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

Case No. 5042

In the Matter of the Accusation
Against:
ST. JOSEPH'S MEDICAL CENTER
1800 N. California Street
Stockton, CA 95204
Pharmacy Permit No. HSP 45514,

Respondent.

**STIPULATION FOR
CONTINUING JURISDICTION**

IT IS HEREBY STIPULATED AND AGREED by and between the undersigned parties that the following is true:

1. The parties to this agreement are **Virginia Herold**, acting in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, and **Donald J. Wiley**, President and Chief Executive Officer authorized representative of Port City Operating Company, LLC, 3400 Data Drive, Rancho Cordova, CA 95670 dba St. Joseph's Medical Center.

2. On or about March 11, 2016, Port City Operating Company, LLC, O3400 Data Drive, Rancho Cordova, CA 95670 dba St. Joseph's Medical Center (hereinafter "applicant") submitted an application to the Board for change of ownership of St. Joseph's Medical Center, 1800 N. California Street, Stockton, CA 95204 (Original Permit No. HSP 45514). The granting of the application would require the cancellation of Original Permit No. HSP 45514 issued to Dignity Health, 185 Berry Street, Suite 300, San Francisco, CA 94107, and the issuance of a new original permit number to applicant pursuant to Business and Professions Code section 4201(f).

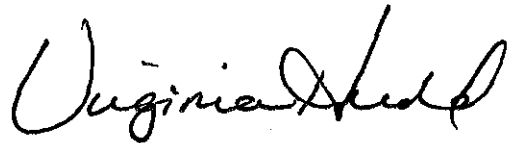
3. The existing permit (Original Permit No. HSP 45514) is currently the subject of a disciplinary order issued effective April, 8, 2015, by the Board in the disciplinary matter entitled

1 *In The Matter of Accusation Against St. Joseph's Medical Center, etc.*, Board of Pharmacy Case
2 No. 5042. A true and correct copy of the decision and order in this matter is attached hereto as
3 **Exhibit A** and incorporated by this reference.

4 4. In exchange for expedited processing and issuance of the new permit pursuant to the
5 change in ownership, applicant understands and agrees that the Board shall have continuing
6 jurisdiction over the new permit issued to applicant such that the disciplinary order issued by the
7 Board in Case No. 5042, including any terms and conditions and remaining tenure of probation,
8 shall carry forward and be applicable to the new permit issued to applicant. The Board hereby
9 waives any right it may have had to deny issuance of the new permit.


10 5. A portable document format (PDF) or facsimile signature on this document shall be
11 binding as an original signature. Parties agree to use of portable document format (PDF) or
12 facsimile signatures in lieu of original signatures for all purposes relevant to enforcement of this
13 Stipulation.

14
15 Dated: 5/26/16



VIRGINIA HEROLD
Executive Officer
California Board of Pharmacy

16
17
18
19 Dated: 05/25/16



DONALD J. WILEY
President and Chief Executive Officer
Authorized Representative
Port City Operating Company, LLC

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

In the Matter of the Accusation Against:

**ST. JOSEPH'S MEDICAL CENTER;
CATHOLIC HEALTHCARE WEST;
DIGNITY HEALTH
1800 North California Street
Stockton, CA 95204**

Original Permit No. HSP 45514

and

**HARRIET FRANCES CATANIA
3949 Glen Abby Circle
Stockton, CA 95219**

Original Pharmacist License No. RPH 26621

Respondents.

Case No. 5042

OAH No. 2014060622

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER (ST.
JOSEPH'S MEDICAL CENTER;
CATHOLIC HEALTHCARE WEST;
DIGNITY HEALTH ONLY)**

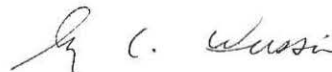
DECISION AND ORDER

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 on April 8, 2015.

