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

In the Matter of the Accusation Against:

Case No. 5221

DAVID ANTHONY VALENCIA, A.K.A. DAVID VALENCIA,

505 Alameda Drive Livermore, CA 94551

Pharmacist License No. RPH 30915

OAH No. 2015010579

BACON EAST PHARMACY

2425 East Street, Suite 5 Concord, CA 95420

and

Pharmacy Permit No. PHY 50632

**BOIES MEDICAL CENTER PHARMACY** 

828 Delbon Avenue Turlock, CA 95382

Pharmacy Permit No. PHY 51468

STIPULATED SURRENDER OF LICENSE AND ORDER AS TO BACON EAST PHARMACY AND BOIES MEDICAL CENTER PHARMACY ONLY

Respondents.

## **DECISION AND ORDER**

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on March 17, 2016.

It is so ORDERED February 16, 2016.

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

By

Amy Gutierrez, Pharm.D.

**Board President** 

| 1  | Kamala D. Harris  |   |
|----|---|---|
| 2  | Attorney General of California DIANN SOKOLOFF           | . *   |
| 3  | Supervising Deputy Attorney General CARTER OTT          |   |
| 4  | Deputy Attorney General<br>State Bar No. 221660         |   |
|    | 1515 Clay Street, 20th Floor                            |   |
| 5  | P.O. Box 70550<br>Oakland, CA 94612-0550                | ·   |
| 6  | Telephone: (510) 622-2219<br>Facsimile: (510) 622-2270  |   |
| 7  | E-mail: Carter.Ott@doj.ca.gov Attorneys for Complainant |   |
| 8  |   | RE THE  |
| 9  | BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS        |   |
| 10 |   | CALIFORNIA  |
| 11 |   |   |
| 12 | In the Matter of the Accusation Against:                | Case No. 5221   |
| 13 | DAVID ANTHONY VALENCIA,<br>A.K.A. DAVID VALENCIA,       | OAH No. 2015010579  |
| 14 | 505 Alameda Drive,<br>Livermore, CA 94551               | STIPULATED SURRENDER OF   |
| 15 | Pharmacist License No. RPH 30915;                       | LICENSES AND ORDER AS TO BACON<br>EAST PHARMACY AND BOIES<br>MEDICAL CENTER PHARMACY ONLY |
| 16 | BACON EAST PHARMACY                                     |   |
| 17 | 2425 East Street, Suite 5                               |   |
| 18 | Concord, CA 95420                                       |   |
| 19 | Pharmacy Permit No. PHY 50632;                          |   |
| 20 | and   |   |
| 21 | BOIES MEDICAL CENTER PHARMACY 828 Delbon Avenue         |   |
| 22 | Turlock, CA 95382                                       |   |
| 23 | Pharmacy Permit No. PHY 51468                           |   |
| 24 | Respondents.  |   |
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IT IS HEREBY STIPULATED AND AGREED by and between Respondents Bacon East
Pharmacy and Boies Medical Center Pharmacy (collectively, Respondents) and Complainant that
the following matters are true:

# **PARTIES**

- Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
   She brought this action solely in her official capacity and is represented in this matter by Kamala
   Harris, Attorney General of the State of California, by Carter Ott, Deputy Attorney General.
- 2. Respondents are represented in this proceeding by Jeremy A. Meier, whose address is Greenberg Traurig LLP, 1201 K Street, Suite 1100, Sacramento, CA 95814.
- 3. On or about June 14, 2011, the Board of Pharmacy issued Pharmacy Permit Number PHY 50632 to Respondent Bacon East Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 5221. On April 16, 2015 the Pharmacy Permit was cancelled.
- 4. On or about June 10, 2013, the Board of Pharmacy issued Pharmacy Permit Number PHY 51468 to Respondent Boies Medical Center Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 5221. On April 16, 2015 the Pharmacy Permit was cancelled.

