Kamala D. Harris	
Attorney General of California	
DIANN ŠOKOLOFF Supervising Deputy Attorney General	
CARTER OTT Deputy Attorney General	
State Bar No. 221660	
1515 Clay Street, 20th Floor P.O. Box 70550	
Oakland, CA 94612-0550	
Telephone: (510) 622-2219 Facsimile: (510) 622-2270	
E-mail: Carter.Ott@doj.ca.gov	·
Attorneys for Complainant	
	RE THE PHARMACY
DEPARTMENT OF	CONSUMER AFFAIRS
STATE OF	CALIFORNIA
]
In the Matter of the Accusation Against:	Case No. 5221
DAVID ANTHONY VALENCIA,	OAH No. 2015010579
A.K.A. DAVID VALENCIA, 505 Alameda Drive,	FIRST AMENDED ACCUSATION
Livermore, CA 94551	
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 Turlock, CA 95382	
Pharmacy Permit No. PHY 51468	
•	
Respondents.	
	-
	1

.

Complainant alleges:

1

2

3

4

5

<u>PARTIES</u>

 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.

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

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 15 PHY 51468 to Respondent Boies Medical Center Pharmacy. The Pharmacy Permit was cancelled 16 on April 16, 2016, but was in full force and effect at all times relevant to the charges brought in 17 this First Amended Accusation.4. Respondent Bacon East Pharmacy is owned by a Bacon East 18 Pharmacy Inc., a California corporation, and Boies Medical Center Pharmacy is owned by Boies 19 Pharmacy Inc., a California corporation. Each of these corporations was owned by Jamil Harb 20 until his passing on January 4, 2015. Following Mr. Harb's passing, his widow inherited 21 ownership in the pharmacy corporations. 22

JURISDICTION

2

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.

27 || /////

23

28 || /////

 4 order 5 any p 6 autho 7 provid 8 discip 9 10 11 has be 12 follow 13 14 15 16 17 18 discret 19 20 21 (comr 22 shall 1 23 action 24 Proce 25 	6. Section 118, subdivision (b) states:
3 board 4 order 5 any p 6 autho 7 provid 8 discip 9	I
 4 order 5 any p 6 autho 7 provid 8 discip 9 10 11 has be 12 follow 13 14 15 16 17 18 discret 19 20 21 (comt 22 shall 1 23 action 24 Proce 25 	"(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a
5 any p 6 autho 7 provid 8 discip 9 1 10 has be 12 follow 13 1 14 1 15 1 16 1 17 18 18 discreet 19 20 21 (common 2) 23 action 24 Procet 25 1	in the department, or its suspension, forfeiture, or cancellation by order of the board or by
 6 autho 7 provid 8 discip 9 10 11 has be 12 follow 13 14 15 16 17 18 discret 19 20 21 (comr 22 shall 1 23 action 24 Proce 25 	of a court of law, or its surrender without the written consent of the board, shall not, during
7 provie 8 discip 9	eriod in which it may be renewed, restored, reissued, or reinstated, deprive the board of its
8 discip 9 10 10 11 11 has box 12 follow 13 14 15 16 17 18 18 discred 19 20 21 (common 22 23 action 24 Proce 25	rity to institute or continue a disciplinary proceeding against the licensee upon any ground
9 10 11 has be 12 follow 13 1 14 1 15 1 16 1 17 1 18 discret 19 20 21 (commonstructure) 23 action 24 Proce 25 1	led by law or to enter an order suspending or revoking the license or otherwise taking
10 has be 11 has be 12 follow 13 1 14 1 15 1 16 1 17 1 18 discree 19 20 21 (commons) 23 action 24 Proce 25 1	linary action against the licensee on any such ground."7. Section 4300 states, in part:
 has be follow follow follow	"(a) Every license issued may be suspended or revoked.
12 follow 13 14 13 14 15 16 17 18 18 discret 19 20 21 (comm 22 shall I 23 action 24 Proce 25 25	"(b) The board shall discipline the holder of any license issued by the board, whose default
 13 14 15 16 17 18 discrete 19 20 21 (commonstructure 22 shall 1 23 action 24 Proce 25 	een entered or whose case has been heard by the board and found guilty, by any of the
 14 15 16 17 18 discrete 19 20 21 (commonstrained on the second on the	ving methods:
 15 16 17 18 discretion 19 20 21 (commonstructure) 22 shall 1 23 action 24 Proce 25 	(1) Suspending judgment.
 16 17 18 discretion 19 20 21 (communication) 22 shall 1 23 action 24 Proce 25 	(2) Placing him or her upon probation.
 17 18 discrete 19 20 21 (commonstrained) 22 shall 1 23 action 24 Proce 25 	(3) Suspending his or her right to practice for a period not exceeding one year.
 18 discret 19 20 21 (commission 22 shall 1 23 action 24 Proce 25 	(4) Revoking his or her license.
 19 20 21 (commission 22 shall 23 action 24 Proce 25 	(5) Taking any other action in relation to disciplining him or her as the board in its
 20 21 (commission 22 shall 23 action 24 Proce 25 	tion may deem proper.
21(comm22shall 123action24Proce25	•••
 22 shall 23 action 24 Proce 25 	"(e) The proceedings under this article shall be conducted in accordance with Chapter 5
23 action24 Proce25	nencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
24 Proce 25	have all the powers granted therein. The action shall be final, except that the propriety of the
25	is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil
	dure."
26	8. Section 4300.1 states:
11	"The expiration, cancellation, forfeiture, or suspension of a board-issued license by
27 opera	tion of law or by order or decision of the board or a court of law, the placement of a license
28 on a r	etired status, or the voluntary surrender of a license by a licensee shall not deprive the board 3
	FIRST AMENDED ACCUSATION In the Matter of the Accusation Against Bacon East Pharmacy et al.

