responded to the Board Inspector had authorized to fill six additional refills of prescription number 721284 for patient MS. (Ex. I.)

Corrective Action

34. On July 22, 2019, respondent completed a 32-page Community Pharmacy Self-Assessment (Form 17M-13, rev. 10/14) in compliance with California Code of Regulations, title 16, section 1715.

35. On August 1, 2020, respondent implemented a standard operating procedure entitled "Fridge Temperature Monitoring." (Exhibit B.) The policy provides that all pharmaceuticals requiring cold storage shall be refrigerated immediately on delivery and that "stock [shall be] rotated to ensure the shortest date stock is used first." (Exhibit B) The policy includes a temperature log for daily temperature readings. Respondent presented evidence of daily entries for the months of June and July 2020.

36. Respondent now maintains a box for outdated medications. Rivera Pharmacy changed its practice and now removes expired medications from the shelves and places them in a large box labeled "expired meds outdate." (Exhibit E.) In addition, Rivera Pharmacy retained Outdate RX to service pharmaceutical returns. (Exhibit F.)

37. Respondent testified that he has operated Rivera Pharmacy and served the community for 56 years, that he “just wants to help,” that he performs many services for no charge, and that he would like to continue operating. He acknowledged that “things [he] did were wrong” and asserted that he “learned a big lesson.”

38. In April 2017, the building in which Rivera Pharmacy was operating was damaged by fire. The building required a new roof and new flooring. Respondent’s operations moved to a smaller facility until the repairs were completed. In 2019, respondent moved the pharmacy back to its original location. In his testimony, respondent attributed some of the “mess” to the process of moving back into the original premises.

39. Respondent presented character reference letters in defense of the accusation. David Bernal, M.D., is aware of the charges against respondent and wrote that he has known respondent for 29 years, and that he considers respondent’s work ethic and desire to serve the community are qualities that set him apart from other pharmacists. Dr. Bernal asserted that respondent’s character “exhibits attributes such as integrity, honesty, valor, loyalty, determination, and other important virtues that promote great performance and habits which play a vital role his success.” (Ex. H, p. H-1.) Victor Law has known respondent for 35 years and describes respondent as “an exceptional human being, not only by providing accurate dispensing prescription medications but, going above and beyond for members of the community.” (*Id.* at H-2.) Jennifer Chang, a pharmacist licensed by the Board, wrote that respondent “has demonstrated that he cares very much about his community, diligently serving the low-income residents of Pico Rivera for decades.” (*Id.* at H-3.) Patrick F. Wickhem, a sales representative for a pharmaceutical company, has known respondent “for more than 40 years” and described respondent as “one of the most dedicated,

compassionate and hard-working people [he has] had the pleasure of working with and observing during [his] 37 year pharmaceutical career.” (*Id.* at H-4.) Ronald E Pinkerton, M.D., described respondent as “highly intelligent, up-to-date with all new pharmaceutical information . . . [and] very giving and caring for the community providing free delivery to elderly patients and now to all COVID-19 patients that are home quarantined.” (*Id.* at H-5.) Jose Manuel Diaz, M.D., described respondent as “reliable, dependable, and courteous with all his customers” adding further, “His most important quality is that he is honest and humble.” (*Id.* at H-6.)

Costs

40. Complainant incurred prosecution costs in the amount of \$5,811.25 and investigation costs in the sum of \$8,418.50, evidenced by declarations and detailed billing statements. The costs, totaling \$14,229.75, are reasonable considering the complexity of the case.

LEGAL CONCLUSIONS

Standard of Proof

1. As the party bringing administrative charges and seeking discipline against licensee, complainant bears the burden of proof. (*Parker v. City of Fountain Valley* (1981) 127 Cal.App.3d 99, 113; *Brown v. City of Los Angeles* (2002) 102 Cal.App.4th 155, 175-176.)

2. In an action seeking disciplinary action against a professional license, the governing agency bears the burden of establishing cause for discipline by clear

and convincing proof to a reasonable certainty. (*Ettinger v. Board of Med. Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

Cause for Discipline

3. Every license issued by the Board may be suspended or revoked. (Bus. & Prof. Code, § 4300, subd. (a).)

4. The Board must take action against any licensee who is guilty of unprofessional conduct. (Bus. & Prof. Code, §4301.)

5. Unprofessional conduct includes 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 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. (Bus. & Prof. Code, § 4301, subd. (o).)

6. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent violated California Code of Regulations, title 16, sections 1714, subdivision (b), 1735.5, subdivisions (a) through (c), and 1735.6, subdivisions (a) through (c), by failing to maintain and document daily the refrigerator and freezer temperatures where compounded medications were stored, not having any compounding policy and procedure in place, and having a dirty workspace for compounding medications.

7. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent violated California Code of Regulations, title 16, sections 1735.4, subdivisions (a) and (c), by failing to properly label compounded prescriptions.

8. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent violated California Code of Regulations, title 16, sections 1735.2, subdivision (e), and 1735.3, subdivision (a), by compounding medications without a master formula or compounding log.

9. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent violated California Code of Regulations, title 16, sections 1715 and 1735.2, subdivision (k), by failing failed to timely complete pharmacy and compounding self-assessments.

10. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent violated Business and Professions Code section 4169, subdivision (a)(2), by holding misbranded or adulterated drugs as part of the pharmacy's active drug stock.

11. Cause does not exist to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License under Business and Professions Code sections 4300, 4301, subdivision (f), and 4306.5, subdivision (a), because it was not established

by clear and convincing evidence that respondent engaged in unprofessional conduct in his billing practices.

12. Cause exists to suspend or revoke respondent's Pharmacy Permit and Registered Pharmacist License Business and Professions Code sections 4300 and 4301, subdivision (o), because respondent failed to maintain an accurate inventory in violation of Business and Professions Code sections 4081.

13. Cause does not exist to suspend or revoke respondent's Pharmacy Permit and Pharmacist License under Business and Professions Code sections 4300 and 4301, subdivision (o), because it was not established by clear and convincing evidence that respondent engaged in unprofessional conduct by furnishing dangerous drugs without a prescription respondent furnished a dangerous drug without a prescription from a physician in violation of Business and Professions Code section 4059, subdivision (a).

Level of Discipline

14. In reaching a decision on the appropriate level of discipline, the Board must consider the *Disciplinary Guidelines, A Manual of Disciplinary Guidelines and Model Disciplinary Orders (Rev. 2/2017)*. The Board has identified four categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the least serious (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violations in one or more categories, may merit revocation.

15. In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the guidelines identify the following factors to be considered: actual or potential harm to the public; actual or potential harm to any consumer; prior disciplinary record, including level of compliance with disciplinary orders; prior warnings, including but not limited to citations and fines, letters of admonishment, and/or correction notices; number and/or variety of current violations; nature and severity of the acts, offenses or crimes under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; compliance with terms of any criminal sentence, parole, or probation; overall criminal record; if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code; 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, the respondent had knowledge of or knowingly participated in such conduct; financial benefit to the respondent from the misconduct; other licenses held by the respondent and license history of those licenses; and Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (see Business and Professions Code Section 315).

16. In this case, although there was no evidence of actual harm to any patient, respondent was operating Rivera Pharmacy in a manner that posed a serious potential for harm. Respondent committed numerous violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. These violations reflect on respondent's competence and diligence. Accordingly, Category II is the most appropriate category of respondent's violations in this case. The guidelines recommend a maximum penalty of revocation and a

minimum penalty of three years' probation including standard terms and conditions and optional terms and conditions deemed appropriate.

17. The task in disciplinary cases is preventative, protective and remedial, not punitive. (*In re Kelley* (1990) 52 Cal.3d 487, 496.) Revocation of respondent's Pharmacy Permit and Registered Pharmacist License would be unduly punitive considering the mitigation evidence presented by respondent at hearing. Respondent has undertaken corrective action to prevent a recurrence of the same violations. He has a lengthy history of licensure with no prior disciplinary record and no prior warnings relating to citable offenses. The character reference letters presented as mitigating evidence portray respondent as a caring and dedicated pharmacist and do not indicate that any inherent character trait prevents respondent from performing in compliance with the Board's regulations. The fire that caused respondent to temporarily relocate does not excuse compliance with the regulations, but may have reasonably contributed to the disorganized state of respondent's practice as he moved back into the reconstructed premises.

18. Under the circumstances, standard terms and conditions of probation for four years will serve the preventative, protective and remedial purposes of discipline.

Recovery of Costs

19. The Board is entitled to recover all reasonable costs incurred to investigate and prosecute this matter. (Bus. & Prof. Code, § 125.3.)

