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8	BEFORE THE				
. 9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
10	STATE OF CALIFORNIA				
11	In the Matter of the Accusation Against: Case No. 3157				
12	C & N PHARMACY,				
13	dba BURBANK MEDICAL PHARMACY, NANCY CHA, Pharmacist-in-ChargeA C C U S A T I O N				
14	2701 West Alameda Avenue Burbank, CA 91505				
15	Original Pharmacy Permit No. PHY 47337				
16	and				
17	NANCY CHA 17104 Maria Avenue				
18	Cerritos, CA 90703				
19	Original Pharmacist License No. RPH 46617				
20	Respondents.				
21					
22	Complainant alleges:				
23	PARTIES				
24	1. Virginia Herold (Complainant) brings this Accusation solely in her				
25	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer				
26	Affairs.				
27	2. On or about April 12, 2006, the Board of Pharmacy issued Original				
28	Pharmacy Permit No. PHY 47337 to C & N Pharmacy Inc. to do business as Burbank Medical				
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Pharmacy (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect 1 at all times relevant to the charges brought herein and will expire on April 1, 2009, unless 2 3 renewed.

Nancy Cha was the President and Pharmacist-in-Charge since April 12, 2006. 4 3. On or about August 19, 1993, the Board of Pharmacy issued Original 5 Pharmacist License No. RPH 46617 to Nancy Cha (Respondent Cha). The Original Pharmacist 6 7 License was in full force and effect at all times relevant herein and will expire on August 31, 8 2009, unless renewed.

JURISDICTION

This Accusation is brought before the Board of Pharmacy (Board), 10 4. Department of Consumer Affairs, under the authority of the following laws. All section 11 references are to the Business and Professions Code (Code) unless otherwise indicated. 12

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13 5. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to 14 proceed with a disciplinary action during the period within which the license may be renewed, 15 16 restored, reissued or reinstated.

17 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 18 19 Substances Act [Health & Safety Code, § 11000 et seq.].

Section 4300(a) of the Code provides that every license issued by the 20 7. 21 Board may be suspended or revoked.

22 8. Section 4402(a) of the Code provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall 23 24 be canceled by operation of law at the end of the three-year period.

STATUTORY PROVISIONS

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

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to 28

inspection by authorized officers of the law, and shall be preserved for at least three years from 1 2 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, 3 laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked 4 certificate, license, permit, registration, or exemption under Division 2 (commencing with 5 Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) 6 of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or 7 8 dangerous devices. "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary 9

food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or
exemptee, for maintaining the records and inventory described in this section."

13 10. Section 4105 of the Code provides, in pertinent part, that all records or
14 other documentation of the acquisition and disposition of dangerous drugs and dangerous
15 devices by any entity licensed by the board shall be retained on the licensed premises in a readily
16 retrievable form for a period of three years from the date of making.

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11. Section 4113, subdivision (b) of the Code states:

18 "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with19 all state and federal laws and regulations pertaining to the practice of pharmacy."

20 Section 4126.5 of the Code provides, in pertinent part, that a pharmacy 12. 21 may furnish dangerous drugs only to: (1) A wholesaler owned or under common control by the 22 wholesaler from whom the dangerous drug was acquired; (2) The pharmaceutical manufacturer 23 from whom the dangerous drug was acquired; (3) A licensed wholesaler acting as a reverse 24 distributor; (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous 25 drug that could result in the denial of health care; (5) A patient or to another pharmacy pursuant 26 to a prescription or as otherwise authorized by law; (6) A health care provider that is not a 27 pharmacy but that is authorized to purchase dangerous drugs; or (7) Another pharmacy under 28 common control. "Common control" means the power to direct or cause the direction of the

management and policies of another, by ownership, voting rights, contract, or other means.
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4 13. Section 4301 of the Code provides, in pertinent part, that the Board shall
5 take action against any holder of a license who is guilty of "unprofessional conduct," defined to
6 include, but not be limited to, any of the following:

"(b) Incompetence.

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"(c) Gross negligence.

10 "(d) The clearly excessive furnishing of controlled substances in violation of
11 subdivision (a) of Section 11153 of the Health and Safety Code.