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."

3

2

1

Section 4081 states, in part: STATUTORY AND REGULATORY PROVISIONS9. "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 4 or dangerous devices shall be at all times during business hours open to inspection by authorized 5 officers of the law, and shall be preserved for at least three years from the date of making. A 6 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary 7 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 8 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 9 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 10 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 11 Institutions Code who maintains a stock of dangerous drugs or dangerous devices." 12

13

10. Section 4105 states:

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

"(b) The licensee may remove the original records or documentation from the licensed 17 premises on a temporary basis for license-related purposes. However, a duplicate set of those 18 records or other documentation shall be retained on the licensed premises. 19

"(c) The records required by this section shall be retained on the licensed premises for a 20 period of three years from the date of making. 21

"(d) Any records that are maintained electronically shall be maintained so that the 22 pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the 23 case of a veterinary food-animal drug retailer or wholesaler, the designated representative on 24 duty, shall, at all times during which the licensed premises are open for business, be able to 25 produce a hard copy and electronic copy of all records of acquisition or disposition or other drug 26 or dispensing-related records maintained electronically. 27

"(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), 2 and (c) be kept on the licensed premises. 3

"(2) A waiver granted pursuant to this subdivision shall not affect the board's authority 4 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 6 of the board, the owner, corporate officer, or manager of an entity licensed by the board shall 7 provide the board with the requested records within three business days of the time the request 8 was made. The entity may request in writing an extension of this timeframe for a period not to 9 exceed 14 calendar days from the date the records were requested. A request for an extension of 10 time is subject to the approval of the board. An extension shall be deemed approved if the board 11 fails to deny the extension request within two business days of the time the extension request was 12 made directly to the board." 13

14

1

5

11. Section 4110 states, in part:

"(a) No person shall conduct a pharmacy in the State of California unless he or she has 15 obtained a license from the board. A license shall be required for each pharmacy owned or 16 17 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. 18 The board may, by regulation, determine the circumstances under which a license may be 19 transferred. 20

"(b) The board may, at its discretion, issue a temporary permit, when the ownership of a 21 pharmacy is transferred from one person to another, upon the conditions and for any periods of 22 time as the board determines to be in the public interest. A temporary permit fee shall be required 23 in an amount established by the board as specified in subdivision (a) of Section 4400. When 24 needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 25 days, and may be issued subject to terms and conditions the board deems necessary. If the board 26 determines a temporary permit was issued by mistake or denies the application for a permanent 27 28 license or registration, the temporary license or registration shall terminate upon either personal

5

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:

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

10

6

7

"(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.