#### JURISDICTION

5. Accusation No. 5221 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and that pleading and all other statutorily required documents were properly served on October 3, 2014. A Notice of Defense was timely filed. On October 13, 2015, a First Amended Accusation was filed and served on Respondents. That pleading is currently pending against Respondents. A copy of First Amended Accusation No. 5221 is attached as Exhibit A and incorporated by reference.

#### ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 5221. Respondents also have carefully

read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.

- Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel, at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their 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. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

## **CULPABILITY**

- 9. Respondents understand and agree that the charges and allegations in the First Amended Accusation No. 5221, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Licenses.
- 10. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation, and that Respondents hereby give up their right to contest those charges.
- 11. Respondents understand that by signing this stipulation they enable the Board to issue an order accepting the surrender of their Pharmacy Permits without further process.

# **CONTINGENCY**

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their 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 Surrender 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.

- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Surrender of License and 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 Surrender of License and 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.
- 15. 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 Order:

### ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 50632 and Pharmacy Permit Number PHY 51468, issued to Respondent Bacon East Pharmacy and Boies Medical Center Pharmacy, respectively, are surrendered and accepted by the Board.

- The surrender of Respondents' Pharmacy Permits and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondents. This stipulation constitutes a record of the discipline and shall become a part of Respondents' license histories with the Board.
- 2. With regard to Pharmacy Permit No. PHY 50632, Respondent Bacon East Pharmacy shall lose all rights and privileges as a Pharmacy in California as of the effective date of the Board's Decision and Order. Respondent Bacon East Pharmacy shall cause to be delivered to the Board its pocket license for Pharmacy Permit No. PHY 50632 and, if one was issued, its wall

certificate for Pharmacy Permit No. PHY 50632 on or before the effective date of the Decision and Order.

- 3. With regard to Pharmacy Permit No. PHY 51468, Respondent Boies Medical Center Pharmacy shall lose all rights and privileges as a Pharmacy in California as of the effective date of the Board's Decision and Order. Respondent Boies Medical Center Pharmacy shall cause to be delivered to the Board its pocket license for Pharmacy Permit No. PHY 51468 and, if one was issued, its wall certificate for Pharmacy Permit No. PHY 51468 on or before the effective date of the Decision and Order.
- 4. Respondents shall pay the Board its costs of investigation and enforcement in the amount of \$4,516.25 within 120 days of the effective date of this Decision and Order.
- 5. If Respondents ever apply for licensure or petitions for reinstatement in the State of California, the Board shall treat such application as a new application for licensure. Respondents must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 5221 shall be deemed to be true, correct and admitted by Respondents when the Board determines whether to grant or deny the application or petition.

#### ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Jeremy A. Meier. I understand the stipulation and the effect it will have on my Pharmacy Permits. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: James 6,2016 Line Harb