It is so ORDERED on April 1, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STAN C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 PHILLIP L. ARTHUR
Deputy Attorney General
4 State Bar No. 238339
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 322-0032
Facsimile: (916) 327-8643
7 E-mail: Phillip.Arthur@doj.ca.gov
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5042

12 **ST. JOSEPH'S MEDICAL CENTER;**
13 **CATHOLIC HEALTHCARE WEST;**
14 **DIGNITY HEALTH**
1800 North California Street
15 Stockton, California 95204

OAH No. 2014060622

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER (ST. JOSEPH'S
MEDICAL CENTER; CATHOLIC
HEALTHCARE WEST; DIGNITY
HEALTH ONLY)**

16 **Original Permit No. HSP 45514**

17 **and**

18 **HARRIET FRANCES CATANIA**
3949 Glen Abby Circle
19 Stockton, California 95219

20 **Original Pharmacist License No. RPH 26621**

21 Respondents.

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 PARTIES

26 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
27 She brought this action solely in her official capacity and is represented in this matter by Kamala
28

1 D. Harris, Attorney General of the State of California, by Phillip L. Arthur, Deputy Attorney
2 General.

3 2. Respondents St. Joseph's Medical Center; Catholic Healthcare West; Dignity Health
4 ("Respondent St. Joseph's") and Harriet F. Catania, PIC ("Respondent Catania") are represented
5 in this proceeding by attorney Allison Cova, whose address is: Dignity Health, 185 Berry Street,
6 Suite 300, San Francisco, CA 94107.

7 3. On or about July 16, 1970, the Board of Pharmacy issued Original Pharmacist
8 License Number RPH 26621 to Respondent Catania. The Original Pharmacist License was in full
9 force and effect at all times relevant to the charges brought herein and will expire on January 31,
10 2016, unless renewed.

11 4. On or about March 15, 2002, the Board of Pharmacy issued Original Permit Number
12 HSP 45514 to Catholic Healthcare West, dba St. Joseph's Medical Center ("Respondent St.
13 Joseph's"). The Original Permit was in full force and effect at all times relevant to the charges
14 brought herein and will expire on March 31, 2015, unless renewed.

15 5. On or about February 13, 2012, the Board of Pharmacy issued Original Permit
16 Number HSP 45514 to Dignity Health, dba St. Joseph's Medical Center ("Respondent St.
17 Joseph's"). The Original Permit was in full force and effect at all times relevant to the charges
18 brought herein and will expire on March 31, 2015, unless renewed.

19 6. Respondent Catania served as the Pharmacist-in-Charge at Respondent St. Joseph's
20 from March 15, 2002, through November 1, 2010.

21 JURISDICTION

22 7. Accusation No. 5042 was filed before the Board of Pharmacy (Board), Department of
23 Consumer Affairs, and is currently pending against Respondents. The Accusation and all other
24 statutorily required documents were properly served on Respondents on May 16, 2014.
25 Respondents timely filed their Notices of Defense contesting the Accusation.

26 8. A copy of Accusation No. 5042 is attached as exhibit A and incorporated herein by
27 reference.

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ADVISEMENT AND WAIVERS

1
2 9. Respondent St. Joseph's has carefully read, fully discussed with counsel, and
3 understands the charges and allegations in Accusation No. 5042. Respondent St. Joseph's has
4 also carefully read, fully discussed with counsel, and understands the effects of this Stipulated
5 Settlement and Disciplinary Order.

6 10. Respondent St. Joseph's is fully aware of its legal rights in this matter, including the
7 right to a hearing on the charges and allegations in the Accusation; the right to be represented by
8 counsel at its own expense; the right to confront and cross-examine the witnesses against them;
9 the right to present evidence and to testify on its own behalf; the right to the issuance of
10 subpoenas to compel the attendance of witnesses and the production of documents; the right to
11 reconsideration and court review of an adverse decision; and all other rights accorded by the
12 California Administrative Procedure Act and other applicable laws.

13 11. Respondent St. Joseph's voluntarily, knowingly, and intelligently waives and gives
14 up each and every right set forth above.

CULPABILITY

15
16 12. Respondent St. Joseph's understands and agrees that if proven at a hearing, the
17 charges and allegations in Accusation No. 5042 constitute cause for disciplining Respondent's
18 Original Permit.

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

CONTINGENCY

21
22 14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
23 St. Joseph's understands and agrees that counsel for Complainant and the staff of the Board of
24 Pharmacy may communicate directly with the Board regarding this stipulation and settlement,
25 without notice to or participation by Respondent St. Joseph's or its counsel. By signing the
26 stipulation, Respondent St. Joseph's understands and agrees that it may not withdraw its
27 agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it.
28 If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and

1 Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible
2 in any legal action between the parties, and the Board shall not be disqualified from further action
3 by having considered this matter.

