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

**In the Matter of the Accusation Against:**

**CARE4U PHARMACY, INC. dba CARE4U PHARMACY;**
**HARMINDER BAJAJ, CHIEF EXECUTIVE OFFICER,**
**Original Pharmacy Permit No. PHY 56024;**

**and**

**HARMINDER BAJAJ,**
**Pharmacist License No. RPH 62181,**

**Respondents.**

**Agency Case No. 7024**

**OAH No. 2021080018**

# DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order 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 April 21, 2022.

It is so ORDERED on March 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
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*Attorneys for Complainant*

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

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|---|---|
| In the Matter of the Accusation Against:<br><br>**CARE4U PHARMACY, INC. DBA CARE4U PHARMACY; HARMINDER BAJAJ, CHIEF EXECUTIVE OFFICER**<br>**901 Campus Dr., Ste. 206**<br>**Daly City, CA 94015**<br><br>**Original Pharmacy Permit No. PHY 56024**<br><br>**HARMINDER BAJAJ**<br>**1149 Millbrae Ave.**<br>**Millbrae, CA 94030**<br><br>**Pharmacist License No. RPH 62181**<br><br>Respondents. | Case No. 7024<br><br>OAH No. 2021080018<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT CARE4U ONLY** |

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation solely with respect to Care4U Pharmacy.

## PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christopher M. Young, Deputy Attorney General.

2. Respondent Care4U Pharmacy, Inc., dba Care4U Pharmacy (Respondent Care4U) is represented in this proceeding by attorney Tony J. Park, whose address is: 55 Cetus, 1st Floor, Irvine, CA 92618-1320

3. On or about February 24, 2018, the Board issued Original Pharmacy Permit No. PHY 56024 to Respondent Care4U. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7024, and will expire on February 1, 2023, unless renewed.

## JURISDICTION

4. Accusation No. 7024 was filed before the Board, and is currently pending against Respondent Care4U. The Accusation and all other statutorily required documents were properly served on Respondent on July 9, 2021. Respondent timely filed its Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7024 is attached as exhibit A and incorporated herein by reference.

## ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7024. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

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

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

**CULPABILITY**

9. Respondent admits the truth of each and every charge and allegation in Accusation No. 7024.

10. Respondent agrees that its Original Pharmacy Permit is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

**CONTINGENCY**

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

**DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Original Pharmacy Permit No. PHY 56024 issued to Respondent Care4U Pharmacy, Inc., dba Care4U Pharmacy, is revoked. However, the revocation is stayed and Respondent is placed on probation for two (2) years on the following terms and conditions:

1. **Definition: Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to Care4U Pharmacy, Inc., dba Care4U 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 seventy- two (72) hours of such occurrence:

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

a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment

a conviction of any crime; or

discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's Original Pharmacy Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous 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(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.

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 (2) 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 its 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. **Consultant Review of Pharmacy Operations**

During the period of probation, respondent shall retain, at its own expense, an independent consultant who shall be responsible for conducting an on-site physical inspection to review the operations of the pharmacy on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of the pharmacy, and compliance by respondent. During the period of probation, the Board or its designee, retains discretion to reduce the frequency and/or form of inspection of the pharmacist consultant's review.

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 thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation.

Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

7. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondents Care4U and Bajaj shall pay to the board, jointly and severally, its costs of investigation and prosecution in the amount of $12,000.00. 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 (1) year prior to the end date of probation.

8. **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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9. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Original Pharmacy Permit with the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's Original Pharmacy Permit 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.

10. **License Surrender While on Probation/Suspension**

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.

Upon acceptance of the surrender, respondent shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

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 sixty (60) days.

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.

11. **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 license 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.

12. **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 fifteen (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.

13. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and 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.

14. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a Pharmacy in California for a minimum of 100 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 100 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 pharmacy in California for a minimum of 100 hours.

Any failure to timely provide such notification(s) shall be considered a violation of probation.

15. **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 (2) 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.

16. **Violation of Probation**

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

If respondent 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, 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.