15

16

17

. . . ."

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.

26 "(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate
27 patient, prescription, and other records pertaining to the performance of any pharmacy function.

28

1	"(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and
2	retain appropriate patient-specific information pertaining to the performance of any pharmacy
3	function."
4	14. Code of Regulations, title 16, section 1707.2 states, in part:
5	"
6	"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall
7	provide oral consultation to his or her patient or the patient's agent in any care setting in which the
8	patient or agent is present:
9	"(A) whenever the prescription drug has not previously been dispensed to a patient; or
10	»» • • • • •
11	15. Code of Regulations, title 16, section 1709 states, in part:
12	"(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy,
13	the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each
14	pharmacy shall, in its initial application on the annual renewal form, report the name of the
15	pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a
16	corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall
17	be reported to the Board within 30 days.
18	"(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more
19	of the beneficial interest in a business entity licensed by the board to a person or entity who did
20	not hold a beneficial interest at the time the original permit was issued, shall require written
21	notification to the board within 30 days.
22	"16. Code of Regulations, title 16, section 1714 states, in part:
23	"· · · ·
24	"(d) Each pharmacist while on duty shall be responsible for the security of the prescription
25	department, including provisions for effective control against theft or diversion of dangerous
26	drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
27	where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.
28	, , , , , , , , , , , , , , , , , , ,
	7 First Amended Accusation
	In the Matter of the Accusation Against Bacon East Pharmacy et al.

ļ	
1	17. Code of Regulations, title 16, section 1718 states, in part:
2	"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
3	Code shall be considered to include complete accountability for all dangerous drugs handled by
4	every licensee enumerated in Sections 4081 and 4332.
5	"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
6	available for inspection upon request for at least 3 years after the date of the inventory."
7	18. Code of Regulations, title 16, section 1735.5 states, in part:
8	"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure
9	manual for compounding that establishes procurement procedures, methodologies for the
10	formulation and compounding of drugs, facilities and equipment cleaning, maintenance,
11	operation, and other standard operating procedures related to compounding.
12	"(b) The policy and procedure manual shall be reviewed on an annual basis by the
13	pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
14	»» • • • •
15	COST RECOVERY
16	19. Section 125.3 provides, in part, that the Board may request the administrative law
17	judge to direct a licentiate found to have committed a violation or violations of the licensing act to
18	pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.
19	
20	FIRST CAUSE FOR DISCIPLINE (Failure to Consult)
21	(Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c); Cal. Code Regs., title 16, § 1707.2, subd. (b)(1)(A))
22	20. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist
23	License and Pharmacy Permit, respectively, to disciplinary action for failing to consult as
24	required by Code California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(A).
25	(Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subd. (a)-(c); Cal. Code Regs., title 16, § 1707.2,
26	subd. (b)(1)(A)). The circumstances are as follows:
27	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
28	Board inspector interviewed a pharmacy clerk who stated he identified prescriptions requiring 8
	FIRST AMENDED ACCUSATION In the Matter of the Accusation Against Bacon East Pharmacy et al.