20. Complainant incurred reasonable costs in the total amount of \$14,229.75. Accordingly, complainant's costs are allowed in the amount of \$14,229.75, to be paid during probation as ordered below.

ORDER

Pharmacy Permit PHY 55692, issued to Raymond Chow doing business as Rivera Pharmacy, and Registered Pharmacist License RPH 23215, issued to Raymond Chow, are revoked; however, the revocations are stayed and respondent is placed on probation for four years upon the following terms and conditions:

1. Definition of Respondent

For the purposes of these terms and conditions, "respondent" shall refer to Raymond Chow, individually and doing business as Rivera Pharmacy. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. 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 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, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another 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.

3. 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 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.

4. 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 or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. Continuing Education

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

7. Reporting of Employment and Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6848 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within 30 days of the effective date of this decision, and within 10 days of undertaking any new employment, respondent shall report to the Board in writing the name, physical address, and mailing address of each of his employers, and the names and telephone numbers of all of his direct supervisors, as well as any pharmacists-in-charge, designated representatives-in-charge, responsible manager, or other compliance supervisors and the work schedule, if known. Respondent shall also include the reasons for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of respondent's employers and supervisors, and authorizing those employers or supervisors to communicate with the Board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number , and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgments are timely submitted to the Board. In the event of a change in the persons serving the roles described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the Board in writing within 15 days of the change acknowledging

that he or she has read the decision in case number 6848, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 6848, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

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

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

8. Notification of Change in Name, Address, or Phone Number

Respondent shall further notify the Board in writing within 10 days of any change in name, residence address, mailing address, e-mail address or phone number.

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

9. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if respondent or that entity retains, at his expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a quarterly basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his supervisory position. Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within 30 days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

10. 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 \$14,229.75, payable in installments of no less than \$474.35 per month beginning on the first day of the month following the effective date of this decision and continuing until paid in full.

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.

Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one year prior to the end date of probation.

11. 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.

12. Status of License

Respondent shall, at all times while on probation, maintain an active, current Pharmacy Permit and Registered Pharmacist License with the Board, including any period during which suspension or probation is tolled.

Failure to maintain an active, current Pharmacy Permit and Registered Pharmacist License shall be considered a violation of probation.

If respondent's Pharmacy Permit or Registered Pharmacist 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.

13. Pharmacist License Surrender While on Probation

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

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board within 10 days of notification by the Board that the surrender is accepted if not already provided.

Respondent may not reapply for any license from the Board for three 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.

14. 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 80 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 calendar month, for any reason (including vacation), respondent shall notify the Board in writing within 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 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 36 months. The Board or its designee may post a notice of the extended probation period on its website.

15. Pharmacy Permit Surrender While on Probation

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take

any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new 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.

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

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

the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding 60 days.

Respondent may not apply for any new license from the board for three 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.

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

16. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the Pharmacy Permit issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the Board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

17. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it

shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within 15 days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

18. Owners and Officers: Knowledge of the Law

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

19. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a pharmacy in California for a minimum of 120 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 with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a pharmacy for a minimum of hours in any 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 minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a [insert license type] in California for a minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

20. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the Board or its designee in a place conspicuous to and readable by the public within two days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

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

21. Violation of Probation

If respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent, and the Board shall provide notice to respondent that 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. The Board or its designee may post a notice of the extended probation period on its website.

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. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, 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.

22. 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: September 29, 2020

DocuSigned by:
Matthew Goldsby
8CC911E7989041F...

Administrative Law Judge

Office of Administrative Hearings

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7

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

11 In the Matter of the Accusation Against:

Case No. 6848

12 **RAYMOND CHOW, DBA RIVERA**
13 **PHARMACY**
14 **9253 Telegraph Rd.**
Pico Rivera, CA 90660

ACCUSATION

15 **Pharmacy Permit No. PHY 55692,**

16 **and**

17 **RAYMOND CHOW**
18 **9253 Telegraph Rd.**
Pico Rivera, CA 90660

19 **Registered Pharmacist License No. RPH**
20 **23215**

21 Respondent.

22
23 **PARTIES**

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

26 2. On or about May 18, 2017, the Board of Pharmacy issued Pharmacy Permit Number
27 PHY 55692 to Raymond Chow, dba Rivera Pharmacy (Respondent Pharmacy). The Pharmacy

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1 Permit was in full force and effect at all times relevant to the charges brought herein and will
2 expire on May 1, 2020, unless renewed.