17. **Completion of Probation**

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

18. **No Additional Ownership or Management of Licensed Premises**

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm , partnership, or corporation currently or hereinafter licensed by the board except as

approved by the board or its designee. Violations of this restriction shall be considered a violation of probation

**ACCEPTANCE**

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

DATED: _____

CARE4U PHARMACY, INC., DBA CARE4U PHARMACY; HARMINDER BAJAJ
*Respondent Care4U*

I have read and fully discussed with Respondent Care4U Pharmacy, Inc., dba Care4U Pharmacy, and Harminder Bajaj, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK
*Attorney for Respondents*

approved by the board or its designee. Violations of this restriction shall be considered a violation of probation

**ACCEPTANCE**

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

DATED: 02/06/2022

Harminder Bajaj

CARE4U PHARMACY, INC., DBA CARE4U PHARMACY; HARMINDER BAJAJ
*Respondent Care4U*

I have read and fully discussed with Respondent Care4U Pharmacy, Inc., dba Care4U Pharmacy, and Harminder Bajaj, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK
*Attorney for Respondents*

approved by the board or its designee. Violations of this restriction shall be considered a violation of probation

**ACCEPTANCE**

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DATED: _____

CARE4U PHARMACY, INC., DBA CARE4U PHARMACY; HARMINDER BAJAJ
*Respondent Care4U*

I have read and fully discussed with Respondent Care4U Pharmacy, Inc., dba Care4U Pharmacy, and Harminder Bajaj, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: **02/07/2022**

TONY J. PARK
*Attorney for Respondents*

**ENDORSEMENT**

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

DATED: February 17, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Christopher M. Young

CHRISTOPHER M. YOUNG
Deputy Attorney General
*Attorneys for Complainant*

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# Exhibit A

**Accusation No. 7024**

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Supervising Deputy Attorney General
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*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
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| In the Matter of the Accusation Against**:**<br><br>**CARE4U PHARMACY, INC. DBA CARE4U PHARMACY; HARMINDER BAJAJ, CHIEF EXECUTIVE OFFICER**<br>**901 Campus Dr., Ste. 206**<br>**Daly City, CA 94015**<br><br>**Original Pharmacy Permit No. PHY 56024**<br><br>**HARMINDER BAJAJ**<br>**1149 Millbrae Ave.**<br>**Millbrae, CA 94030**<br><br>**Pharmacist License No. RPH 62181**<br><br>Respondents. | Case No. 7024<br><br>**ACCUSATION** |

## PARTIES

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

2. On or about February 24, 2018, the Board issued Original Pharmacy Permit Number PHY 56024 to Care4U Pharmacy, Inc. dba Care4U Pharmacy; Harminder Bajaj, Chief Executive

Officer (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2022, unless renewed.

3. On or about February 4, 2009, the Board issued Registered Pharmacist License Number RPH 62181 to Harminder Bajaj (Respondent Bajaj). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2022, unless renewed. At all times relevant to the allegations in this pleading, Respondent Bajaj served as the Pharmacist in Charge (PIC) of Respondent Pharmacy.

## JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Code section 4011 provides that the Board shall administer and enforce the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.]. Further pursuant to Code section 4011, the Board also administers and enforces the Uniform Controlled Substances Act.

6. Code section 4300, subdivision (a), provides that every license issued by the Board may be suspended or revoked.

7. Code section 4300.1 provides that the expiration, cancellation, forfeiture, suspension, or voluntary surrender of a license "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."

## STATUTORY PROVISIONS

8. Business and Professions Code section 680 states, in pertinent part:

> (a) Except as otherwise provided in this section, a health care practitioner shall disclose, while working, his or her name and practitioner's license status, as granted by this state, on a name tag in at least 18-point type. A health care practitioner in a practice or an office, whose license is prominently displayed, may opt to not wear a name tag. If a health care practitioner or a licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the name tag requirement for individual safety or therapeutic concerns. In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference to himself or herself and in any capacity, except for an individual who is a registered nurse or a licensed vocational nurse, or as otherwise provided in

> Section 2800. Nothing in this section shall prohibit a certified nurse assistant from using his or her title.
>
> . . .
>
> (c) For purposes of this article, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under this division or under any initiative act referred to in this division.

9. Business and Professions Code section 4113, subdivision (c), states that the "pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Business and Professions Code section 4058 states:

"Every person holding a license issued under this chapter to operate a premises shall display the original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public."

11. Business and Professions Code section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:
>
> . . .
>
> (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
>
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
>
> . . .
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
>
> . . .

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12. Business and Professions Code section 4306.5 states, in pertinent part:

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

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

. . .