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

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

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

17 **DISCIPLINARY ORDER**

18 IT IS HEREBY ORDERED that Original Permit No. HSP 45514 issued to Respondent St.
19 Joseph's is revoked. However, the revocation is stayed and Respondent St. Joseph's is placed on
20 probation for four (4) years on the following terms and conditions.

21 **1. Obey All Laws**

22 Respondent St. Joseph's shall obey all state and federal laws and regulations.

23 Respondent St. Joseph's shall report any of the following occurrences to the board, in
24 writing, within seventy-two (72) hours of such occurrence:

- 25 an arrest or issuance of a criminal complaint for violation of any provision of the
26 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
27 substances laws
28 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any

- 1 criminal complaint, information, or indictment
- 2 a conviction of any crime
- 3 discipline, citation, or other administrative action filed by any state or federal agency
- 4 which involves Respondent St. Joseph's Original Permit or which is related to the
- 5 practice of pharmacy or the manufacturing, obtaining, handling or distributing,
- 6 billing, or charging for any drug, device, or controlled substance.

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

8 **2. Report to the Board**

9 Respondent St. Joseph's shall report to the board quarterly, on a schedule as directed by the
10 board or its designee. The report shall be made either in person or in writing, as directed. Among
11 other requirements, Respondent St. Joseph's shall state in each report under penalty of perjury
12 whether there has been compliance with all the terms and conditions of probation. Failure to
13 submit timely reports in a form as directed shall be considered a violation of probation. Any
14 period(s) of delinquency in submission of reports as directed may be added to the total period of
15 probation. Moreover, if the final probation report is not made as directed, probation shall be
16 automatically extended until such time as the final report is made and accepted by the board.

17 **3. Interview with the Board**

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

23 **4. Cooperate with Board Staff**

24 Respondent St. Joseph's shall cooperate with the board's inspection program and with the
25 board's monitoring and investigation of Respondent St. Joseph's compliance with the terms and
26 conditions of its probation. Failure to cooperate shall be considered a violation of probation.

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1 **5. Reimbursement of Board Costs**

2 As a condition precedent to successful completion of probation, Respondent St. Joseph's
3 shall pay to the board its costs of investigation and prosecution in the amount of \$3,593.75
4 Respondent St. Joseph's shall make said payments on a payment plan approved by the board.
5 There shall be no deviation from this schedule absent prior written approval by the board or its
6 designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
7 probation.

8 The filing of bankruptcy by Respondent St. Joseph's shall not relieve Respondent St.
9 Joseph's of its responsibility to reimburse the board its costs of investigation and prosecution.

10 **6. Probation Monitoring Costs**

11 Respondent St. Joseph's shall pay any costs associated with probation monitoring as
12 determined by the board each and every year of probation. Such costs shall be payable to the
13 board on a schedule as directed by the board or its designee. Failure to pay such costs by the
14 deadline(s) as directed shall be considered a violation of probation.

15 **7. Status of License**

16 Respondent St. Joseph's shall, at all times while on probation, maintain current licensure
17 with the board. If Respondent St. Joseph's submits an application to the board, and the
18 application is approved, for a change of location, change of permit, or change of ownership, the
19 board shall retain continuing jurisdiction over the license, and Respondent St. Joseph's shall
20 remain on probation as determined by the board. Failure to maintain current licensure shall be
21 considered a violation of probation.

22 If Respondent St. Joseph's license expires or is cancelled by operation of law or otherwise
23 at any time during the period of probation, including any extensions thereof or otherwise, upon
24 renewal or reapplication Respondent St. Joseph's license shall be subject to all terms and
25 conditions of this probation not previously satisfied.

26 **8. License Surrender While on Probation/Suspension**

27 Following the effective date of this decision, should Respondent St. Joseph's discontinue
28 business, Respondent St. Joseph's may tender the premises license to the board for surrender.

1 The board or its designee shall have the discretion whether to grant the request for surrender or
2 take any other action it deems appropriate and reasonable. Upon formal acceptance of the
3 surrender of the license, Respondent St. Joseph's will no longer be subject to the terms and
4 conditions of probation.

