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

In the Matter of the Accusation Against:

Case No. 4723

SAN GORGONIO MEMBORIAL HOSPITAL, DBA SAN GORGONIO MEMORIAL HOSPITAL DISTRICT 600 N. Highland Springs Avenue Banning, CA 92220 OAH 2014060643

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

Hospital Pharmacy Permit No. HPE 21784

Respondent.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is here by adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on January 9, 2015.

It is so ORDERED on January 2, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

STAN C. WEISSER, Board President

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1 2	KAMALA D. HARRIS Attorney General of California JAMES M. LEDAKIS Supervising Deputy Attorney General		
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7	Facsimile: (619) 645-2061 Attorneys for Complainant		
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9	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 4723	
12	SAN GORGONIO MEMORIAL		
13	HOSPITAL, DBA SAN GORGONIO MEMORIAL HOSPITAL DISTRICT	OAH No. 2014060643	
14	600 N. Highland Springs Avenue Banning, CA 92220	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER	
15	TOWNWIE OLE ANNEO	·	
16	Hospital Pharmacy Permit No. HPE 21784		
17	Respondents.	•	
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19			
20	IT IS HEREBY STIPULATED AND AGI	REED by and between the parties to the above-	
21	entitled proceedings that the following matters are true:		
22	<u>PARTIES</u>		
23	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
24	She brought this action solely in her official capacity and is represented in this matter by Kamala		
25	D. Harris, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney		
26	General.		
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- 2. Respondent San Gorgonio Memorial Hospital, dba San Gorgonio Memorial Hospital District ("Respondent") is represented in this proceeding by attorney Tom Curtis of Nossaman, LLP whose address is: 18101 Von Karman Avenue, Suite 1800, Irvine, CA 92612.
- 3. On or about November 16, 1981, the Board of Pharmacy issued Hospital Pharmacy Permit No. HPE 21784 to San Gorgonio Memorial Hospital, dba San Gorgonio Memorial Hospital District (Respondent). The Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 4723 and will expire on November 1, 2015, unless renewed.

JURISDICTION

- 4. Accusation No. 4723 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on February 17, 2014.

 Respondent timely filed its Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 4723 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4723. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent admits the truth of each and every charge and allegation in Accusation No. 4723.
- 10. Respondent agrees that its Hospital Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Hospital Pharmacy Permit No. HPE 21784 issued to Respondent San Gorgonio Memorial Hospital, dba San Gorgonio Memorial Hospital District (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the

 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's hospital pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically

extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

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

4. Cooperate with Board Staff

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of \$3,397.33. Respondent owner shall make said payment by the effective date of the decision. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

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

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain

continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

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

Respondent owner may not apply for any new licensure from the board for three (3) years

from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

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

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

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

10. Owners and Officers: Knowledge of the Law

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

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during

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the entire period of probation.

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

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

12. Violation of Probation

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

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

13. Completion of Probation

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

ACCEPTANCE

As the authorized agent on behalf of Respondent San Gorgonio Memorial Hospital, doing business as San Gorgonio Memorial Hospital District, I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with Respondent San Gorgonio Memorial Hospital, doing business as San Gorgonio Memorial Hospital District's attorney, Tom Curtis. I understand the stipulation and the effect it will have on the Hospital Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree that San Gorgonio Memorial Hospital, doing business as San Gorgonio Memorial Hospital District will be bound by the Decision and Order of the Board of Pharmacy.

AGENT FOR SAN GORGONIO MEMORIAL HOSPITAL, DBA SAN GORGONIO MEMORIAL HOSPITAL DISTRICT Respondent

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DATED:

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I have read and fully discussed with the authorized agent for Respondent San Gorgonio Mernorial Hospital, doing business as San Gorgonio Memorial Hospital District, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content,

