In the Matter of the Accusation Against:

C & N Pharmacy, Inc., dba BURBANK MEDICAL PHARMACY, NANCY CHA, PHARMACIST-IN-CHARGE Original Pharmacy Permit No. PHY 47337,

and,

NANCY CHA, Original Pharmacist License No. RPH 46617,

Respondents.

Case No. 3157

OAH No. 2011010422

DECISION AFTER RECONSIDERATION

Eric Sawyer, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on December 11-12, 2012, in Los Angeles, California.

Michael Brown, Deputy Attorney General, represented the Complainant, Virginia Herold, Executive Officer of the Board of Pharmacy ("Board"). Richard A. Moss, Esq., represented the Respondents. Nancy Cha was present. Oral and documentary evidence was presented and the record was closed and the matter was submitted.

The Administrative Law Judge issued his Proposed Decision on January 22, 2013. The Proposed Decision of the Administrative Law Judge was submitted to the Board of Pharmacy on January 24, 2013. After due consideration thereof, the Board of Pharmacy adopted said proposed decision on March 6, 2013 to become effective on April 5, 2013. On May 1, 2013, Respondents filed a petition to "stay commencement date for period of actual suspension" with the Board, seeking to delay the effective date of the Board's

suspension order to July 1, 2013. On April 2, 2013, the Board granted reconsideration and stay of execution of the effective date of its order, only to consider delaying the commencement date of the actual suspension to July 1, 2013. The Order extended the stay of the decision until the Board rendered a decision on the matter.

Having reviewed the proposed decision and Respondents' petition, and the time requested for stay of the execution of the Order having now passed, the Board of Pharmacy now makes and enters its decision after reconsideration as follows:

<u>Order</u>

The Board of Pharmacy hereby adopts the attached Proposed Decision of the Administrative Law Judge dated January 22, 2013 as its decision in this matter.

This Decision shall become effective on September 16, 2013.

IT IS SO ORDERED this 15th day of August, 2013.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

& C. Wussi

By

STANLEY C. WEISSER Board President

In the Matter of the Accusation Against:

C & N PHARMACY

dba BURBANK MEDICAL PHARMACY 2701 W Alameda Avenue Burbank, CA 91505 Original Pharmacy Permit No. PHY 47337

NANCY CHA

17104 Maria Avenue Cerritos, CA 90703 Pharmacist License No. RPH 46617

Respondents.

Case No. 3157

OAH No. 2011010422

ORDER GRANTING PETITION FOR RECONSIDERATION AND STAY OF EXECUTION OF THE EFFECTIVE DATE OF DECISION AND ORDER

Complainant having requested reconsideration of the decision in the above-entitled matter, and good cause appearing, IT IS HEREBY ORDERED:

- (1) That reconsideration be, and is, hereby granted, said reconsideration to be solely on the issue of delaying the commencement date of the actual suspension to July 1, 2013.
- (2) The board has determined that it is not necessary to order the transcript of the hearing in this matter, and hereby sets the date for submission of written arguments to be no later than May 2, 2013.
- (3) The Decision of the Board in this matter issued on March 6, 2013 and effective April 5, 2013 is hereby stayed until the Board renders its decision on reconsideration.

The board itself will decide the case upon the record, including the exhibits and written argument of the parties, without taking additional evidence.

IT IS SO ORDERED this 2nd day of April 2013.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

(. Jusi

STANLEY WEISSER Board President

By

In the Matter of the Accusation Against:

C & N PHARMACY dba BURBANK MEDICAL PHARMACY 2701 W Alameda Ave. Burbank, CA 91505

Original Pharmacy Permit No. PHY 47337

NANCY CHA 17104 Maria Avenue Cerritos, CA 90703

Pharmacist License No. RPH 46617

Respondent.

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge 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 5, 2013.

It is so ORDERED on March 6, 2013.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

la C. Jusi

STANLEY C. WEISSER Board President

By

Case No. 3157

OAH No. 2011010422

In the Matter of the First Amended Accusation Against:

Case No. 3157

C & N PHARMACY, INC., dba BURBANK MEDICAL PHARMACY, NANCY CHA, PHARMACIST-IN-CHARGE Original Pharmacy Permit No. PHY 47337, .

OAH No. 2011010422

and

NANCY CHA, Original Pharmacist License No. RPH 46617,

Respondents.

PROPOSED DECISION

This matter was heard by Eric Sawyer, Administrative Law Judge, Office of Administrative Hearings, State of California, on December 11-12, 2012, in Los Angeles.

Michael Brown, Deputy Attorney General, represented Virginia K. Herold (Complainant). Richard A. Moss, Esq., represented Respondents. Nancy Cha was present.

The record remained open after the hearing for Respondents to present further information concerning exhibit 6. On December 14, 2012, Respondents' counsel withdrew the request to present further information. The record was reopened on January 18, 2013, for a telephonic conference during which the parties stipulated to sealing the following exhibits that contain confidential information regarding several patients: 5, 7-8, 10, 14-36, 40-42, 45-46, 48, H, T, and U. The record was reclosed and the matter resubmitted for decision on January 18, 2013.