5 Upon acceptance of the surrender, Respondent St. Joseph's shall relinquish the premises
6 wall and renewal license to the board within ten (10) days of notification by the board that the
7 surrender is accepted. Respondent St. Joseph's shall further submit a completed Discontinuance
8 of Business form according to board guidelines and shall notify the board of the records inventory
9 transfer.

10 Respondent St. Joseph's shall also, by the effective date of this decision, arrange for the
11 continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written
12 notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that
13 identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating
14 as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five
15 days of its provision to the pharmacy's ongoing patients, Respondent St. Joseph's shall provide a
16 copy of the written notice to the board. For the purposes of this provision, "ongoing patients"
17 means those patients for whom the pharmacy has on file a prescription with one or more refills
18 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)
19 days.

20 Respondent St. Joseph's may not apply for any new licensure from the board for three (3)
21 years from the effective date of the surrender. Respondent St. Joseph's shall meet all
22 requirements applicable to the license sought as of the date the application for that license is
23 submitted to the board.

24 Respondent St. Joseph's further stipulates that it shall reimburse the board for its costs of
25 investigation and prosecution prior to the acceptance of the surrender.

26 **9. Notice to Employees**

27 Respondent St. Joseph's shall, upon or before the effective date of this decision, ensure that
28 all employees involved in permit operations are made aware of all the terms and conditions of

1 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
2 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
3 remain posted throughout the probation period. Respondent St. Joseph's shall ensure that any in-
4 patient pharmacy employees hired or used after the effective date of this decision are made aware
5 of the terms and conditions of probation by posting a notice, circulating a notice, or both.
6 Additionally, Respondent St. Joseph's shall submit written notification to the board, within
7 fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to
8 submit such notification to the board shall be considered a violation of probation.

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

12 **10. Owners and Officers: Knowledge of the Law**

13 Respondent St. Joseph's shall provide, within thirty (30) days after the effective date of this
14 decision, signed and dated statements from its owners, including any owner or holder of ten
15 percent (10%) or more of the interest in Respondent St. Joseph's or Respondent St. Joseph's
16 stock, and any officer, stating under penalty of perjury that said individuals have read and are
17 familiar with state and federal laws and regulations governing the practice of pharmacy. The
18 failure to timely provide said statements under penalty of perjury shall be considered a violation
19 of probation.

20 **11. Posted Notice of Probation**

21 Respondent St. Joseph's shall prominently post a probation notice provided by the board in
22 a place conspicuous and readable to the public. The probation notice shall remain posted during
23 the entire period of probation.

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

28 Failure to post such notice shall be considered a violation of probation.

1 **12. Violation of Probation**

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

7 If Respondent St. Joseph's violates probation in any respect, the board, after giving
8 Respondent St. Joseph's notice and an opportunity to be heard, may revoke probation and carry
9 out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for
10 those provisions stating that a violation thereof may lead to automatic termination of the stay
11 and/or revocation of the license. If a petition to revoke probation or an accusation is filed against
12 Respondent St. Joseph's during probation, the board shall have continuing jurisdiction and the
13 period of probation shall be automatically extended until the petition to revoke probation or
14 accusation is heard and decided.

15 **13. Completion of Probation**

16 Upon written notice by the board or its designee indicating successful completion of
17 probation, Respondent St. Joseph's license will be fully restored.

18 **14. Separate File of Records**

19 Respondent St. Joseph's shall maintain and make available for inspection a separate file of
20 all records pertaining to the acquisition or disposition of all controlled substances. Failure to
21 maintain such file or make it available for inspection shall be considered a violation of probation.

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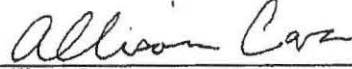
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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Allison Cova. I understand the stipulation and the effect it will have on my Original Permit. 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. As Respondent St. Joseph's President and CEO, I have the authority to bind Respondent St. Joseph's to all of the terms contained in this agreement.