3 3. On or about July 22, 1963, the Board of Pharmacy issued Registered Pharmacist
4 License Number RPH 23215 to Raymond Chow (Respondent Chow). The Registered Pharmacist
5 License was in full force and effect at all times relevant to the charges brought herein and will
6 expire on April 30, 2020, unless renewed.

7 **JURISDICTION**

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

11 5. Section 4300 of the Code states:

12 (a) Every license issued may be suspended or revoked.

13 (b) The board shall discipline the holder of any license issued by the board,
14 whose default has been entered or whose case has been heard by the board and found
guilty, by any of the following methods:

15 (1) Suspending judgment.

16 (2) Placing him or her upon probation.

17 (3) Suspending his or her right to practice for a period not exceeding one year.

18 (4) Revoking his or her license.

19 (5) Taking any other action in relation to disciplining him or her as the board in
20 its discretion may deem proper.

21 (c) The board may refuse a license to any applicant guilty of unprofessional
22 conduct. The board may, in its sole discretion, issue a probationary license to any
23 applicant for a license who is guilty of unprofessional conduct and who has met all
other requirements for licensure. The board may issue the license subject to any
terms or conditions not contrary to public policy, including, but not limited to, the
following:

24 (1) Medical or psychiatric evaluation.

25 (2) Continuing medical or psychiatric treatment.

26 (3) Restriction of type or circumstances of practice.

27 (4) Continuing participation in a board-approved rehabilitation program.

28 (5) Abstention from the use of alcohol or drugs.

1 (6) Random fluid testing for alcohol or drugs.

2 (7) Compliance with laws and regulations governing the practice of pharmacy.

3 (d) The board may initiate disciplinary proceedings to revoke or suspend any
4 probationary certificate of licensure for any violation of the terms and conditions of
probation. Upon satisfactory completion of probation, the board shall convert the
probationary certificate to a regular certificate, free of conditions.

5 (e) The proceedings under this article shall be conducted in accordance with
6 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
7 Government Code, and the board shall have all the powers granted therein. The
action shall be final, except that the propriety of the action is subject to review by the
superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

8 6. Section 4300.1 of the Code states:

9 The expiration, cancellation, forfeiture, or suspension of a board-issued license
10 by operation of law or by order or decision of the board or a court of law, the
11 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
12 investigation of, or action or disciplinary proceeding against, the licensee or to render
a decision suspending or revoking the license.

13 7. Section 4307(a) of the Code states:

14 Any person who has been denied a license or whose license has been revoked
15 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,
16 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
17 been denied or revoked, is under suspension or has been placed on probation, and
while acting as the manager, administrator, owner, member, officer, director,
18 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,
19 suspended, or placed on probation, shall be prohibited from serving as a manager,
administrator, owner, member, officer, director, associate, partner, or in any other
20 position with management or control of a licensee as follows:

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

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

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STATUTORY PROVISIONS

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2 8. Section 4036.5 states: “Pharmacist-in-charge” means a pharmacist proposed by a
3 pharmacy and approved by the board as the supervisor or manager responsible for ensuring the
4 pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of
5 pharmacy.”

6 9. Section 4063 states: “No prescription for any dangerous drug or dangerous device
7 may be refilled except upon authorization of the prescriber. The authorization may be given orally
8 or at the time of giving the original prescription. No prescription for any dangerous drug that is a
9 controlled substance may be designated refillable as needed.”

10 10. Section 4169 states, in pertinent part:

11 (a) A person or entity shall not do any of the following:

12 (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably
13 should have known were adulterated, as set forth in Article 2 (commencing with Section 111250)
14 of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

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

18 11. Section 4301 of the Code states:

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

21 (a) Procurement of a license by fraud or misrepresentation.

22 (b) Incompetence.

23 (c) Gross negligence.

24 (d) The clearly excessive furnishing of controlled substances in violation of
25 subdivision (a) of Section 11153 of the Health and Safety Code.

26 (e) The clearly excessive furnishing of controlled substances in violation of
27 subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be
28 considered in determining whether the furnishing of controlled substances is clearly
excessive shall include, but not be limited to, the amount of controlled substances
furnished, the previous ordering pattern of the customer (including size and frequency

1 of orders), the type and size of the customer, and where and to whom the customer
2 distributes its product.