13. Code section 4307, subdivision (a), states:

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

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

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

14. Business and Professions Code section 4342 states, in pertinent part:

(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).

. . .

15. Health and Safety Code section 111260 states:

"Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess."

16. Health and Safety Code section 111295 states:

"It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated."

17. Health and Safety Code section 111330 states:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

18. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform with the requirements of Chapter 4."

19. Health and Safety Code section 111340 provides that any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

20. Health and Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell deliver, hold or offer for sale any drug or device that is misbranded."

21. Health and Safety Code section 111615 states, in pertinent part:

"No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable. . . ."

22. 21 U.S.C. § 351 provides definitions for "Adulterated Drugs and Devices." Subdivision (a) thereof states, in pertinent part:

> A drug or device shall be deemed to be adulterated--
> **(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture**
> (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .

23. 21 U.S.C. § 352, "Misbranded Drugs and Devices," states, in pertinent part:

> A drug or device shall be deemed to be misbranded—
> **(a) False or misleading label**
> (1) If its labeling is false or misleading in any particular. . . .
>
> **(b) Package form; contents of label**
> If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.
>
> . . .
> **(f) Directions for use and warnings on label**
> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.
>
> . . .
>
> **(i) Drug; misleading container; imitation; offer for sale under another name**
> (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

. . .

**(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances**

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 371(a) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.", . . . .

**(o) Drugs or devices from nonregistered establishments**
If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 360 of this title, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 381(s) of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

. . .

**(aa) Unpaid fees; failure to submit identifying information**
If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 379j-42(a)(4) of this title or for which identifying information required by section 379j-42(f) of this title has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

**(bb) False or misleading advertisement or promotion of compounded drug**
If the advertising or promotion of a compounded drug is false or misleading in any particular.

**(cc) Failure to bear product identifier**
If it is a drug and it fails to bear the product identifier as required by section 360eee-1 of this title.

. . .

(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.

24. 21 U.S.C. § 353a, in pertinent part, provides for "Pharmacy Compounding" under certain conditions defined by the statute:

> (a) In general
> Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—
>
> (1) is by—
> (A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or
> (B) a licensed physician,
> on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or
> (2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and
> (B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—
> (i) the licensed pharmacist or licensed physician; and
> (ii)(I) such individual patient for whom the prescription order will be provided; or
> (II) the physician or other licensed practitioner who will write such prescription order.
>
> (b) Compounded drug
> (1) Licensed pharmacist and licensed physician
> A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—
> (A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—
> (i) that—
> (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
> (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
> (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);
> (ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and
> (iii) that are accompanied by valid certificates of analysis for each bulk drug substance;
> (B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
> (C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or

removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and
(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

**REGULATORY PROVISIONS**

25. California Code of Regulations, title 16, section 1707.6 states, in pertinent part:

. . .

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

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

. . .

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

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

. . .

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

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or

section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

. . .

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

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

(1) Active ingredients to be used.

(2) Equipment to be used.

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

(4) Inactive ingredients to be used.

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

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

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

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

. . .

(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 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a

new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . .

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

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

(1) The master formula document.

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

. . .

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

. . .

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

. . .

30. California Code of Regulations, title 16, section 1735.4 states, in pertinent part:

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

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

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

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

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

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

. . .

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

(a) Any pharmacy engaged in compounding shall 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

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

. . .

32. California Code of Regulations, title 16, section 1735.7 states, in pertinent part:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

. . .

33. California Code of Regulations, title 16, section 1735.8 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

. . .

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

. . .

**COST RECOVERY**

34. Code section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of

the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

## FACTUAL BACKGROUND

35. A Board inspector conducted a routine inspection of Respondent Pharmacy, located in Daly City, California, on November 3, 2019. Respondent Bajaj, the Pharmacist in Charge, was present during the inspection. Several violations of the Pharmacy Law were found during the inspection, as detailed below in paragraphs 36 through 50.

36. Respondent Pharmacy did not display its original license and current renewal license in a location where it could be clearly read by the public entering the pharmacy. Both the original and current renewal license were located in Respondent Bajaj's office, out of public view. Additionally, Respondent Pharmacy failed to display a Notice to Consumers in public view, as required in any pharmacy dispensing dangerous drugs, indicating that interpreter services would be provided for foreign language speakers.

37. Respondent Bajaj was not wearing a visible tag with her name or practitioner's license status while working at Respondent Pharmacy and serving the public, nor was Respondent Bajaj's practitioner's license displayed prominently in Respondent Pharmacy in public view.