BACON EAST PHARMACY BOIES MEDICAL CENTER PHARMACY Respondents

| 1  | I have read and fully discussed with Respondents   | Bacon East Pharmacy and Boies Medical  |
|----|--|--|
| 2  | Center Pharmacy the terms and conditions and other ma                                    | atters contained in this Stipulated  |
| 3  | Surrender of License and Order. I approve its form and                                   | content.   |
| 4  | DATED: 01/06/2016  | My New   |
| 5  | Attorne  | Y A/MEIER<br>y for Respondent  |
| 6  |  | ***************************************  |
| 7  | <u>ENDORSEMENT</u>   |  |
| 8  | The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted |  |
| 9  | for consideration by the Board of Pharmacy of the Department of Consumer Affairs.        |  |
| 10 | Dated: Res   | spectfully submitted,  |
| 11 | KA   | MALA D. HARRIS<br>corney General of California   |
| 12 | DIA.   | ANN SOKOLOFF pervising Deputy Attorney General   |
| 13 | - N  | on the state of th |
| 14 |  | _  |
| 15 | De   | RTER OTT puty Attorney General   |
| 16 | Att  | orneys for Complainant   |
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| 1   | I have read and fully discussed with Respon  | dents Bacon East Pharmacy and Boies Medical                                       |
|-----|--|---|
| 2   | Center Pharmacy the terms and conditions and other matters contained in this Stipulated  |   |
| 3   | Surrender of License and Order. I approve its form and content.                          |   |
| 4 - | DATED:   |   |
| 5   |  | REMY A. MEIER torney for Respondent   |
| 6   | ENDODG   | CN ATONITE  |
| 7   | <u>ENDORSEMENT</u>   |   |
| 8   | The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted |   |
| 9   | for consideration by the Board of Pharmacy of the  | Department of Consumer Affairs.   |
| 10  | Dated: 1/7 (16   | Respectfully submitted,   |
| 11  |  | KAMALA D. HARRIS<br>Attorney General of California                                |
| 12  | ,  | Attorney General of California DIANN SOKOLOFF Supervising Deputy Attorney General |
| 13  |  | (1000 - 00 -  |
| 14  |  | Medel   |
| 15  |  | CARTER OTT Deputy Attorney General  |
| 16  |  | Attorneys for Complainant   |
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# Exhibit A

First Amended Accusation No. 5221

| KAMALA D, HARRIS<br>Attorney General of California                  |                                |
|---|--------------------------------|
| DIANN SOKOLOFF  |                                |
| Supervising Deputy Attorney General CARTER OTT                      |                                |
| Deputy Attorney General<br>State Bar No. 221660                     |                                |
| 1515 Clay Street, 20th Floor  |                                |
| P.O. Box 70550 Oakland, CA 94612-0550                               |                                |
| Telephone: (510) 622-2219<br>Facsimile: (510) 622-2270              | •                              |
| E-mail: Carter,Ott@doj.ca,gov                                       | •                              |
| Attorneys for Complainant   |                                |
| BEFORE THE<br>BOARD OF PHARMACY                                     |                                |
| DEPARTMENT OF C   | CONSUMER AFFAIRS<br>CALIFORNIA |
| STATE OF  |                                |
| In the Matter of the Accusation Against:                            | Case No. 5221                  |
| DAVID ANTHONY VALENCIA,   | OAH No. 2015010579             |
| A.K.A. DAVID VALENCIA,<br>505 Alameda Drive,<br>Livermore, CA 94551 | FIRST AMENDED ACCUSATION       |
| Pharmacist License No. RPH 30915;                                   | ·                              |
|   | _                              |
| BACON EAST PHARMACY 2425 East Street, Suite 5                       |                                |
| Concord, CA 95420   |                                |
| Pharmacy Permit No. PHY 50632;                                      |                                |
| and   |                                |
| BOIES MEDICAL CENTER PHARMACY                                       |                                |
| 828 Delbon Avenue<br>Turlock, CA 95382                              |                                |
| ·   |                                |
| Pharmacy Permit No. PHY 51468                                       |                                |
| Respondents.  |                                |
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|   | FIRST AMENDED ACCUSA           |

Complainant alleges:

# <u>PARTIES</u>

- 1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about July 27, 1977, the Board of Pharmacy issued Pharmacist License Number RPH 30915 to Respondent David Anthony Valencia (Valencia). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2015, unless renewed. Respondent Pharmacist is and has been the Pharmacist-in-Charge at Bacon East Pharmacy since March 11, 2013.
- 3. On or about June 14, 2011, the Board of Pharmacy issued Pharmacy Permit Number PHY 50632 to Respondent Bacon East Pharmacy. The Pharmacy Permit was cancelled on April 16, 2015, but was in full force and effect at all times relevant to the charges brought in this First Amended Accusation.
- 4. On or about June 10, 2013, the Board of Pharmacy issued Pharmacy Permit Number PHY 51468 to Respondent Boies Medical Center Pharmacy. The Pharmacy Permit was cancelled on April 16, 2016, but was in full force and effect at all times relevant to the charges brought in this First Amended Accusation.4. Respondent Bacon East Pharmacy is owned by a Bacon East Pharmacy Inc., a California corporation, and Boies Medical Center Pharmacy is owned by Boies Pharmacy Inc., a California corporation. Each of these corporations was owned by Jamil Harb until his passing on January 4, 2015. Following Mr. Harb's passing, his widow inherited ownership in the pharmacy corporations.