Tom Curtis

Attorney for Respondent

DATED: Nww 14,2014

ENDORSEMENT

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

Respectfully submitted,

KAMALA D. HARRIS Attorney General of California

JAMES M. LEDAKIS
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4723

- 11	•		
1	Kamala D. Harris		
	Attorney General of California	·	
2	LINDA K. SCHNEIDER Supervising Deputy Attorney General		
3	DESIREE I. KELLOGG		
4	Deputy Attorney General State Bar No. 126461		
[]	110 West "A" Street, Suite 1100		
5	San Diego, CA 92101 P.O. Box 85266	·	
6	San Diego, CA 92186-5266		
7	Telephone: (619) 645-2996 Facsimile: (619) 645-2061		
	Attorneys for Complainant		
8	BEFORE T	THE	
9	BOARD OF PHA	RMACY	
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
j			
11	In the Matter of the Accusation Against:	Case No. 4723	
12			
13	SAN GORGONIO MEMORIAL HOSPITAL DBA SAN GORGONIO MEMORIAL		
14	HOSPITAL DISTRICT	ACCUSATION	
	600 N. Highland Springs Avenue Banning, CA 92220		
15	Hospital Pharmacy Permit No. HPE 21784		
16	·		
17	EKENE CHIDIMMA NNAH 12926 Foxwood Dr.		
	Yucaipa, CA 92399		
18	Pharmacist License No. RPH 65349	1	
19			
20	and		
• •	PRINCE NNAMDI NNAH		
21	12926 Foxwood Dr. Yucaipa, CA 92399		
22			
23	Pharmacist License No. RPH 67849		
	Respondents		
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Accusation

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PARTIES

- 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about November 16, 1981, the Board of Pharmacy issued Hospital Pharmacy Permit Number HPE 21784 to San Gorgonio Memorial Hospital, doing business as San Gorgonio Memorial Hospital District (Respondent San Gorgonio Memorial Hospital Pharmacy). The Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2013, unless renewed. Ekene Chidimma Nnah was the Pharmacist-in-Charge from August 17, 2011 to March 6, 2013.
- 3. On or about April 11, 2011, the Board of Pharmacy issued Pharmacist License No. RPH 65349 to Ekene Chidimma Nnah (Respondent Ekene Nnah). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2015, unless renewed.
- 4. On or about August 23, 2012, the Board of Pharmacy issued Pharmacist License No. RPH 67849 to Prince Nnamdi Nnah (Respondent Prince Nnah.) The Pharmacist License will expire on December 31, 2013, unless renewed.

JURISDICTION

- 5. 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.
- 6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

8. Section 4300.1 of the Code 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 PROVISIONS

9. Section 4022 of the Code states:

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

- (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Section 4051(a) of the Code states:

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

11. Section 4081 of the Code states:

- (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.
- (b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the

pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

12. Section 4113(c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with state and federal laws and regulations pertaining to the practice of pharmacy.

13. Section 4116(a) of the Code states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

14. Section 4332 of the Code states:

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

15. Section 4301 of the Code states in part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

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1	(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		
2	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		
3	federal regulatory agency,		
4			
5	STATE REGULATORY PROVISIONS		
6	16. California Code of Regulations, title 16, section 1714(b) and (d) states:		
7	· •••		
8	(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained,		
9	secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.		
10	•••		
11	(d) Each pharmacist while on duty shall be responsible for the security of		
12	the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and		
13	devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.		
14	***		
15			
16	17. California Code of Regulations, title 16, section 1717(b)(1) states:		
17.			
18	In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and		
19	shall be readily receivable:		
20	(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be		
initialed by the supervising pharmacist before they are dispensed.			
22	18. California Code of Regulations, title 16, section 1718 states:		
23			
24	"Current inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include compete accountability for all		
25	dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.		
26	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		
27	inventory.		
28	: <u>\</u>		