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

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

8 (h) The administering to oneself, of any controlled substance, or the use of any
9 dangerous drug or of alcoholic beverages to the extent or in a manner as to be
10 dangerous or injurious to oneself, to a person holding a license under this chapter, or
11 to any other person or to the public, or to the extent that the use impairs the ability of
12 the person to conduct with safety to the public the practice authorized by the license.

13 (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving
14 away, or administering, or offering to sell, furnish, give away, or administer, any
15 controlled substance to an addict.

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

18 (k) The conviction of more than one misdemeanor or any felony involving the
19 use, consumption, or self-administration of any dangerous drug or alcoholic beverage,
20 or any combination of those substances.

21 (l) The conviction of a crime substantially related to the qualifications,
22 functions, and duties of a licensee under this chapter. The record of conviction of a
23 violation of Chapter 13 (commencing with Section 801) of Title 21 of the United
24 States Code regulating controlled substances or of a violation of the statutes of this
25 state regulating controlled substances or dangerous drugs shall be conclusive
26 evidence of unprofessional conduct. In all other cases, the record of conviction shall
27 be conclusive evidence only of the fact that the conviction occurred. The board may
28 inquire into the circumstances surrounding the commission of the crime, in order to
fix the degree of discipline or, in the case of a conviction not involving controlled
substances or dangerous drugs, to determine if the conviction is of an offense
substantially related to the qualifications, functions, and duties of a licensee under this
chapter. A plea or verdict of guilty or a conviction following a plea of nolo
contendere is deemed to be a conviction within the meaning of this provision. The
board may take action when the time for appeal has elapsed, or the judgment of
conviction has been affirmed on appeal or when an order granting probation is made
suspending the imposition of sentence, irrespective of a subsequent order under
Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of
guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or
dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing
with Section 801) of Title 21 of the United States Code regulating controlled
substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9
of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license
to practice pharmacy, operate a pharmacy, or do any other act for which a license is
required by this chapter that would be grounds for revocation, suspension, or other
discipline under this chapter. Any disciplinary action taken by the board pursuant to

1 this section shall be coterminous with action taken by another state, except that the
2 term of any discipline taken by the board may exceed that of another state, consistent
with the board's enforcement guidelines. The evidence of discipline by another state
is conclusive proof of unprofessional conduct.

3 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
4 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,
5 including regulations established by the board or by any other state or federal
regulatory agency.

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

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

9 (r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to
10 Section 256b of Title 42 of the United States Code to any person a licensee knows or
reasonably should have known, not to be a patient of a covered entity, as defined in
paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

11 (s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a
12 pharmacy that primarily or solely dispenses prescription drugs to patients of long-
term care facilities. Factors to be considered in determining whether the furnishing of
13 dangerous drugs is clearly excessive shall include, but not be limited to, the amount
of dangerous drugs furnished to a pharmacy that primarily or solely dispenses
14 prescription drugs to patients of long-term care facilities, the previous ordering
pattern of the pharmacy, and the general patient population to whom the pharmacy
15 distributes the dangerous drugs. That a wholesaler has established, and employs, a
tracking system that complies with the requirements of subdivision (b) of Section
16 4164 shall be considered in determining whether there has been a violation of this
subdivision. This provision shall not be interpreted to require a wholesaler to obtain

17 personal medical information or be authorized to permit a wholesaler to have access
to personal medical information except as otherwise authorized by Section 56 and
18 following of the Civil Code. For purposes of this section, long-term care facility shall
19 have the same meaning given the term in Section 1418 of the Health and Safety Code.

20 12. Section 4059 of the Code states, in pertinent part, that a person may not furnish any
21 dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist,
22 veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any
23 dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist,
24 veterinarian, or naturopathic doctor pursuant to Section 3640.7.

25 13. Section 4081 of the Code states:

26 (a) All records of manufacture and of sale, acquisition, or disposition of
27 dangerous drugs or dangerous devices shall be at all times during business hours open
to inspection by authorized officers of the law, and shall be preserved for at least
28 three years from the date of making. A current inventory shall be kept by every
manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician,

1 dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or
2 establishment holding a currently valid and unrevoked certificate, license, permit,
3 registration, or exemption under Division 2 (commencing with Section 1200) of the
4 Health and Safety Code or under Part 4 (commencing with Section 16000) of
5 Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous
6 drugs or dangerous devices.