"(e) The clearly excessive furnishing of controlled substances in violation of
subdivision (a) of Section 11153 of the Health and Safety Code. Factors to be considered in
determining whether the furnishing of controlled substances is clearly excessive shall include,
but not be limited to, the amount of controlled substances furnished, the previous ordering
pattern of the customer (including size and frequency of orders), the type and size of the
customer, and where and to whom the customer distributes its product.

"(j) The violation of any of the statutes of this state or of the United States
regulating controlled substances and dangerous drugs.

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

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."

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15. California Code of Regulations, title 16, section 1717, states in part:

5 "(a) No medication shall be dispensed on prescription except in a new container 6 which conforms with standards established in the official compendia. Notwithstanding the 7 above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean 8 multiple-drug patient medication package (patient med pak) provided: (1) a patient med pak is 9 reused only for the same patient; (2) no more than a one-month supply is dispensed at one time; 10 and (3) each patient med pak bears an auxiliary label which reads, 'store in a cool, dry place.'"

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

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

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

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17. California Code of Regulations, title 16, section 1761, states:

"(a) No pharmacist shall compound or dispense any prescription which contains
any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of
any such prescription, the pharmacist shall contact the prescriber to obtain the information
needed to validate the prescription.

22 "(b) Even after conferring with the prescriber, a pharmacist shall not compound or
23 dispense a controlled substance prescription where the pharmacist knows or has objective reason
24 to know that said prescription was not issued for a legitimate medical purpose."

18. California Code of Regulations, title 16, section 1770, states:
"For the purpose of denial, suspension, or revocation of a personal or facility
license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions
Code, a crime or act shall be considered substantially related to the qualifications, functions or

duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or 2 registration in a manner consistent with the public health, safety, or welfare." 3

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19. Title 21, Code of Federal Regulations, section 1307.11 (hereinafter "21 4 5 C.F.R. § 1307.11") provides in pertinent part that a practitioner who is registered to dispense a 6 controlled substance may distribute (without being registered to distribute) a quantity of such 7 substance to (1) another practitioner registered to dispense that substance for the purpose of general dispensing by the practitioner to patients, or to (2) a reverse distributor who is registered 8 9 to receive such controlled substance(s).

10 20. Title 21, Code of Federal Regulations, section 1307.21 (hereinafter "21 C.F.R. § 1307.21") provides in pertinent part that any person in possession of any controlled 11 substance and desiring or required to dispose of such substance may request assistance from the 12 Special Agent in Charge of the Drug Enforcement Administration (DEA) in the area in which the 13 person is located for authority and instructions to dispose of such substance. In the event of a 14 properly-made request, the Special Agent in Charge shall authorize and instruct the applicant to 15 dispose of the controlled substance by transfer to a person registered under the Drug 16 Enforcement Act and authorized to possess the substance, by delivery to an agent of the DEA, by 17 18 destruction in the present of an agent of the DEA or other authorized person, or by other 19 appropriate means.

Section 125.3 of the Code provides, in pertinent part, that the Board may 20 21. request the administrative law judge to direct a licentiate found to have committed a violation of 21 the licensing act to pay a sum not to exceed its reasonable costs of investigation and 22 23 enforcement.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

22. Section 4021 of the Code states:

26 "Controlled substance' means any substance listed in Chapter 2 (commencing 27 with Section 11053) of Division 10 of the Health and Safety Code."

> 23. Section 4022 of the Code states, in pertinent part:

"Dangerous drug' or 'dangerous device' means any drug or device unsafe for
 self-use, except veterinary drugs that are labeled as such, and includes the following:

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

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

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24. Health and Safety Code section 11153 states, in pertinent part:

9 "(a) A prescription for a controlled substance shall only be issued for a legitimate 10 medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is 11 upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist 12 who fills the prescription. Except as authorized by this division, the following are not legal 13 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 14 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or 15 16 habitual user of controlled substances, which is issued not in the course of professional treatment 17 or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use." 18

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20 25. <u>Dilaudid</u> - a trade name for the narcotic substance hydromorphone, is
21 classified as a Schedule II controlled substance pursuant to Health and Safety Code section
22 11055, subdivision (b)(1)(k), and is a dangerous drug within the meaning of Business and
23 Professions Code section 4022.