		19.	California Code of Regulations, title 16, section 1735.2(j) states:
1			•••
2			(j) Prior to allowing any drug product to be compounded in a pharmacy,
3		the ph	armacist-in-charge shall complete a self-assessment for compounding acies developed by the board, (Incorporated by reference is "Community
4		Pharm	nacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 39 Rev. 02/12.) That form contains a first section applicable to all
5	: 	compo	ounding, and a second section applicable to sterile injectable compounding. rst section must be completed by the pharmacist-in-charge before any
6	•	compo	ounding is performed in the pharmacy. The second section must be leted by the pharmacist-in-charge before any sterile injectable compounding
7.		is perf	formed in the pharmacy. The applicable sections of the self-assessment shall
8		days c	quently be completed before July 1 of each odd-numbered year, within 30 of the start of a new pharmacist-in-charge, and within 30 days of the issuance ew pharmacy license. The primary purpose of the self-assessment is to
9		promo	ote compliance through self-examination and education.
10		20.	California Code of Regulations, title 16, section 1735.3(a) states:
11			California Code of Regulations, title 16, section 1735.3 states:
12		includ	(a) For each compounded drug product, the pharmacy records shall de:
13			(1) The master formula record.
14			(2) The date the drug product was compounded.
15		•	(3) The identity of the pharmacy personnel who compounded the drug
16		produ	uct.
17			(4) The identity of the pharmacist reviewing the final drug product.
18		· mmod	(5) The quantity of each component used in compounding the drug
19		prod	
20		If the	(6) The manufacturer, expiration date and lot number of each component. e manufacturer name is demonstrably unavailable, the name of the supplier
21		nrod	be substituted. Exempt from the requirements in this paragraph are sterile lucts compounded on a one-time basis for administration within seventy-two hours and stored in accordance with standards for "Redispensed CSPS" found
22		in C	Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF)
23		inpa	th Revision, Effective May 1, 2012), hereby incorporated by reference, to an attent in a health care facility licensed under section 1250 of the Health and ety Code.
24	.		(7) A pharmacy assigned reference or lot number for the compounded drug
25	5	pro	duct,
20	5		(8) The expiration date of the final compounded drug product.
2	7 ∥ .		(9) The quantity or amount of drug product compounded.

1	21. California Code of Regulations, title 16, section 1751(b)(5) states:
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3	(b) Any pharmacy compounding sterile injectable drug products shall have a
4	designated area for the preparation of sterile injectable products which shall meet the following standards.
5	
6	(5) The pharmacy shall be arranged in accordance with Section 1250 of Title
7	24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an according area shall be
8	stored in such a way as to maintain the integrity of an aseptic environment.
9	***
10	22. Code of Federal Regulations, title 21, section 1304.04(f)(2) states:
11	
12	Bach registered manufacturer, distributor, importer, exporter, narcotic
13	treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:
14	•••
15	Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained separately from all other records of the registrant or in such
16	form that the information required is readily retrievable from the ordinary records of the registrant.
17	
18	23. Code of Federal Regulations, title 21, section 1304,11(c) states:
19	23. Code of Federal Regulations, title 21, section 1304.11(c) states:
20	•••
21	(c) Biennial inventory date. After the initial inventory is taken, the registrant
22	shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two
23	years of the previous biennial inventory date.
24	
25	
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COST RECOVERY

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

DRUGS

- 25. <u>Dronabinol</u> is a Schedule II controlled substance pursuant to Health and Safety Code section 11056(b) and is a dangerous drug pursuant to Business and Professions Code section 4022.
- 26. <u>Epinephrine</u> is a dangerous drug pursuant to Business and Professions Code section 4022.
- 27. <u>Lidocaine</u> is a dangerous drug pursuant to Business and Professions Code section 4022.
- 28. Norco, is a brand name for acetaminophen and hydrocodone bitartrate, a Schedule II controlled substance pursuant to Health and Safety Code section 11056(3) and is a dangerous drug pursuant to Business and Professions Code section 4022.
- 29. <u>Tetracaine</u> is a dangerous drug pursuant to Business and Professions Code section 4022.
- 30. Tylenol #3 is a brand name for acetaminophen with not more than 1.8 grams of Codeine per 100 milliliters or not more than 90 milligrams per dosage unit and with one or more active, non-narcotic ingredients in recognized therapeutic amount. It is a Controlled Substance pursuant to Health and Safety Code section 11056(e) and is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

31. From on or about August 17, 2011 to March 6, 2013, Respondent Ekene Nnah was the Pharmacist-in-Charge of Respondent San Gorgonio Memorial Hospital Pharmacy. From on

or about July 18, 2011 to August 23, 2012, Respondent Prince Nnah was the Chief of Pharmacy Services for Respondent San Gorgonio Memorial Hospital Pharmacy.