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

i

1	consultation by a pharmacist by looking for a "consult" stamp on the receipt. However, this
2	process was not being executed by the pharmacy staff, as the Board inspector identified three (3)
3	new prescriptions which were not stamped with "consult" on the receipt.
4	b. During a previous inspection, conducted on or about October 17, 2011, the
5	Board identified this as an issue Respondent Bacon East Pharmacy must correct.
6	
7	SECOND CAUSE FOR DISCIPLINE (Failure to Maintain Written Policy and Procedure Manual)
8	(Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and (b))
9	21. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist
10	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain a written
11	policy and procedure manual for compounding pharmacy activities as required by Code
12	California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (b). (Cal. Bus. &
13	Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and
14	(b)). The circumstances are as follows:
15	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
16	Board inspector found, according to Respondent's written policy and procedure manual for
17	compounding, that their manual had not been updated since June 2011.
18	b. During a previous inspection, conducted on or about October 17, 2011, the
19	Board identified this as an issue Respondent Bacon East Pharmacy must correct.
20	
21	THIRD CAUSE FOR DISCIPLINE (Failure to Maintain Records of Acquisition and Disposition)
22	(Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code Regs., title 16, § 1718)
23	22. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist
24	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain records
25	accounting for the records of acquisition and disposition and the current inventory of dangerous
26	drugs as required by Business and Professions Code sections 4081, subdivision (a), and 4105.
27	
28	////
	9 EIDET AMENDED A COULATION
	FIRST AMENDED ACCUSATION In the Matter of the Accusation Against Bacon East Pharmacy et al.

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

1	(Cal. Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal. Code
2	Regs., title 16, § 1718). The circumstances are as follows:
3	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
4	Board inspector found that Respondents did not have accurate records of acquisition and/or
5	disposition to account for an inventory shortage for 4,252 tablets of oxycodone 30 mg tablets.
6	Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section
7	11055, subdivision (b)(1)(M), and a dangerous drug according to Business and Professions Code
8	section 4022 in that it can be lawfully dispensed only by prescription.
9	
10 11	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))
12	23. Respondents Valencia and Bacon East Pharmacy have subjected their Pharmacist
13	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain the
14	security of the prescription department, including provisions for effective control against theft or
15	diversion of dangerous drugs and records for such drugs as required by Code California Code of
16	Regulations, title 16, section 1714, subdivision (d). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5,
17	subds. (a)-(c); and Cal. Code Regs., title 16, § 1714, subd. (d)). The circumstances are as follows:
18	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
19	Board inspector found that Respondents had an inventory shortage (purchases/acquisitions greater
20	than sales/disposition) of 4,252 tablets of oxycodone 30 mg tablets. Oxycodone is a Schedule II
21	controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M),
22	and a dangerous drug according to Business and Professions Code section 4022 in that it can be
23	lawfully dispensed only by prescription.
24	FIFTH CAUSE FOR DISCIPLINE
25	(Failure to Notify of Change of Ownership) (Cal. Code Regs., title 16, § 1709, subds. (a) and (b))
26	24. Respondents Valencia, Bacon East Pharmacy, and Boies Medical Center Pharmacy
27	have subjected their Pharmacist License and Pharmacy Permits, respectively, to disciplinary
28	
	10 First Amended Accusation
ļ	FIRST AMENDED ACCUSATION In the Matter of the Accusation Against Bacon East Pharmacy et al.

m or Educe - .

1	action for failing to notify the Board regarding a change in the ownership of the pharmacies.
2	(Cal. Code Regs., title 16, § 1709, subds. (a) and (b)). The circumstances are as follows:
3	a. The Respondent pharmacies were formerly owned by Jamil Harb, until his
4	passing on January 4, 2015. Following Mr. Harb's passing, his widow inherited ownership of the
5	pharmacies.
6	b. Between January 4, 2015 and April 15, 2015, Bacon East Pharmacy and Boies
7	Medical Center Pharmacy continued to operate but Respondents failed to submit change in
8	ownership applications, based on the transfer of ownership from Jamil Harb to his widow, or
9	request a temporary permit from the Board.
10 11	SIXTH CAUSE FOR DISCIPLINE (Unlicensed Activity) (Bus. & Prof. Code § 4110, subds. (a) and (b))
12	25. Respondents Bacon East Pharmacy and Boies Medical Center Pharmacy have
13	subjected their Pharmacy Permits to disciplinary action for operating without a license. (Bus. &
14	Prof. Code § 4110, subds. (a) and (b)). The circumstances are as follows:
15	a. Upon the January 4, 2015 passing of Jamil Harb, the former owner of Bacon
16	East Pharmacy and Boies Medical Center Pharmacy, the permits the Board issued to those
17	pharmacies expired. Between January 4, 2015 and April 15, 2015, Bacon East Pharmacy and
18	Boies Medical Center Pharmacy continued to operate without submitting change in ownership
19	applications or requesting a temporary permit from the Board. During this period of time
20	(between January 4, 2015 and April 15, 2015), these pharmacies were operating without a license.
21	PRAYER
22	WHEREFORE, Complainant requests that a hearing be held on these matters, and that
23	following the hearing, the Board of Pharmacy issue a decision:
24	1. Revoking or suspending Pharmacist License Number RPH 30915, issued to
25	Respondent David Anthony Valencia;
26	2. Revoking or suspending Pharmacy Permit Number PHY 50632, issued to Respondent
27	Bacon East Pharmacy;
28	11