24 26. <u>OxyContin</u> - a brand name formation of oxycodone hydrochloride, is an
25 opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.
26 OxyContin is for use in opioid tolerant patients only. It is a Schedule II controlled substance
27 pursuant to Health and Safety Code section 11055(b)(1)(n) and a dangerous drug pursuant to
28 Business and Professions Code section 4022.

CHARGES AND ALLEGATIONS

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2 27. On December 3, 2007, the Board received a written complaint from the
3 California Department of Healthcare Services (DHCS). The complaint stated that on November
4 1, 2007, DHCS completed an unannounced visit at Respondent Pharmacy which revealed only
5 Dilaudid 4mg (43 prescriptions) and OxyContin 80mg (42 prescriptions) were dispensed that
6 day. Review of the patient and physician addresses revealed none of the patients or physicians
7 either lived or practiced in the Burbank area.

8 28. On or about January 9, 2008, Board inspectors conducted a routine
9 inspection of Respondent Pharmacy and collected records. Respondent Cha was interviewed
10 during the inspection, she stated that she worked with drivers Nate Newhouse and Rosa
11 Perdomo, who are patient representatives that drop-off and pick-up patient medications.

Board inspectors requested Respondent Cha provide them with the records 29. 12 indicating Nate Newhouse and Rosa Perdomo serve as patient representatives. Respondent Cha 13 provided Board inspectors 750 to 800 files in which Nate Newhouse and Rosa Perdomo 14 represented approximately 350 to 400 patients each. Respondent Cha stated she did not have 15 any information on Nate Newhouse and Rosa Perdomo except their phone numbers. Respondent 16 17 Cha stated the Respondent pharmacy contacts patients after Nate Newhouse and Rosa Perdomo pick-up the medications for them to verify that the patients had received their prescriptions. 18 Respondent Cha did not have any records or documentation indicating patient phone 19 verification. 20

30. Board inspectors requested Respondent Cha provide them copies of all
Respondent Pharmacy records of acquisition and disposition of tablets of Dilaudid 4mg and
tablets of OxyContin 80mg for the period of time from October 9, 2006 through December 30,
2007. A Board inspector conducted a drug audit of Respondent Pharmacy's acquisition and
disposition of tablets of Dilaudid 4mg and tablets of OxyContin 80mg. The audit result
indicated 2,252 tablets of Dilaudid 4mg and 12,610 tablets of OxyContin 80mg were
unaccounted for.

FIRST CAUSE FOR DISCIPLINE

As to	Respondents	Cha and	Pharmacy

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(Furnishing Dangerous Drugs to Unauthorized Persons)

31. Respondents Cha and Pharmacy are subject to discipline under Code 3 4 section 4301(b) and/or 4301(c) and/or 4301(o) in that between October 23, 2006 to December 17, 2007, Respondent Cha gave Schedule II controlled substances to drivers Nathaniel 5 Newhouse and Rosa Perdomo, who represented a total of 714 patients. Respondent Cha did not 6 have any information about Nathaniel Newhouse and Rosa Perdomo other than their phone 7 numbers. No documents existed showing a family relationship to the patients, nor information 8 on how both drivers were paid for their services. Respondent Cha had no documentation 9 reflecting the patients actually received the medication. Nathaniel Newhouse and Rosa Perdomo 10 are not licensed reverse distributors nor are they otherwise entities to which Respondents 11 are/were authorized to furnish dangerous drugs and/or controlled substances pursuant to Code 12 13 section 4126.5 and/or 21 C.F.R. § 1307.11.

Respondents Cha and Pharmacy are subject to discipline under Code sections 4301(b) and/or 4301(c) in that, as described in Paragraph 31 above, large quantities of OxyContin 80mg and Dilaudid 4mg were given to two persons who Respondents did not have any information about other than their phone numbers and with no system in place to ensure that the large quantities of Schedule II controlled substances were not diverted for illegal street use, acts constituting incompetence and/or gross negligence in the professional practice of pharmacy.