- 32. The Chief of Pharmacy Services' principal tasks, duties and responsibilities included overseeing the "purchase, inventory maintenance, and distribution of all pharmaceutical items and ensures compliance by departmental locations and patient care units with established inventory control standards/procedures and federal and state regulations." The job summary explained that among other tasks, the Chief of Pharmacy Services "directs and controls the purchase/maintenance of pharmacy inventory including all pharmaceutical and related substances/supplies." Possession of a current California State license was a qualification for the Chief of Pharmacy Services for Respondent San Gorgonio Memorial Hospital Pharmacy. On or about July 18, 2011, Respondent Prince Nnah executed the document describing the Job Summary, Principal Tasks, Duties and Responsibilities and Qualifications for the Chief of Pharmacy Services and certified that he had "received, read and under[stood] both my job description and standards of performance."
- 33. Respondent Prince Nnah was not licensed as a pharmacist in California until August 23, 2012.
- 34. On or about July 30, 2012 and after the Board received an anonymous complaint alleging that an unlicensed person was in charge of the San Gorgonio Memorial Hospital Pharmacy with unauthorized access to controlled substances, two Board inspectors conducted an inspection of Respondent San Gorgonio Memorial Hospital Pharmacy.
- 35. During the inspection, the Board inspector requested Respondent San Gorgonio Memorial Hospital Pharmacy's Compounding Self-Assessment Form. The Compounding Self-Assessment form had not been completed even though the pharmacy compounded drugs.
- 36. The Board inspector reviewed the compounding log and discovered that the records for the "LET" topical solution compounded on June 14, 2012 were incomplete. Specifically, the records did not identify the ingredients used in compounding, the lot numbers and the expiration dates for each ingredient and the name of the dispensing pharmacist.

- 37. The Board inspector observed that the designated area for compounding and storing sterile injectable drugs was located in a high traffic area, which did not maintain the integrity of an aseptic environment for the compounded drugs. On February 27, 2008, the Board inspector had noted this same deficiency and brought it to the attention of Respondent San Gorgonio Memorial Hospital Pharmacy. He was advised by the hospital pharmacy that it would be corrected. However, the designated compounding area was in the same location as it had been in 2008.
- 38. The Biennial inventory for controlled substances as required by the Drug Enforcement Administration was requested by the Board inspectors. However, Respondent San Gorgonio Memorial Hospital Pharmacy was not able to produce it during the inspection. The Board inspector also observed that the invoices for Schedule III-V controlled substances were comingled and not maintained separately.
- 39. During the inspection, the Board inspector observed that Respondent Prince Nnah, who was an unlicensed person at that time, had access to Accudose, had his own user ID code and possessed the key to the night locker closet containing drugs and the keys, including the alarm key to Respondent San Gorgonio Memorial Hospital Pharmacy.
- 40. On January 16, 2013, a Board Inspector requested audits of selected controlled substances from San Gorgonio Memorial Hospital Pharmacy. On that same day, the Board inspector received three Drug Enforcement Administration audits of controlled substances dated April 1, 2010, April 26, 2012 and July 30, 2012. On January 29, 2013, Respondent Prince Nnah submitted to the Board inspector the completed Selected Drug Audit Summary form for April 26, 2011 to July 30, 2012, the completed Selected Drug Audit Summary form for July 30, 2012 to January 17, 2013 and the "Stock on Hand" taken on January 17, 2013.

Accudose" is a trade name for the automatic single-unit dose medication dispensing system that records information such as patient name, physician orders, the date and time the medication was withdrawn, and the name of the licensed individual who withdrew and administered the medication. Each user/operator is given a user identification code to operate the control panel. Controlled substances are stored in Accudose.

41. A review of these audits revealed discrepancies. Namely, the audit from April 26, 2011 to July 30, 2012 showed that there were overages in the amount of 103 tablets for the hydrocodone/apap (Norco) 10/325 inventory, shortages in the amount of 15 capsules for the Marinol 2.5, dronabinol inventory and shortages in the amount of 8 tablets for the Tylenol #3, acetaminophen w/codeine 300 mg/30 mg inventory. The audit from July 30, 2012 to January 17, 2013 showed that there were overages in the amount of 19 tablets for the hydrocodone/apap (Norco) 10/325 inventory, overages in the amount of 16 capsules for the Marinol 2.5, dronabinol inventory and overages in the amount of 157 tablets for the Tylenol #3, acetaminophen w/codeine 300 mg/30mg inventory.