DATED: 03/03/15 
ST. JOSEPH'S MEDICAL CENTER; CATHOLIC
HEALTHCARE WEST; DIGNITY HEALTH;
DONALD WILEY, PRESIDENT AND CEO
Respondent

I have read and fully discussed with Respondent St. Joseph's the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/3/15 
Allison Cova
Attorney for Respondent St. Joseph's

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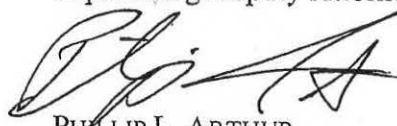
ENDORSEMENT

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

Dated: 3/5/15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General



PHILLIP L. ARTHUR
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5042

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 PHILLIP L. ARTHUR
Deputy Attorney General
4 State Bar No. 238339
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 322-0032
Facsimile: (916) 327-8643
7 E-mail: Phillip.Arthur@doj.ca.gov
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5042

12 **ST. JOSEPH'S MEDICAL CENTER;**
13 **CATHOLIC HEALTHCARE WEST;**
14 **DIGNITY HEALTH**
1800 North California Street
Stockton, California 95204

ACCUSATION

15 **Original Permit No. HSP 45514**

16 and

17 **HARRIET FRANCES CATANIA**
18 3949 Glen Abby Circle
Stockton, California 95219

19 **Original Pharmacist License No. RPH 26621**

20 Respondents.

21
22
23 Complainant alleges:

24 **PARTIES**

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

27 2. On or about July 16, 1970, the Board of Pharmacy issued Original Pharmacist License
28 Number RPH 26621 to Harriet F. Catania (Respondent Catania). The Original Pharmacist

1 License was in full force and effect at all times relevant to the charges brought herein and will
2 expire on January 31, 2016, unless renewed.

3 3. On or about March 15, 2002, the Board of Pharmacy issued Original Permit Number
4 HSP 45514 to Catholic Healthcare West, dba St. Joseph's Medical Center (Respondent St.
5 Joseph's). The Original Permit was in full force and effect at all times relevant to the charges
6 brought herein and will expire on March 31, 2015, unless renewed.

7 4. On or about February 13, 2012, the Board of Pharmacy issued Original Permit
8 Number HSP 45514 to Dignity Health, dba St. Joseph's Medical Center (Respondent St.
9 Joseph's). The Original Permit was in full force and effect at all times relevant to the charges
10 brought herein and will expire on March 31, 2015, unless renewed.

11 5. Respondent Harriet F. Catania served as the Pharmacist-in-Charge at Respondent St.
12 Joseph's from March 15, 2002, through November 1, 2010.

13 JURISDICTION

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

17 7. Section 4300 of the Code states, in pertinent part:

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

19 STATUTORY PROVISIONS

20 8. Section 4022 of the Code states:

21 "Dangerous drug" or "dangerous device" means any drug or device unsafe for self use in
22 humans or animals, and includes the following:

23 "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without
24 prescription," "Rx only," or words of similar import.

25 "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale
26 by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled
27 in with the designation of the practitioner licensed to use or order use of the device.

28 ///

1 (c) Any other drug or device that by federal or state law can be lawfully dispensed only on
2 prescription or furnished pursuant to Section 4006."

3 9. Section 4081 of the Code states, in pertinent part:

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

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

16 10. Section 4105 of the Code states, in pertinent part:

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

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

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

25 (d) Any records that are maintained electronically shall be maintained so that the
26 pharmacist in charge, the pharmacist on duty if the pharmacist in charge is not on duty, or, in the
27 case of a veterinary food animal drug retailer or wholesaler, the designated representative on duty,
28 shall, at all times during which the licensed premises are open for business, be able to produce a

1 hard copy and electronic copy of all records of acquisition or disposition or other drug or
2 dispensing related records maintained electronically. . . .”

3 11. Section 4300.1 of the Code states:

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

9 12. Section 4301 of the Code states, in pertinent part:

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

13 “ . . .

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

18 13. Section 4333 of the Code states, in pertinent part, that all prescriptions filled by a
19 pharmacy and all other records required by Section 4081 shall be maintained on the premises and
20 available for inspection by authorized officers of the law for a period of at least three years. In
21 cases where the pharmacy discontinues business, these records shall be maintained in a board
22 licensed facility for at least three years.

23 REGULATIONS

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

25 “ . . .

26 “(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
27 equipment so that drugs are safely and properly prepared, maintained, secured and distributed.

28

1 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice
2 of pharmacy.

3 "...