SECOND CAUSE FOR DISCIPLINE

As to Respondents Cha and Pharmacy

(Filling of Erroneous or Uncertain Prescriptions and Failure to Assume Co-Responsibility in
 Legitimacy of a Prescription)

33. Respondents Cha and Pharmacy are subject to discipline under Code
sections 4301(j) and/or 4301(o) in conjunction with H&S Code section 11153 and California
Code of Regulations, title 16, section 1761, in that from October 23, 2006 to December 17, 2007,
Respondent Cha continuously and excessively filled and dispensed OxyContin and Dilaudid
prescriptions without a legitimate medical purpose, clearly falling below the standard of care of a

reasonable prudent pharmacist. The circumstances are as follows: 1 2 From 11/10/2006 to 6/19/2007, Respondent Cha filled 8 prescriptions . a. 3 early for 7 or more days for patient MB¹. 4 111 5 b. From 12/13/2006 to 12/17/2007, Respondent Cha filled 22 prescriptions 6 7 for 7 or more days early for patient WC. From 4/2/2007 to 6/1/2007, Respondent Cha filled 5 prescriptions early 8 c. and filled separate prescriptions from 2 different doctors for patient KH. 9 From 11/15/2006 to12/11/2007, Respondent Cha filled prescriptions for d. 10 Dilaudid 4mg from Doctors Alva Marsh, Felix Cedraro, Dr. Samuel Sanchez and Daniel Pearce 11 with no regard as to filling the prescriptions early for patient TH. This patient did obtain these 12 prescriptions from 4 other pharmacies; Respondent Cha did not assume her co-responsibility in 13 obtaining a Controlled Substance Utilization Review and Evaluation System (CURES) report. 14 From 1/4/2007 to 6/21/2007, Respondent Cha filled 4 prescriptions 7 or 15 e. more days early also for 2 separate doctors for patient TJ. 16 From 11/14/2006 to 8/11/2007, Respondent Cha filled 18 prescriptions 7 17 f. or more days early for patient JM. 18 19 From 12/8/2006 to 12/10/2007, Respondent Cha filled 13 prescriptions 7 g. or more days early for patient MM. 20 21 h. From 11/21/2006 to 2/20/2007, Respondent Cha filled 2 prescriptions for 22 Dilaudid 7 or more days early for patient AO from 2 separate doctors. From 1/12/2007 to 9/1/2007, Respondent Cha filled 14 prescriptions for 23 i. 24 OxyContin 7 or more days early for patient RP. From 12/1/2006 to 8/20/2007, Respondent Cha filled 12 prescriptions for 25 j. 26 27 1. Initials are used to protect the privacy of the patients. Full names will be provided 28 following a request for discovery. 10

1 OxyContin 80mg 7 or more days early for patient MP.

2 k. From 2/7/2007 to 12/17/2007, Respondent Cha filled 11 prescriptions for
3 OxyContin 80mg 7 or more days early for patient CP.

4 I. From 1/15/2007 to 8/27/2007, Respondent Cha filled 16 prescriptions for
5 OxyContin 80mg 7 or more days early for patient JS.

m. From 11/16/2006 to 10/31/2007, Respondent Cha filled 5 prescriptions for
OxyContin 80mg 7 or more days early for patient JS. Respondent Cha also filled 2 prescriptions
each for Dilaudid and OxyContin 80mg on 1/9/2007.

9 n. From 10/27/2006 to 8/2/2007, Respondent Cha filled 9 prescriptions early
10 for OxyContin 7 or more days early for patient ES.

o. From 2/21/2007 to 3/1/2007, Respondent Cha filled 1 prescription early
 for Dilaudid 7 or more days early for patient RS.

p. From 7/23/2007 to 12/10/2007, Respondent Cha filled 6 prescriptions for
Dilaudid 4mg7 or more days early for patient TS from 2 separate doctors.

q. From 10/23/2006 to 10/24/2007, Respondent Cha filled 20 prescriptions
for Dilaudid 4mg 7 or more days early for patient FT from 2 separate doctors.

17 r. From 10/23/2006 to 11/5/2007, Respondent Cha filled 17 prescriptions for
18 Dilaudid 4mg 7 or more days early for patient ST from 2 separate doctors.

s. From 11/30/2006 to 4/12/2007, Respondent Cha filled 3 prescriptions for
OxyContin 80mg 7 or more days early for patient KK.