7 (b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary
8 food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge
9 or representative-in-charge, for maintaining the records and inventory described in
10 this section.

11 (c) The pharmacist-in-charge or representative-in-charge shall not be criminally
12 responsible for acts of the owner, officer, partner, or employee that violate this
13 section and of which the pharmacist-in-charge or representative-in-charge had no
14 knowledge, or in which he or she did not knowingly participate.

15 14. Section 4306.5 states, in pertinent part:

16 “Unprofessional conduct for a pharmacist may include any of the following:

17 (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or
18 her education, training, or experience as a pharmacist, whether or not the act or omission arises in
19 the course of the practice of pharmacy or the ownership, management, administration, or
20 operation of a pharmacy or other entity licensed by the board.”

21 15. Section 4332 states: “Any person who fails, neglects, or refuses to maintain the
22 records required by Section 4081 or who, when called upon by an authorized officer or a member
23 of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time,
24 or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.”

25 **REGULATORY PROVISIONS**

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

27 “(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
28 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.”

17. California Code of Regulations, title 16, section 1715 states, in pertinent part:

///

1 “(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
2 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's
3 compliance with federal and state pharmacy law. The assessment shall be performed before July 1
4 of every odd-numbered year. The primary purpose of the self-assessment is to promote
5 compliance through self-examination and education.”

6 ...

7 (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is
8 performed.”

9 18. California Code of Regulations, title 16, section 1718, states:

10 “Current Inventory” as used in Sections 4081 and 4332 of the Business and
11 Professions Code shall be considered to include complete accountability for all
12 dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

13 The controlled substances inventories required by Title 21, CFR, Section 1304
14 shall be available for inspection upon request for at least 3 years after the date of the
15 inventory.”

16 19. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

17 “(e) A drug preparation shall not be compounded until the pharmacy has first prepared a
18 written master formula document that includes at least the following elements:

19 (1) Active ingredients to be used.

20 (2) Equipment to be used.

21 (3) The maximum allowable beyond use date for the preparation, and the rationale or reference
22 source justifying its determination.

23 (4) Inactive ingredients to be used.

24 (5) Specific and essential compounding steps used to prepare the drug.

25 (6) Quality reviews required at each step in preparation of the drug.

26 (7) Post-compounding process or procedures required, if any.

27 (8) Instructions for storage and handling of the compounded drug preparation.”

28 ...

 “(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the
pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by
the board (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy
Compounding Self-Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title

1 16, Division 17, of the California Code of Regulations. That form contains a first section
2 applicable to all compounding, and a second section applicable to sterile injectable compounding.
3 The first section must be completed by the pharmacist-in-charge before any compounding is
4 performed in the pharmacy. The second section must be completed by the pharmacist-in-charge
5 before any sterile compounding is performed in the pharmacy. The applicable sections of the self-
6 assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30
7 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of
8 the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote
9 compliance through self-examination and education.”

10 20. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

11 “(a) For each compounded drug preparation, pharmacy records shall include:

12 (1) The master formula document.

13 (2) A compounding log consisting of a single document containing all of the following:

14 (A) Name and Strength of the compounded drug preparation.

15 (B) The date the drug preparation was compounded.

16 (C) The identity of any pharmacy personnel engaged in compounding the drug
17 preparation.

18 (D) The identity of the pharmacist reviewing the final drug preparation.

19 (E) The quantity of each ingredient used in compounding the drug preparation.

20 (F) The manufacturer, expiration date and lot number of each component. If the
21 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If
22 the manufacturer does not supply an expiration date for any component, the records shall include
23 the date of receipt of the component in the pharmacy, and the limitations of section 1735.2,
24 subdivision (I) shall apply.

25 (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile
26 preparations compounded in a single lot for administration within seventy-two (72) hours to a
27 patient in a health care facility licensed under section 1250 of the Health and Safety Code and
28 stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United
States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th
Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug
preparation.

1 (H) The beyond use date or beyond use date and time of the final compounded drug
preparation, expressed in the compounding document in a standard date and time format.

2 (I) The final quantity or amount of drug preparation compounded for dispensing.

3 (J) Documentation of quality reviews and required post-compounding process and
4 procedures.”