4 (d) Each pharmacist while on duty shall be responsible for the security of the prescription
5 department, including provisions for effective control against theft or diversion of dangerous
6 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
7 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist. . .
8 ."

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

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

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

15 16. Code of Federal Regulations, title 21, section 1304.21, states:

16 "(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain on a
17 current basis a complete and accurate record of each such substance manufactured, imported,
18 received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant
19 shall be required to maintain a perpetual inventory.

20 "(b) Separate records shall be maintained by a registrant for each registered location except
21 as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the
22 control of a registrant at a location for which he is not registered, the substances shall be included
23 in the records of the registered location to which they are subject to control or to which the person
24 possessing the substance is responsible.

25 "(c) Separate records shall be maintained by a registrant for each independent activity for
26 which he/she is registered, except as provided in § 1304.22(d).

27 (d) In recording dates of receipt, importation, distribution, exportation, or other transfers,
28 the date on which the controlled substances are actually received, imported, distributed, exported,

1 or otherwise transferred shall be used as the date of receipt or distribution of any documents of
2 transfer (e.g., invoices or packing slips).”

3 COST RECOVERY

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

8 DANGEROUS DRUGS/CONTROLLED SUBSTANCES

9 18. *Hydrocodone/acetaminophen (hc/apap)* is a Schedule III controlled substance as
10 designated by Health and Safety Code section 11056, subdivision (e)(4).

11 19. *Ambien/zolpidem* is a Schedule IV controlled substance as designated by Health and
12 Safety Code section 11057, subdivision (d)(32).

13 20. *Lunesta*, which contains *Eszopiclone*, is a Schedule IV controlled substance as
14 designated by Code of Federal Regulations, title 21, section 1308.14, subdivision (c)(53).

15 21. *Alprazolam* is a Schedule IV controlled substance as designated by Health and Safety
16 Code section 11057, subdivision (d)(1).

17 22. *Diazepam* is a Schedule IV controlled substance as designated by Health and Safety
18 Code section 11057, subdivision (d)(9).

19 23. *Lorazepam* is a Schedule IV controlled substance as designated by Health and Safety
20 Code section 11057, subdivision (d)(16).

21 FACTUAL BACKGROUND

22 24. Respondent St. Joseph's was a 300-bed acute care hospital. It had a traditional
23 "inpatient" pharmacy (IPRX) to care for hospitalized patients, and an outpatient pharmacy
24 (OPRX), a traditional walk-up type pharmacy, located in another wing of the hospital than the
25 IPRX, which dispensed medication solely to St. Joseph's employees and an occasional homeless
26 or indigent patient being discharged from acute care. The OPRX was staffed by one pharmacist
27 and one pharmacy technician. The OPRX opened on May 2, 2005, and closed on September 23,
28 2011, consolidating its records and drugs with the IPRX.

1 25. On or about December 20, 2010, the Board received a "Report of Theft or Loss of
2 Controlled Substances" from Respondent St. Joseph's. According to the report, an internal audit
3 revealed the loss of 24,311 tablets of hydrocodone with acetaminophen in seven strengths, as well
4 as 92 alprazolam 1 mg tablets, from the OPRX. According to the report, the cause of the loss was
5 employee pilferage.

6 26. Upon receipt of the report, the Board conducted an investigation. As part of the
7 investigation, a Board inspector visited Respondent St. Joseph's on or about August 25, 2011.
8 During this visit, the Board inspector noted that: (1) the loss of controlled substances appeared to
9 be only at the OPRX; and (2) Respondent St. Joseph's OPRX and IPRX did not have invoices or
10 records of acquisition on hand for the last three years—the oldest invoices in the IPRX were from
11 August 30, 2010, and the oldest packing slips were from February 1, 2010.