38. The medication refrigerator at Respondent Pharmacy did not have a temperature log, and the electronic thermometer had stopped working, making it impossible to know if the medication stored in the refrigerator was maintained at the proper temperature. Additionally, the Flow Sciences compounding hood had not been certified annually as required by the pharmacy policies and procedures. Because California regulations require that a pharmacy be properly maintained and equipped, Respondents failed to ensure that the above equipment was adequately maintained, equipped, and certified, as required.

39. Each room of Respondent Pharmacy contained boxes of trash, drugs and other items stacked up to the point it was hard to move through Respondent Pharmacy or to find a place to work. There were boxes full of expired drugs in Respondent Pharmacy. The sink in the compounding room did not drain properly, and was full of dirty compounding equipment. The sink in the filling room dripped constantly.

40. Respondent Pharmacy had many expired drugs and ingredients in its active inventory. Mixed medications were stored in containers in Respondent Pharmacy and some prescription vials were not labeled.

41. The Ohaus Balance at Respondent Pharmacy had not been certified by an outside vendor annually, and daily calibration had not been checked, as required by the pharmacy policies and procedures. Respondents' failure to ensure the Ohaus Balance was certified and calibrated, as required by Respondent Pharmacy's policies and procedures, violated regulations applicable to any pharmacy conducting compounding.

42. There was no documentation of an annual review by Respondent Bajaj of Respondent Pharmacy's compounding policies and procedures.

43. Respondent Pharmacy had a pharmacy self-assessment dated April 20, 2018. A community pharmacy self-assessment had not been performed by Respondent Bajaj prior to July 1 of every odd-numbered year.

44. Respondent Pharmacy compounds non-sterile compounded products. Respondent Pharmacy's compounding self-assessment was blank. Respondent Bajaj failed to fill out an initial compounding self-assessment, or to complete a compounding self-assessment prior to July 1 of every odd-numbered year prior to compounding. Moreover, Respondent Bajaj was aware of the requirement to perform a compounding self-assessment. During a prior inspection on or about May 18, 2016, at a different pharmacy, Respondent Bajaj, while pharmacist-in-charge, also failed to produce compounding self-assessment at that pharmacy, as required.

45. Respondent Pharmacy did not have documentation of ongoing compounding training for Respondent Bajaj, the only staff member performing compounding. The last documentation of compounding training for Respondent Bajaj was dated June 2014.

46. Numerous prescription labels failed to list the name, strength, volume, and/or weight of each active ingredient on the prescription label prior to being dispensed and sold by Respondent Pharmacy. Additionally, numerous prescription labels did not state the instructions for storage and handling prior to being dispensed and sold by Respondent Pharmacy.

47. The compounded drug records were incomplete. Respondent Pharmacy's records for compounded drugs, in numerous instances, lacked documentation of the lot number, expiration date, and manufacturer for at least one of the ingredients used in the compounded drug. Moreover, Respondent Pharmacy's records for compounded drugs lacked documentation of quality reviews in numerous instances.

48. Respondent Bajaj was required to prepare a written master formula document prior to compounding drug preparations. In numerous instances, the master formulas did not: (1) state the equipment to be used in preparing the compounded drugs, (2) state the specific and essential compounding steps used to prepare the compounded drugs, or (3) state the instructions for storage and handling of the compounded drug preparation.

49. Respondents failed to perform an annual test on a compounded drug to ensure integrity, potency, quality, and labeled strength. There was no documentation at Respondent Pharmacy of end-product testing on any compounded product.

50. Respondent Bajaj provided inaccurate documents to the pharmacy inspector after the November 3, 2019 inspection. At the time of the inspection, Respondent Bajaj provided the inspector with compounding logs, and indicated to the inspector she had all the ingredients documented in her computer at Respondent Pharmacy. Later, Respondent Bajaj provided supplemental records with handwritten weights of compounded drugs, instead of computerized records as Respondent Bajaj had previously indicated were available. The supplemental, handwritten documents were inconsistent with the original compounding logs obtained by the inspector on November 3, 2019, in numerous instances. There should only be one weight for each ingredient used in compounding a specific lot of a drug. Additionally, Respondent Bajaj sent several versions of signed compounding logs in which the quantity of the similar ingredients used were different, and some ingredients had different names, in numerous instances. These numerous inaccuracies and discrepancies, whether by mistake or dishonesty, between the versions of compounding logs violate statutes and/or regulations requiring complete records of compounded drugs.