1	3. Revoking or suspending Pharmacy Permit Number PHY 51468, issued to Respondent	
2	Boies Medical Center Pharmacy;	
3	4. Ordering Respondents David Anthony Valencia, Bacon East Pharmacy, and Boies	
4	Medical Center Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation	
5	and enforcement of this case, pursuant to Business and Professions Code section 125.3; and	
6	5. Taking such other and further action as deemed necessary and proper.	
7		
8	inblic () $()$	
9	DATED: 10/2/15 Urginia Hirold	
10	Executive Officer Board of Pharmacy Department of Consumer Affairs	
11	State of California Complainant	
12	Comptunium	
13	SF2014902527	
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28	12	
	FIRST AMENDED ACCUSATION In the Matter of the Accusation Against Bacon East Pharmacy et al.	

.

-

-1

ŀ		1
1	KAMALA D. HARRIS Attorney General of California	
2	DIANN SOKOLOFF Supervising Deputy Attorney General	
3	CARTER OTT	
4	Deputy Attorney General State Bar No. 221660	
5	1515 Clay Street, 20th Floor P.O. Box 70550	
6	Oakland, CA 94612-0550 Telephone: (510) 622-2219	
7	Facsimile: (510) 622-2270 E-mail: Carter.Ott@doj.ca.gov	
8	Attorneys for Complainant	
9	BEFORE THE BOARD OF PHARMACY	
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
11		
12	In the Matter of the Accusation Against:	Case No. 5221
13	DAVID ANTHONY VALENCIA, A.K.A. DAVID VALENCIA,	
14	505 Alameda Driye, Livermore, CA 94551	ACCUSATION
15	Pharmacist License No. RPH 30915,	
16	and	
17	BACON EAST PHARMACY	
. 18	2425 East Street, Suite 5 Concord, CA 95420	
19	Pharmacy Permit No. PHY 50632	
20	Respondents.	
21		
22	Complainant alleges:	
23	PARTIES	
24	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity	
25	as the Executive Officer of the Board of Pharma	cy, Department of Consumer Affairs.
26	2. On or about June 14, 2011, the Board	d of Pharmacy issued Pharmacy Permit Number
27	PHY 50632 to Respondent Bacon East Pharmac	y (Respondent Pharmacy). The Pharmacy Permit
28		,
		1 Accusation
		Case No. 5221

.

was in full force and effect at all times relevant to the charges brought in this Accusation and will 1 expire on June 1, 2015, unless renewed. 2 On or about July 27, 1977, the Board of Pharmacy issued Pharmacist License 3. 3 Number RPH 30915 to Respondent David Anthony Valencia (Respondent Pharmacist). The 4 Pharmacist License was in full force and effect at all times relevant to the charges brought herein 5 and will expire on November 30, 2015, unless renewed. Respondent Pharmacist is and has been 6 the Pharmacist-in-Charge since March 11, 2013. 7 8 JURISDICTION This Accusation is brought before the Board of Pharmacy (Board), Department of 4. 9 Consumer Affairs, under the authority of the following laws. All section references are to the 10 Business and Professions Code unless otherwise indicated. 11 Section 2764 of the Code provides, in part, that the expiration of a license shall not 5. 12 deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or 13 to render a decision imposing discipline on the license. 14 **REGULATORY PROVISIONS** 15 6. Section 4081 of the Code states in relevant part: 16 "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 17 or dangerous devices shall be at all times during business hours open to inspection by authorized 18 officers of the law, and shall be preserved for at least three years from the date of making. A 19 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary 20 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 21 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 22 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 23 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 24 Institutions Code who maintains a stock of dangerous drugs or dangerous devices." 25 1111 26 ///// 27 ///// 28 2