12 27. On or about September 8, 2011, a Board inspector and two investigators from the
13 Drug Enforcement Administration Diversion (DEA) interviewed several staff members of
14 Respondent St. Joseph's. And, on or about November 15, 2011, a Board investigator and DEA
15 investigator interviewed Respondent Catania. These interviews revealed that: (1) a pharmacy
16 technician was regularly allowed to enter the OPRX pharmacy alone, by using an unsecured key,
17 thirty minutes before a pharmacist arrived; (2) the after-hours security alarm at the OPRX
18 pharmacy frequently was not activated; (3) a pharmacy technician regularly entered orders for
19 medications at the OPRX, and these orders were never reviewed by a pharmacist;
20 (4) hydrocodone products were stored in a "fast-mover" section at the OPRX, rather than the
21 narcotic storage cabinet, and when the hydrocodone products were later moved to the narcotic
22 storage cabinet, the cabinet was never locked; (5) housekeeping staff were allowed to clean,
23 unsupervised by any pharmacy staff, in the "fast mover" area of the OPRX pharmacy; (6) OPRX
24 pharmacy staff never checked to make sure there were no drug shortages, and there was no
25 process in place to check for drug shortages; (7) there was no policy or procedure detailing access
26 to the OPRX and IPRX; (8) the IPRX was missing 642 controlled substance invoices; (9) the
27 OPRX was missing 194 controlled substance prescriptions; and (10) Catania was responsible for
28 the OPRX and IPRX.

1 28. Three audits were subsequently conducted regarding the controlled substance loss at
2 Respondent St. Joseph's OPRX and IPRX—St. Joseph's internal audit, a verification audit by
3 Chan Healthcare Auditors (Chan), and a DEA audit. The results of these audits are as follows:

4 a. Respondent St. Joseph's audit, for variances¹ in controlled substances from July 1,
5 2008, through December 2, 2010, revealed the following:

- 6 i. -1,814 variance for hc/apap 5 mg/325 mg
- 7 ii. +714 variance for hc/apap 5 mg/500 mg
- 8 iii. -106 variance for hc/apap 7.5 mg/325 mg
- 9 iv. -2,983 variance for hc/apap 7.5 mg/500 mg
- 10 v. -5,361 variance for hc/apap 7.5 mg/ 750 mg
- 11 vi. -13,507 variance for hc/apap 10 mg/325 mg
- 12 vii. -6,363 variance for hc/apap 10 mg/500 mg

13 b. The Chan audit, for variances in controlled substances from July 1, 2008, through
14 December 2, 2010, revealed the following:

- 15 i. -214 variance for hc/apap 5 mg/325 mg
- 16 ii. -1,786 variance for hc/apap 5 mg/500 mg
- 17 iii. -206 variance for hc/apap 7.5 mg/325 mg
- 18 iv. -2,983 variance for hc/apap 7.5 mg/500 mg
- 19 v. -1,861 variance for hc/apap 7.5 mg/ 750 mg
- 20 vi. -13,507 variance for hc/apap 10 mg/325 mg
- 21 vii. -6,363 variance for hc/apap 10 mg/500 mg

22 c. The DEA audit, for variances from June 30, 2008, through September 8, 2011,
23 revealed the following:

- 24 i. -6,660 variance for hc/apap 5 mg/325 mg

25 ¹ The variances were calculated by comparing the total amount of each controlled
26 substance that Respondent St. Joseph's acquired from Cardinal Health (the sole vendor that St.
27 Joseph's purchased controlled substances from) with the total amount of each controlled
28 substance that St. Joseph's dispensed during the audit period. A negative variance indicates
missing and unaccounted for dosage units. A positive variance indicates that St. Joseph's
acquired more dosage units than St. Joseph's possesses records for.

- 1 ii. +839 variance for hc/apap 5 mg/500 mg
- 2 iii. -106 variance for hc/apap 7.5 mg/325 mg
- 3 iv. -3,403 variance for hc/apap 7.5 mg/500 mg
- 4 v. -1,840 variance for hc/apap 7.5 mg/ 750 mg
- 5 vi. -13,051 variance for hc/apap 10 mg/325 mg
- 6 vii. -4,590 variance for hc/apap 10 mg/500 mg
- 7 viii. +23 variance for Ambien CR 12.5 mg
- 8 iv. +128 variance for Lunesta 2 mg
- 9 v. -363 variance for alprazolam 1 mg
- 10 vi. +63 variance for alprazolam 0.5 mg
- 11 vii. +78 variance for alprazolam 0.25 mg
- 12 viii. -181 variance for diazepam 10 mg
- 13 ix. -48 variance for diazepam 5 mg
- 14 x. -141 variance for diazepam 2 mg
- 15 xi. -252 variance for lorazepam 2 mg
- 16 xii. -8 variance for lorazepam 0.5 mg
- 17 xiii. +32 variance for lorazepam 1 mg

18 29. On or about October 2012, the DEA audit disclosed that a Respondent St. Joseph's
19 had a total of 836 missing invoices for controlled substances, and 570 invoices without the date
20 received.