### JURISDICTION |

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

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6. Section 118, subdivision (b) states:

"(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground."7. Section 4300 states, in part:

- "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
  - (1) Suspending judgment.
  - (2) Placing him or her upon probation.
  - (3) Suspending his or her right to practice for a period not exceeding one year.
  - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
- "(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the 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. Section 4300.1 states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board

of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

# STATUTORY AND REGULATORY PROVISIONS9. Section 4081 states, in part:

"(a) All records of manufacture and of sale, acquisition, or disposition of 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 three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

#### 10. Section 4105 states:

- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- "(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.
- "(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.
- "(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

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 "(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

- "(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.
- "(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board."

# 11. Section 4110 states, in part:

- "(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.
- "(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal

 service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

. . . . .

#### 12. Section 4301 states, in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct.... Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

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

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#### 13. Section 4306.5 states:

"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.
- "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
- "(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

| "(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and   |
|---|
| retain appropriate patient-specific information pertaining to the performance of any pharmacy |
| function,"  |

14. Code of Regulations, title 16, section 1707.2 states, in part:

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or

- 15. Code of Regulations, title 16, section 1709 states, in part:
- "(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.
- "(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.

...."16. Code of Regulations, title 16, section 1714 states, in part:

"

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

, . . . , , ,

17. Code of Regulations, title 16, section 1718 states, in part:

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

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

- 18. Code of Regulations, title 16, section 1735.5 states, in part:
- "(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual 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.
- "(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

#### COST RECOVERY

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

# FIRST CAUSE FOR DISCIPLINE

(Failure to Consult)
(Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c);
Cal. Code Regs., title 16, § 1707.2, subd. (b)(1)(A))

- 20. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to consult as required by Code California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(A). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subd. (a)-(c); Cal. Code Regs., title 16, § 1707.2, subd. (b)(1)(A)). The circumstances are as follows:
- a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector interviewed a pharmacy clerk who stated he identified prescriptions requiring

consultation by a pharmacist by looking for a "consult" stamp on the receipt. However, this process was not being executed by the pharmacy staff, as the Board inspector identified three (3) new prescriptions which were not stamped with "consult" on the receipt.

b. During a previous inspection, conducted on or about October 17, 2011, the Board identified this as an issue Respondent Bacon East Pharmacy must correct.

#### SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policy and Procedure Manual) (Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and (b))

- 21. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain a written policy and procedure manual for compounding pharmacy activities as required by Code California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (b). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and (b)). The circumstances are as follows:
- a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector found, according to Respondent's written policy and procedure manual for compounding, that their manual had not been updated since June 2011.
- b. During a previous inspection, conducted on or about October 17, 2011, the Board identified this as an issue Respondent Bacon East Pharmacy must correct.

#### THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition and Disposition)
(Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code Regs., title 16, § 1718)

22. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain records accounting for the records of acquisition and disposition and the current inventory of dangerous drugs as required by Business and Professions Code sections 4081, subdivision (a), and 4105.

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(Cal. Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code Regs., title 16, § 1718). The circumstances are as follows:

a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector found that Respondents did not have accurate records of acquisition and/or disposition to account for an inventory shortage for 4,252 tablets of oxycodone 30 mg tablets. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug according to Business and Professions Code section 4022 in that it can be lawfully dispensed only by prescription.

# FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Prescription Department) (Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c); and Cal. Code Regs., title 16, § 1714, subd. (d))

- 23. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and records for such drugs as required by Code California Code of Regulations, title 16, section 1714, subdivision (d). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c); and Cal. Code Regs., title 16, § 1714, subd. (d)). The circumstances are as follows:
- a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector found that Respondents had an inventory shortage (purchases/acquisitions greater than sales/disposition) of 4,252 tablets of oxycodone 30 mg tablets. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug according to Business and Professions Code section 4022 in that it can be lawfully dispensed only by prescription.

# FIFTH CAUSE FOR DISCIPLINE (Failure to Notify of Change of Ownership) Cal. Code Poor, 4ttle 16, 8, 1700, gable, (a) and (b))

(Cal. Code Regs., title 16, § 1709, subds. (a) and (b))

24. Respondents Valencia, Bacon East Pharmacy, and Boies Medical Center Pharmacy have subjected their Pharmacist License and Pharmacy Permits, respectively, to disciplinary

action for failing to notify the Board regarding a change in the ownership of the pharmacies. (Cal. Code Regs., title 16, § 1709, subds. (a) and (b)). The circumstances are as follows:

- a. The Respondent pharmacies were formerly owned by Jamil Harb, until his passing on January 4, 2015. Following Mr. Harb's passing, his widow inherited ownership of the pharmacies.
- b. Between January 4, 2015 and April 15, 2015, Bacon East Pharmacy and Boies Medical Center Pharmacy continued to operate but Respondents failed to submit change in ownership applications, based on the transfer of ownership from Jamil Harb to his widow, or request a temporary permit from the Board.

# SIXTH CAUSE FOR DISCIPLINE (Unlicensed Activity)

(Bus. & Prof. Code § 4110, subds. (a) and (b))

- 25. Respondents Bacon East Pharmacy and Boies Medical Center Pharmacy have subjected their Pharmacy Permits to disciplinary action for operating without a license. (Bus. & Prof. Code § 4110, subds. (a) and (b)). The circumstances are as follows:
- a. Upon the January 4, 2015 passing of Jamil Harb, the former owner of Bacon East Pharmacy and Boies Medical Center Pharmacy, the permits the Board issued to those pharmacies expired. Between January 4, 2015 and April 15, 2015, Bacon East Pharmacy and Boies Medical Center Pharmacy continued to operate without submitting change in ownership applications or requesting a temporary permit from the Board. During this period of time (between January 4, 2015 and April 15, 2015), these pharmacies were operating without a license.

#### PRAYER

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

- 1. Revoking or suspending Pharmacist License Number RPH 30915, issued to Respondent David Anthony Valencia;
- Revoking or suspending Pharmacy Permit Number PHY 50632, issued to Respondent Bacon East Pharmacy;

FIRST AMENDED ACCUSATION

In the Matter of the Accusation Against Bacon East Pharmacy et al.

|          | J   |  |  |
|----------|---|--|--|
| 1        | KAMALA D. HARRIS  |  |  |
| 2        | Attorney General of California DIANN SOKOLOFF   |  |  |
| 3        | Supervising Deputy Attorney General CARTER OTT  |  |  |
| 4        | Deputy Attorney General<br>State Bar No. 221660   |  |  |
| 5        | 1515 Clay Street, 20th Floor<br>P.O. Box 70550  |  |  |
| 6        | Oakland, CA 94612-0550<br>Telephone: (510) 622-2219                                     |  |  |
| 7        | Facsimile; (510) 622-2270<br>E-mail; Carter.Ott@doj.ca.gov                              |  |  |
| 8        | Attorneys for Complainant   |  |  |
| 9        | BEFORE THE<br>BOARD OF PHARMACY   |  |  |
| 10       | DEPARTMENT OF CONSUMER AFFAIRS<br>STATE OF CALIFORNIA                                   |  |  |
| 11       |   |  |  |
| 12       | In the Matter of the Accusation Against:  | Case No. 5221  |  |
| 13       | DAVID ANTHONY VALENCIA,<br>A.K.A. DAVID VALENCIA,                                       |  |  |
| 14       | 505 Alameda Driye,<br>Livermore, CA 94551   | ACCUSATION   |  |
| 15       | Pharmacist License No. RPH 30915,   | ,  |  |
| 16       | and   |  |  |
| 17<br>18 | BACON EAST PHARMACY 2425 East Street, Suite 5   |  |  |
|          | Concord, CA 95420   |  |  |
| 19       | Pharmacy Permit No. PHY 50632   |  |  |
| 20       | Respondents.  |  |  |
| 21       |   |  |  |
| 22       | Complainant alleges:  |  |  |
| 23       | <u>PARTTES</u>  |  |  |
| 24       | 1. Virginia Herold (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 June 14, 2011, the Board of Pharmacy Issued Pharmacy Permit Number       |  |  |
| 27       | PHY 50632 to Respondent Bacon East Pharmac  | y (Respondent Pharmacy). The Pharmacy Permit   |  |
| 28       |   | 1  |  |
|          |   | Accusation<br>Case No. 5221  |  |
|          | ·   | The state of the s |  |