> ACCUSATION CASE NO. 5221

3

4

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.

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

8 "(c) The records required by this section shall be retained on the licensed premises for a
9 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.

19 "(2) A waiver granted pursuant to this subdivision shall not affect the board's authority
20 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 21 of the board, the owner, corporate officer, or manager of an entity licensed by the board shall 22 provide the board with the requested records within three business days of the time the request 23 was made. The entity may request in writing an extension of this timeframe for a period not to 24 exceed 14 calendar days from the date the records were requested. A request for an extension of 25 time is subject to the approval of the board. An extension shall be deemed approved if the board 26 fails to deny the extension request within two business days of the time the extension request was 27 made directly to the board." 28

3

4

9

10

11

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:

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

. . . . , ,,

8.

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."

25 /////

26 /////

27 || /////

28 /////

1	STATUTORY PROVISIONS
2	10. Code of Regulations, title 16, section 1707.2 states, in relevant part:
3	"
4	"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall
5	provide oral consultation to his or her patient or the patient's agent in any care setting in which
6	the patient or agent is present:
7	"(A) whenever the prescription drug has not previously been dispensed to a patient; or
8	2)
9	11. Code of Regulations, title 16, section 1714 states, in relevant part:
10	«« • • • •
11	"(d) Each pharmacist while on duty shall be responsible for the security of the prescription
12	department, including provisions for effective control against theft or diversion of dangerous
13	drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
14	where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.
15	»» · · · · ·
16	12. Code of Regulations, title 16, section 1718 states, in relevant part:
17	"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
18	Code shall be considered to include complete accountability for all dangerous drugs handled by
19	every licensee enumerated in Sections 4081 and 4332.
20	"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
21	available for inspection upon request for at least 3 years after the date of the inventory."
22	13. Code of Regulations, title 16, section 1735.5 states, in relevant part:
23	"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure
24	manual for compounding that establishes procurement procedures, methodologies for the
25	formulation and compounding of drugs, facilities and equipment cleaning, maintenance,
26	operation, and other standard operating procedures related to compounding.
27	
28	///// E
	5 ACCUSATION
	Case No. 5221

ALL YOU DWD DWD IN U.

-

1.1.1

1	"(b) The policy and procedure manual shall be reviewed on an annual basis by the
2	pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
3	,)) • • • •
4	COST RECOVERY
5	14. Section 125.3 of the Code provides, in relevant part, that the Board may request the
6	administrative law judge to direct a licentiate found to have committed a violation or violations of
7	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
8	enforcement of the case.
9	
10	<u>CAUSES FOR DISCIPLINE</u>
11	FIRST CAUSE FOR DISCIPLINE (Failure to Consult)
12	(Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c); Cal. Code Regs., title 16, § 1707.2, subd. (b)(1)(A))
13	15. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist
14	License and Pharmacy Permit, respectively, to disciplinary action for failing to consult as
15	required by Code California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(A).
16	(Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subd. (a)-(c); Cal. Code Regs., title 16, § 1707.2,
17	subd. (b)(1)(A)). The circumstances are as follows:
18	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
19	Board inspector interviewed a pharmacy clerk who stated he identified prescriptions requiring
20	consultation by a pharmacist by looking for a "consult" stamp on the receipt. However, this
21	process was not being executed by the pharmacy staff, as the Board inspector identified three (3)
22	new prescriptions which were not stamped with "consult" on the receipt.
23	b. During a previous inspection, conducted on or about October 17, 2011, the
24	Board identified this as an issue Respondents must correct.
25	
26	
27	
28	////
	6
	Accusation Case No. 5221

i.