34. Respondents Cha is subject to discipline under Code section 4301(d) in
conjunction within H&S Code sections 11153, in that from October 23, 2006 to December 17,
2007, Respondent Cha failed to assume her corresponding responsibility by validating correct
addresses, requesting and using a CURES patient profile to determine if patients were abusing
controlled substances and failing to examine her patient profiles to determine if patients were
requesting prescriptions early or from multiple doctors.

27 35. Respondents Cha and Pharmacy are subject to discipline under Code
28 sections 4301(b) and/or 4301(c) and/or 4301(o) in that, as described in Paragraphs 33 and 34

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1	above, Respondents' behavior is considered to be incompetence and/or gross negligence in the		
2	professional practice of pharmacy.		
3	THIRD CAUSE FOR DISCIPLINE		
4	As to Respondents Cha and Pharmacy		
5	(Failure to Meet Requirements for Maintaining an Accurate Inventory)		
6	36. Respondents are subject to disciplinary action pursuant to Code sections		
7	4301(b) and/or 4301(c) and/or 4301(o) for violating Code section 4081(a) conjunction with		
8	111		
9	California Code of Regulations, title 16, section 1718, for failing to meet requirements for		
10	maintaining an accurate inventory. The circumstances are as follows:		
11	a. Between October 9, 2006 to December 30, 2007, Respondent Pharmacy		
12	purchased 1,397,100 tablets of Dilaudid 4mg and 698,236 tablets of OxyContin 80mg. The		
13	Board inspector's audit of Respondent Pharmacy indicated that 2,252 tablets of Dilaudid 4mg		
14	and 12,610 tablets of OxyContin 80mg were unaccounted for.		
15	37. Respondents Cha and Pharmacy are subject to discipline under Code		
16	sections 4301(b) and/or 4301(c) and/or 4301(o) in that Respondents' failure to maintain an		
17	accurate inventory of Dilaudid and OxyContin falls below the standard of care of a reasonable		
18	prudent pharmacist and is considered to be incompetence and/or gross negligence.		
19	FOURTH CAUSE FOR DISCIPLINE		
20	As to Respondents Cha and Pharmacy		
21	(Failure to Maintain Records - Incomplete Acquisition Record)		
22	38. Respondents are subject to disciplinary action pursuant to Code sections		
23	4081(a) and/or 4081(b) in conjunction with Code section 4113(b), for failing to meet		
24	requirements for maintaining records and an accurate inventory. The circumstances are as		
25	follows:		
26	a. The Board inspector's audit comparing Respondents' purchasing invoices		
27	records and wholesalers' disposition invoices records revealed Respondents failed to maintain 13		
28	invoices (Invoice No. 797786, 886332, 7624231, 8053054, 8255341, 12706, 133253, 461871,		
	II · · · · · · · · · · · · · · · · · ·		

1 483146, 518952, 636558, 723307, 849208) between October 9, 2006 to December 30, 2007. 2 **OTHER MATTERS** 39. Business and Professions Code section 4307(a) provides, in pertinent part, 3 4 that any person whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administer, 5 6 owner, member, officer, director, associate, or partner and while acting as the manager, 7 administer, owner, member, officer, director, associate, or partner had knowledge of or 8 knowingly participated in any conduct for which the license was denied, revoked, suspended, or 9 placed on probation, shall be prohibited from serving as a manager, administrator, owner, 10 member, officer, director, associate, or partner of a licensee. PRAYER 11 WHEREFORE, Complainant requests that a hearing be held on the matters herein 12 13 alleged, and that following the hearing, the Board of Pharmacy issue a decision: 1. Revoking or suspending Original Pharmacy Permit No. PHY 47337, 14 issued to C & N Pharmacy Inc. to do business as Burbank Medical Pharmacy. 15 2. 16 Revoking or suspending Original Pharmacist License No. RPH 46617, 17 issued to Nancy Cha. 18 3. Ordering Burbank Medical Pharmacy and Nancy Cha to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to 19 Business and Professions Code section 125.3. 20 4. Taking such other and further action as deemed necessary and proper. 21 22 DATED: 5/4 23 24 25 26 Executive Office Board of Pharmacy 27 Department of Consumer Affairs 28 State of California