was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on June 1, 2015, unless renewed,

3. On or about July 27, 1977, the Board of Pharmacy issued Pharmacist License Number RPH 30915 to Respondent David Anthony Valencia (Respondent Pharmacist). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2015, unless renewed. Respondent Pharmacist is and has been the Pharmacist-in-Charge since March 11, 2013.

# **JURISDICTION**

- 4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 2764 of the Code provides, in part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license.

# REGULATORY PROVISIONS

- 6. Section 4081 of the Code states in relevant part:
- "(a) All records of manufacture and of sale, acquisition, or disposition of 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 three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

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7. Section 4105 of the Code states:

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

"(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

"(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

"(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

"(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board."

8. Section 4301 of the Code states in relevant part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:

"(0) 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.

9. Section 4306.5 of the Code states:

"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.
- "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
- "(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.
- "(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function."

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10. Code of Regulations, title 16, section 1707.2 states, in relevant part:

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or

11. Code of Regulations, title 16, section 1714 states, in relevant part:

".,

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

12. Code of Regulations, title 16, section 1718 states, in relevant part:

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

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

13. Code of Regulations, title 16, section 1735.5 states, in relevant part:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual 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.

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CASE No. 5221

 SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policy and Procedure Manual) (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and (b))

- 16. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain a written policy and procedure manual for compounding pharmacy activities as required by Code California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (b). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and (b)). The circumstances are as follows:
- a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector found, according to Respondent's written policy and procedure manual for compounding, that their manual had not been updated since June 2011.
- b. During a previous inspection, conducted on or about October 17, 2011, the Board identified this as an issue Respondents must correct.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition and Disposition) (Cal. Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code Regs., title 16, § 1718)

- 17. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain records accounting for the records of acquisition and disposition and the current inventory of dangerous drugs as required by Business and Professions Code sections 4081, subdivision (a), and 4105. (Cal. Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code Regs., title 16, § 1718). The circumstances are as follows:
- a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a Board inspector found that Respondents did not have accurate records of acquisition and/or disposition to account for an inventory shortage for 4,252 tablets of oxycodone 30 mg tablets. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug according to Business and Professions Code section 4022 in that it can be lawfully dispensed only by prescription.

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| 3        | 3. Ordering Respondents David Anthony Valencia and Bacon East Pharmacy to pay the         |  |
| 4        | Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, |  |
| 5        | pursuant to Business and Professions Code section 125.3; and                              |  |
| 6        | 4. Taking such other and further action as deemed necessary and proper.                   |  |
| 7        |   |  |
| 8        | DATED: 9/25/14 (horner Sud  |  |
| 9        | VIRGINIA HEROLD  Executive Officer  |  |
| 10       | Board of Pharmacy Department of Consumer Affairs  |  |
| 11       | State of California  Complainant  |  |
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