FIRST CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy and Ekene Nnah)

(Failure to Complete Compounding Self-Assessment Form)

42. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1735.2(j), in that Respondents did not complete a self-assessment form prior to compounding drug products, as set forth in paragraphs 31-41, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy Ekene Nnah and Prince Nnah)

(Failure to Secure Drugs)

43. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, section 1714(d), in that Respondents allowed an unlicensed individual to possess keys to the pharmacy premises, the night locker containing drugs and the access code to the Accudose system, as set forth in paragraphs 31-41, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy

Ekene Nnah and Prince Nnah)

(Permitting Unauthorized Access to Drugs)

44. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and(o) for violation of Business and Professions Code section 4116(a), in that Respondents permitted a person other than a pharmacist, intern pharmacist, authorized officer of the law or a person authorized to prescribe in the area, place or premises described in the license issued by the Board wherein controlled substances, dangerous drugs or dangerous devices were stored, possessed, compounded or dispensed, as set forth in paragraphs 31-41, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy and Ekene Nnah) (Failure to Conduct Biennial Controlled Substances Inventory)

45. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Code of Federal Regulations, title 21, section 1304.11(c) and California Code of Regulations, title 16, section 1718, in that Respondents did not possess the Biennial Drug Enforcement Administration inventory readily retrievable during the inspection, as set forth in paragraphs 31-41, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy and Ekene Nnah) (Failure to Maintain Proper Inventory of Controlled Substances)

46. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of Code of Federal Regulations, title 21, section 1304.04(f)(2), in that Respondents failed to properly maintain its records for controlled substances, as set forth in paragraphs 31-41, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy and Ekene Nnah)

(Improper Record-Keeping for Compounded Drugs)

47. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, sections 1735.3(a) and 1717(b)(1), in that Respondents did not maintain a complete record for the "LET" topical solution compounded on June 14, 2012 and failed to record the dispensing pharmacist for the "LET" topical solution, as set forth in paragraphs 31-41, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Against Respondents San Gorgonio Memorial Hospital Pharmacy and Ekene Nnah)

(Failure to Properly Maintain Compounded Facilities)

48. Respondents are subject to disciplinary action under section 4301, subdivision (o) for violation of California Code of Regulations, title 16, sections 1714(b) and 1751(b)(5), in that Respondents failed to maintain its facilities so that compounded drugs could be safely and properly prepared and maintained, as set forth in paragraphs 31-41, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Against Respondent Prince Nnah)

(Dishonest Acts)

49. Respondent is subject to disciplinary action under section 4301, subdivision (f) for committing acts of dishonesty when he gained unauthorized access as an unlicensed person to Accudose and the premises of Respondent San Gorgonio Memorial Hospital Pharmacy and when he executed the document describing the Chief of Pharmacy Services' Job Summary, Principal Tasks, Duties and Responsibilities and Qualifications and certified that he understood both the job description and standards of performance for the Chief of Pharmacy Services for Respondent San Gorgonio Memorial Hospital Pharmacy, as set forth in paragraphs 31-41, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

Against Respondents San Gorgonio Memorial Hospital Pharmacy

Ekene Nnah and Prince Nnah)

(Unlicensed Pharmacist Activities)

Respondents are subject to disciplinary action under section 4301, subdivisions (j) 50. and(o) for violation of Business and Professions Code section 4051(a), in that Respondents allowed a person, Respondent Prince Nnah who was not licensed in California as a pharmacist to manufacture, compound, furnish, sell or dispense dangerous drugs or dangerous devices, as set forth in paragraphs 31-41 which are incorporated herein by reference,

PRAYER

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

- 1. Revoking or suspending Hospital Pharmacy Permit Number HPE 21784, issued to San Gorgonio Memorial Hospital, dba San Gorgonio Memorial Hospital District;
- Revoking or suspending Pharmacist License Number RPH 65349, issued to Ekene Chidimma Nnah;
- Revoking or suspending Pharmacist License Number RPH 67849, issued to Prince Nnamdi Nnah;
- Ordering San Gorgonio Memorial Hospital, dba San Gorgonio Memorial Hospital 4, District, Ekene Chidimma Nnah and Prince Nnamdi Nnah 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;

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1	5. Taking such other and further a	action as deemed necessary and proper.
2 .		/ I
3	DATED: 2/17/14	
4		VIRGINIA HEROLD
5		Executive Officer Board of Pharmacy
6		Executive Officer Board of Pharmacy Department of Consumer Affairs State of California
7		Complainant
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Accusation