1.111.111.111.111.111.111.1

A MARY AND AND AND AND

÷

.

1	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))
3	16. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist
4	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain a written
5	policy and procedure manual for compounding pharmacy activities as required by Code
6	California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (b). (Cal. Bus. &
7	Prof. Code §§ 4301 and 4306.5, subds. (a)-(d); Cal. Code Regs., title 16, § 1735.5, subds. (a) and
8	(b)). The circumstances are as follows:
9	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
10	Board inspector found, according to Respondent's written policy and procedure manual for
11	compounding, that their manual had not been updated since June 2011.
12	b. During a previous inspection, conducted on or about October 17, 2011, the
13	Board identified this as an issue Respondents must correct.
14	
15 16	<u>THIRD CAUSE FOR DISCIPLINE</u> (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	17. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist
18	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain records
19	accounting for the records of acquisition and disposition and the current inventory of dangerous
20	drugs as required by Business and Professions Code sections 4081, subdivision (a), and 4105.
21	(Cal. Bus. & Prof. Code §§ 4081, subd. (a); 4105; 4301; and 4306.5, subds. (a)-(d); and Cal.
22	Code Regs., title 16, § 1718). The circumstances are as follows:
23	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
24	Board inspector found that Respondents did not have accurate records of acquisition and/or
25	disposition to account for an inventory shortage for 4,252 tablets of oxycodone 30 mg tablets.
26	Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section
27	11055, subdivision (b)(1)(M), and a dangerous drug according to Business and Professions Code
28	section 4022 in that it can be lawfully dispensed only by prescription.
	7 Accusation
	Case No. 5221

1 2	FOURTH CAUSE FOR DISCIPLINE (Failure to Maintain Security of Prescription Department) (Cal. Bus. & Prof. Code §§ 4301 and 4306.5, subds. (a)-(c); and Cal. Code Regs., title 16, § 1714, subd. (d))
3	18. Respondent Pharmacist and Respondent Pharmacy have subjected their Pharmacist
4	License and Pharmacy Permit, respectively, to disciplinary action for failing to maintain the
5	security of the prescription department, including provisions for effective control against theft or
6	diversion of dangerous drugs and records for such drugs as required by Code California Code of
7	Regulations, title 16, section 1714, subdivision (d). (Cal. Bus. & Prof. Code §§ 4301 and 4306.5,
8	subds. (a)-(c); and Cal. Code Regs., title 16, § 1714, subd. (d)). The circumstances are as
9	follows:
10	a. On or about July 16, 2013, during an inspection at Bacon East Pharmacy, a
11	Board inspector found that Respondents had an inventory shortage (purchases/acquisitions
12	greater than sales/disposition) of 4,252 tablets of oxycodone 30 mg tablets. Oxycodone is a
13	Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision
14	(b)(1)(M), and a dangerous drug according to Business and Professions Code section 4022 in that
15	it can be lawfully dispensed only by prescription.
16	PRAYER
17	WHEREFORE, Complainant requests that a hearing be held on these matters, and that
18	following the hearing, the Board of Pharmacy issue a decision:
19	1. Revoking or suspending Pharmacist License Number RPH 30915, issued to
20	Respondent David Anthony Valencia;
21	2. Revoking or suspending Pharmacy Permit Number PHY 50632, issued to Respondent
22	Bacon East Pharmacy;
23	
24	11/1/
25	
26	
27	
28	
	8 Accusation
	Case No. 5221

||||| 3. Ordering Respondents David Anthony Valencia and Bacon East Pharmacy 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 4. Taking such other and further action as deemed necessary and proper. 9/25/14 DATED: VIRGINIA HERO Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant SF2014902527 ACCUSATION CASE NO. 5221