RESPONDENT ST. JOSEPH'S
FIRST CAUSE FOR DISCIPLINE
(Unsecured Pharmacy)

24 30. Respondent St. Joseph's is subject to disciplinary action under California Code of
25 Regulations, title 16, section 1714, subsection (b), in that Respondent failed to maintain its
26 facilities, space, fixtures, and equipment so that drugs are safely and properly prepared,
27 maintained, secured and distributed, as alleged above in paragraphs 26-29, and all of their
28 subparts.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

31. Respondent St. Joseph's is subject to disciplinary action under section 4081, subsection (a), of the Code, and California Code of Regulations, title 16, section 1718, in that Respondent failed to keep a controlled substance current inventory for at least three years after the date of the inventory, as alleged above in paragraphs 26-27, and 29.

THIRD CAUSE FOR DISCIPLINE

(Incomplete Records)

32. Respondent St. Joseph's is subject to disciplinary action under sections 4081, subsection (a), 4105, and 4133 of the Code in that Respondent failed to maintain all records of manufacture, sale, acquisition, or disposition of controlled substances open to inspection by authorized officers of the law, and failed to preserve these records for at least three years from the date of making, as alleged above in paragraphs 26-29 and all of their subparts.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Records)

33. Respondent St. Joseph's is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (a), by and through Business and Professions Code sections 4081, 4105, and 4333, in that Respondent failed to maintain an accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of, as alleged above in paragraphs 26-29 and all of their subparts.

FIFTH CAUSE FOR DISCIPLINE

(Incomplete Records)

34. Respondent St. Joseph's is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (d), by and through Business and Professions Code sections 4081, 4105, and 4333, in that Respondent failed to record dates of receipt, importation, distribution, exportation, or other transfers of controlled substances, as alleged above in paragraphs 26-29 and all of their subparts.

///

1 **NINTH CAUSE FOR DISCIPLINE**

2 **(Incomplete Records)**

3 38. Respondent Catania is subject to disciplinary action under Code of Federal
4 Regulations, title 21, section 1304.21, subdivision (a), by and through Business and Professions
5 Code sections 4081, 4105, and 4333, in that as the Pharmacist-in-Charge for Respondent St.
6 Joseph's, Catania failed to maintain an accurate record of each substance manufactured, imported,
7 received, sold, delivered, exported, or otherwise disposed of, as alleged above in paragraphs 26-
8 29 and all of their subparts.

9 **TENTH CAUSE FOR DISCIPLINE**

10 **(Incomplete Records)**

11 39. Respondent Catania is subject to disciplinary action under Code of Federal
12 Regulations, title 21, section 1304.21, subdivision (d), by and through Business and Professions
13 Code sections 4081, 4105, and 4333, in that as the Pharmacist-in-Charge for Respondent St.
14 Joseph's, Catania failed to record dates of receipt, importation, distribution, exportation, or other
15 transfers of controlled substances, as alleged above in paragraphs 26-29 and all of their subparts.

16 **PRAYER**

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

19 1. Revoking or suspending Original Permit Number HSP 45514, issued to St. Joseph's
20 Medical Center; Catholic Healthcare West; Dignity Health;

21 2. Revoking or suspending Original Pharmacist License Number RPH 26621, issued to
22 Harriet Frances Catania, Pharmacist-in-Charge at St. Joseph's Medical Center;

23 3. Ordering St. Joseph's Medical Center and Harriet F. Catania to pay the Board of
24 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
25 Business and Professions Code section 125.3; and

26 ///

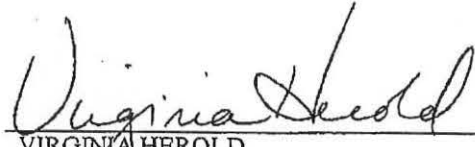
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4. Taking such other and further action as deemed necessary and proper.

DATED: 5/10/14



VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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