5 21. California Code of Regulations, title 16, section 1735.4 states:

6 “(a) Each compounded drug preparation shall be affixed with a container label prior to
7 dispensing that contains at least:

8 (1) Name of the compounding pharmacy and dispensing pharmacy (if different);

9 (2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For
10 admixed IV solutions, the intravenous solution utilized shall be included;

11 (3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate
of infusion shall be included;

12 (4) The beyond use date for the drug preparation;

13 (5) The date compounded; and

14 (6) The lot number or pharmacy reference number.

15 (b) Any compounded drug preparation dispensed to a patient or readied for dispensing to
16 a patient shall also include on the label the information required under Business and Professions
17 Code section 4076 and California Code of Regulations, title 16, section 1707.5.

18 (c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a
19 patient shall also include, on the container label or on a receipt provided to the patient, a
statement that the drug has been compounded by the pharmacy.

20 (d) Prior to dispensing drug preparations compounded into unit-dose containers that are
21 too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be
22 labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if
23 different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation,
24 pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font
size requirements. Once dispensed, outer packaging must comply with 1735.4(a) - (c).

25 (e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of
26 Properly” or “Hazardous - Dispose of Properly.”

27 22. California Code of Regulations, title 16, section 1735.5 states:

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

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

9 (c) The policies and procedures shall include at least the following:

10 (1) Procedures for notifying staff assigned to compounding duties of any changes in
11 policies or procedures.

12 (2) A written plan for recall of a dispensed compounded drug preparation where subsequent
13 information demonstrates the potential for adverse effects with continued use. The plan shall
14 ensure that all affected doses can be accounted for during the recall and shall provide steps to
15 identify which patients received the affected lot or compounded drug preparation(s).

16 (3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment
17 used in compounding, and for training on these procedures as part of the staff training and
18 competency evaluation process.

19 (4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility
20 (physical plant) used for compounding, and for training on these procedures as part of the staff
21 training and competency evaluation process.

22 (5) Documentation of the methodology used to validate integrity, potency, quality, and
23 labeled strength of compounded drug preparations. The methodology must be appropriate to
24 compounded drug preparations.

25 (6) Documentation of the methodology and rationale or reference source used to determine
26 appropriate beyond use dates for compounded drug preparations.

27 (7) Dates and signatures reflecting all annual reviews of the policies and procedures by the
28 pharmacist-in-charge.

 (8) Dates and signatures accompanying any revisions to the policies and procedures
approved by the pharmacist-in-charge.

 (9) Policies and procedures for storage of compounded drug preparations in the pharmacy
and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

1 (10) Policies and procedures regarding ensuring appropriate functioning of refrigeration
2 devices, monitoring refrigeration device temperatures, and actions to take regarding any out of
3 range temperature variations within the pharmacy.

4 (11) Policies and procedures for proper garbing when compounding with hazardous
5 products. This shall include when to utilize double shoe covers.”

6 23. California Code of Regulations, title 16, section 1735.6 states, in pertinent part:

7 “(a) Any pharmacy engaged in compounding shall maintain written documentation
8 regarding the facilities and equipment necessary for safe and accurate compounding of
9 compounded drug preparations. This shall include records of maintenance and cleaning of the
10 facilities and equipment. Where applicable, this shall also include records of certification(s) of
11 facilities or equipment.

12 (b) Any equipment used to compound drug preparations shall be stored, used, maintained,
13 and cleaned in accordance with manufacturers' specifications.

14 (c) Any equipment that weighs, measures, or transfers ingredients used to compound drug
15 preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on
16 a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.
17 Documentation of each such calibration shall be recorded in a form which is not alterable and
18 these records of calibration shall be maintained and retained in the pharmacy.”

19 COST RECOVERY

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

24 DANGEROUS DRUGS

25 25. Albuterol, is a dangerous drug pursuant to Business and Professions Code section
26 4022.

27 26. Sucralfate, is a dangerous drug pursuant to Business and Professions Code section
28 4022.

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FACTUAL ALLEGATIONS

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2 27. On or about May 16, 2018, the Board received a complaint from a Pharmacy Benefit
3 Manager (PBM) alleging Respondent Pharmacy had submitted claims to PBM that may be
4 indicative of fraud, waste or abuse. PBM conducted an onsite audit of Respondent Pharmacy,
5 which identified the following deficiencies: invoice quantity shortages, unauthorized refill, miss
6 prescription elements and dispensing a prescription to a patient that was not inspected by the
7 pharmacist.