/ / /

**FIRST CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Display of License)

51. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and section 4058, which requires that the original license and current renewal license of Respondent Pharmacy be displayed in view of the public. As described above in paragraph 36, Respondents failed to ensure the licenses were posted in view of the public.

**SECOND CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Notice to Consumers)

52. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1707.6, subdivision (c), which requires that a notice to consumers be displayed indicating that an interpreter is available free of charge. As described above in paragraph 36, Respondents failed to ensure an adequate Notice to Consumers was displayed in Respondent Pharmacy in public view.

**THIRD CAUSE FOR DISCIPLINE**

(Respondent Bajaj: Health Care Practitioner Name Disclosure)

53. Respondent Bajaj is subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), and section 680, which requires that a health care practitioner wear a name tag for individual safety concerns. As described above in paragraph 37, Respondent Bajaj did not wear a name tag with her name and license status while working at Respondent Pharmacy and serving the public, nor was her pharmacist license displayed prominently in view of the public.

**FOURTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Operational Standards and Security)

54. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1714, subdivisions (b) and (c), which require that a licensed pharmacy be

properly maintained and equipped. As described above in paragraphs 38-39, Respondent Bajaj failed to ensure Respondent Pharmacy's equipment was properly maintained and inspected. Moreover, Respondent Pharmacy was disorganized and cluttered with trash and expired drugs.

**FIFTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Expired and Unlabeled Drugs)

55. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and Code section 4342, subdivision (a), and/or Health and Safety Code sections 111260, 111295, 111330, 111335, 111340, and/or 111440, and/or 21 U.S.C. § 351 and/or 352, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 40 above, Respondents sold, delivered, held or offered for sale dangerous drugs that were adulterated and/or misbranded, including maintaining expired drugs in its active inventory and unlabeled medications stored in prescription vials.

**SIXTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Failure to Follow Compounding Policies and Procedures)

56. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.5, subdivision (a), which requires that "[a]ny pharmacy engaged in compounding shall 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action." Respondent Pharmacy failed to certify its Ohaus Balance by an outside vendor, or to check its calibration on a daily basis, as required by Respondent Pharmacy's policies and procedures, as described above in paragraph 41.

/ / /

/ / /

**SEVENTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Failure to Follow Compounding Policies and Procedures)

57. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.5, subdivision (b), which requires that Respondent Pharmacy's compounding policies and procedures be reviewed on an annual basis by the pharmacist-in-charge. Respondent Bajaj failed to conduct the annual review, as described above in paragraph 42.

**EIGHTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Failure to Complete Self-Assessment)

58. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1715, subdivision (b), which requires that Respondent Bajaj complete a self-assessment of the pharmacy's compliance with pharmacy laws. The self-assessment was not timely prepared, as described above in paragraph 43.

**NINTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Failure to Conduct Compounding Self-Assessment)

59. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.2, subdivision (k), which requires that Respondent Bajaj complete a compounding self-assessment prior to any compounding, and thereafter prior to July 1 of each odd-numbered year, as described above in paragraph 44. Respondents failed to complete and/or maintain the required self-assessments.

**TENTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Failure to Maintain Master Formula Documentation)

60. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.2, subdivision (e), which requires that Respondent Bajaj complete a

compounding master formula with specific details, as described above in paragraph 48. Respondents failed to complete and/or maintain the required compounding master formulas.

**ELEVENTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Training of Compounding Staff)

61. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.7, subdivision (b), which requires that a pharmacy conducting compounding have an ongoing competency evaluation process and training for compounding staff. As described above in paragraph 45, Respondents did not have appropriate documentation of ongoing compounding training.

**TWELFTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Labeling of Compounded Drug Preparations)

62. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.4, subdivision (a), for mislabeling numerous compounded drugs as described above in paragraph 46.

**THIRTEENTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Recordkeeping for Compounded Drug Preparations)

63. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.3, subdivision (a), for maintaining incomplete records of compounded drugs as described above in paragraph 47.

**FOURTEENTH CAUSE FOR DISCIPLINE**

(Respondents Pharmacy and Bajaj: Compounding Quality Assurance)

64. Respondents Pharmacy and Bajaj are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of Regulations, section 1735.8, subdivision (c), for failing to perform end-product testing of compounded drugs as described above in paragraph 49.