8 28. On or about July 18, 2019, a Board inspector performed a complaint investigation and
9 inspection of Respondent Pharmacy. The Board inspector interviewed both Respondent Chow,
10 Pharmacist-in-Charge, and the pharmacy technician. The Board inspector noted that Respondents
11 failed to maintain and document daily refrigerator and freezer temperature where compounded
12 drug preparations were stored. Respondents also failed to have a compounding policy and
13 procedure and maintained a dirty compounding space.

14 29. The Board inspector noted that Respondents were not properly labeling compounded
15 prescriptions. Specifically, prescription number 805056 was not properly labeled with the name
16 (*brand or generic*) and strength, volume or weight of each active ingredient, the date
17 compounded the lot number or pharmacy reference number, instructions for storage, handling and
18 a statement that the drug has been compounded by the pharmacy. Subsequently, the Board
19 inspector received additional compounded prescriptions from Respondents, which also lacked the
20 required labeling elements.

21 30. The Board inspector noted that Respondents compounded prescriptions without using
22 a compounding log or master formula. Specifically, Respondents compounded approximately
23 twenty-two (22) prescriptions without having a master formula or compounding log.

24 31. The Board inspector noted that Respondents failed to complete pharmacy and
25 compounding self-assessments, with Respondent Chow indicating he did not know what a self-
26 assessment was. The Board inspector also observed multiple expired medications, unlabeled
27 prescription vials and return to stock medications in the pharmacy's active stock area.

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1 (a) in that Respondents compounded prescriptions without using a master formula or
2 compounding log. Complainant refers to, and by this reference incorporates the allegations set
3 forth in paragraphs 26 through 32, inclusive, as though set forth fully.

4 **FOURTH CAUSE FOR DISCIPLINE**

5 (Failure to Complete a Pharmacy Self-Assessment)

6 37. Respondent Pharmacy and Respondent Chow are subject to disciplinary action under
7 California Code of Regulations title 16, sections 1715 subdivision (a)(d) and 1735.2 subdivision
8 (k) in that Respondents failed to complete a pharmacy self-assessment and compounded
9 prescriptions without having a compounding self-assessment. Complainant refers to, and by this
10 reference incorporates the allegations set forth in paragraphs 26 through 32, inclusive, as though
11 set forth fully.

12 **FIFTH CAUSE FOR DISCIPLINE**

13 (Misbranded and Adulterated Drugs)

14 38. Respondent Pharmacy and Respondent Chow are subject to disciplinary action under
15 Code section 4169 subdivision (a)(2) in that Respondents held as part of the pharmacy's active
16 drug stock, misbranded and adulterated drugs. Complainant refers to, and by this reference
17 incorporates the allegations set forth in paragraphs 26 through 32, inclusive, as though set forth
18 fully.

19 **SIXTH CAUSE FOR DISCIPLINE**

20 (Unprofessional Conduct)

21 39. Respondent Pharmacy and Respondent Chow are subject to disciplinary action under
22 Code sections 4301 subdivision (f) and 4306.5 subdivision (a) and in that Respondents billed
23 prescriptions to patients' insurance without dispensing and inappropriately exercising education,
24 training, or experience. Complainant refers to, and by this reference incorporates the allegations
25 set forth in paragraphs 26 through 32, inclusive, as though set forth fully.

26 **SEVENTH CAUSE FOR DISCIPLINE**

27 (Failure to Maintain Current Inventory)

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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 55692, issued to Raymond Chow, dba Rivera Pharmacy;

2. Revoking or suspending Registered Pharmacist License Number RPH 23215, issued to Raymond Chow;

3. Prohibiting Raymond Chow, dba Rivera Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55692 is placed on probation or until Original Permit Number PHY 55692 is reinstated if Original Permit Number PHY 55692 issued to Raymond Chow, dba Rivera Pharmacy is revoked;

4. Prohibiting Raymond Chow from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55692 is placed on probation or until Original Permit Number PHY 55692 is reinstated if Original Permit Number PHY 55692 issued to Raymond Chow, dba Rivera Pharmacy is revoked;

5. Ordering Raymond Chow, dba Rivera Pharmacy, and Raymond Chow 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,

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

DATED: February 28, 2020



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

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