**FIFTEENTH CAUSE FOR DISCIPLINE**

(Respondent Bajaj: Unprofessional Conduct)

65. Respondent Bajaj is subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), and Code section 4306.5, in that Respondent Bajaj repeatedly failed to complete a compounding self-assessment, even though she had prior, specific notice of the requirement from the Board as described above in paragraph 44. Failure to complete and/or maintain the required compounding self-assessments constitutes a misuse of experience and education required of a PIC.

**SIXTEENTH CAUSE FOR DISCIPLINE**

(Respondent Bajaj: Unprofessional Conduct)

66. Respondent Bajaj is subject to disciplinary action under Code section 4301, subdivisions (f) and/or (g), in that Respondent Bajaj provided inaccurate and dishonest documents to the pharmacy inspector as described above in paragraph 50, and did not maintain a complete and uniform records.

**DISCIPLINE CONSIDERATIONS**

67. To determine the degree of discipline, if any, to be imposed on Respondent Bajaj, Complainant alleges that on or about May 3, 2016, in a prior action, the Board of Pharmacy issued Citation and Fine Number CI 2015 70148 and ordered Respondent Bajaj to pay a fine of $5,000. During the time period of June 5, 2012 through April 30, 2013, an employee or employees under Respondent Bajaj's supervision as Pharmacist In Charge admitted to theft of controlled substances from the pharmacy, and Respondent failed to maintain accurate and complete records of controlled substances are required by the Pharmacy Law (Cal. Code Regs., tit. 16, section 1714, subd. (d), Cal. Code Regs., tit. 16, section 1718; Bus. & Prof. Code section 4081, subd. (a)). That Citation was paid, and is now final.

68. To determine the degree of discipline, if any, to be imposed on Respondent Bajaj, Complainant alleges that on or about July 29, 2016, in a prior action, the Board of Pharmacy issued Citation and Fine Number CI 2016 71297 and ordered Respondent Bajaj to pay a fine of $500. While Respondent Bajaj was Pharmacist In Charge of Care4U Pharmacy, on or about

March 10, 2015, and April 20, 2015, Respondent Bajaj informed the Board of Pharmacy in writing that the new pharmacy was ready to open, and would open. The Board issued the Pharmacy license on or about April 20, 2015. Inspections later occurred in May and June 2015, and the Pharmacy was not open. Respondent Bajaj was cited for unprofessional conduct, that is, knowingly and falsely representing the existence or nonexistence of a state of facts (Bus. & Prof. Code section 4301, subd. (g)). That Citation was paid, and is now final.

**OTHER MATTERS**

69. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number PHY 56024, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Number PHY 56024 is placed on probation, or until reinstatement if Respondent Pharmacy License Number PHY 56024 is revoked.

70. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number PHY 56024 issued to Respondent Pharmacy while Respondent Bajaj was the pharmacist-in-charge, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Bajaj shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Number PHY 56024 is placed on probation, or until reinstatement if Respondent Pharmacy License Number PHY 56024 is revoked.

71. Pursuant to Code section 4307, if discipline is imposed on Respondent Bajaj's Pharmacist License Number RPH 62181, Respondent Bajaj shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if License Number RPH 62181 is placed on probation, or until reinstatement if License Number RPH 62181 is revoked.

**PRAYER**

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

1. Revoking or suspending Original Pharmacy Permit Number PHY 56024, issued to Care4U Pharmacy, Inc. dba Care4U Pharmacy (Respondent Pharmacy);

2. Revoking or suspending Registered Pharmacist License Number RPH 62181, issued to Harminder Bajaj (Respondent Bajaj);

3. Prohibiting Care4U Pharmacy, Inc. dba Care4U Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 56024 is placed on probation, or until reinstatement if Original Pharmacy Permit Number PHY 56024 is revoked.

4. Prohibiting Harminder Bajaj from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 56024 is placed on probation, or until reinstatement if Original Pharmacy Permit Number PHY 56024 is revoked.

5. Prohibiting Harminder Bajaj from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 62181 is placed on probation, or until reinstatement if Pharmacist License Number RPH 62181 is revoked.

6. Ordering Respondent Pharmacy and Respondent Bajaj, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 7/1/2021

Signature on File

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

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