FACTUAL FINDINGS

1. Complainant brought the First Amended Accusation in her official capacity as Executive Officer of the Board of Pharmacy (Board), which is within the Department of Consumer Affairs. Respondents had previously submitted a Notice of Defense, which contained a request for a hearing. 2. On April 12, 2006, the Board issued Original Pharmacy Permit Number PHY 47337 to C & N Pharmacy, Inc., to do business as Burbank Medical Pharmacy (Respondent Pharmacy). The permit was in full force and effect at all times relevant and will expire on April 1, 2013, unless renewed. Nancy Cha has been the President and Pharmacist-in-Charge since April 12, 2006.

3. On August 19, 1993, the Board issued Original Pharmacist License Number RPH 46617 to Nancy Cha (Respondent Cha). The license was in full force and effect at all times relevant and will expire on August 31, 2013, unless renewed.

The Board's Inspection and Audit of Respondents' Records

4. On December 3, 2007, the Board received a written complaint against Respondents from the California Department of Healthcare Services (DHCS). The complaint explained that DHCS had selected Respondents for an unannounced visit because Medi-Cal payment data indicated that Respondent Pharmacy ranked first statewide for hydromorphone billing and second statewide for Oxycodone billing; and that Respondent Pharmacy's sales for both drugs had increased sharply in the last six months. The complaint stated that on November 1, 2007, DHCS completed the unannounced visit at Respondent Pharmacy, which revealed that only Dilaudid 4mg (43 prescriptions) and OxyContin 80mg (42 prescriptions) had been dispensed that day. Review of the patient and physician addresses revealed none of the involved patients or physicians either lived or practiced in the Burbank area.

5. As a result of the complaint received from DHCS, Board inspectors conducted an unannounced inspection of Respondent Pharmacy on January 9, 2008, in which they collected records, audited information obtained, and interviewed various people.

6. Respondent Cha was interviewed during the inspection. She described how she worked with drivers NN and RP,¹ who were "patient representatives" that would pick up and drop-off medications for the patients they represented. Respondent Cha had developed a following of HIV and other patients who were prescribed Dilaudid and OxyContin for pain relief, because she was sympathetic to their problems and the stigmas attached to their diseases. Many of these patients were referred by NN and RP. Those patients would generally come to Respondent Pharmacy the first time they had their prescriptions filled, accompanied by NN or RP. They would provide their prescription, identification and Medi-Cal information, and sign a document Respondent Cha created (a Protective Health Information form or "PHI"), which authorized Respondents to share the customers' confidential medical information with NN or RP. Thereafter, NN and RP would usually pick up prescription refills for the customers they represented and purportedly deliver the medications to them. Sometimes, the involved customers accompanied NN or RP to the pharmacy or came alone to pick up their medications. Respondents kept the information they

¹ Initials are used to protect the privacy of the involved individuals and customers. At the parties' request, exhibits 6, K and L were also sealed to protect the confidentiality of the investigations and individuals referred to therein.

received from the customers in individual files. Respondents' sales of Dilaudid and OxyContin generated over \$1 million in payments from Medi-Cal.

7. Board inspectors requested that Respondent Cha provide them with records indicating NN and RP served as patient representatives. Respondent Cha provided Board inspectors with 714 files in which NN represented 321 patients and RP 393 patients. Included in those files were PHI forms executed by the involved patients, which Respondent Cha had erroneously assumed provided authorization for NN or RP to pick up their medications for them. However, the PHI forms did not do so. Moreover, Respondent Cha did not have any information on NN or RP except their phone numbers.

8. Although Respondent Cha told Board inspectors that she or her staff contacted customers after NN and RP picked up the medications for them to verify that they had received them, Respondent Cha did not have any records or documentation corroborating such verification. Respondent Cha was unable to provide documentation showing that the involved customers actually received the medications that were picked up by NN and RP, who were not family members or relatives, licensed reverse distributors, or entities to which Respondents were authorized to furnish dangerous drugs and/or controlled substances pursuant to Business and Professions Code section 4126.5 or 21 Code of Federal Regulations part 1307.11.

9. Board inspectors attempted to contact a representative sample of the 714 customers involved regarding their contacts with NN and RP and whether they received their medications from them. Board inspectors were unable to contact most of those on their list. The few they were able to contact stated that they, in fact, had received their medications from NN or RP. However, there was also persuasive evidence presented at the hearing indicating that NN and RP probably diverted medications they picked up for many of the involved customers for street sale. Regardless, Respondent Cha was unaware that NN or RP were doing anything other than giving the drugs to their intended recipients until being advised otherwise by the Board inspectors during their inspection.

10. Board inspectors also requested and received copies of all Respondent Pharmacy records of acquisition and disposition of tablets of Dilaudid 4mg and tablets of OxyContin 80mg for October 9, 2006, through December 30, 2007.

11. A Board inspector conducted a drug audit of Respondent Pharmacy's aforementioned acquisition and disposition records for tablets of Dilaudid 4mg and OxyContin 80mg. The audit of those records revealed that:

A. From November 10, 2006, to June 19, 2007, Respondent Cha filled seven prescriptions early by seven or more days for patient MB.

B. From December 13, 2006, to December 17, 2007, Respondent Cha filled 12 prescriptions early by seven or more days for patient WC.

C. From November 14, 2006, to August 11, 2007, Respondent Cha filled seven prescriptions early by seven or more days for patient JM.

D. From December 1, 2006, to August 20, 2007, Respondent Cha filled five prescriptions early by seven or more days for patient MP.

E. For the time period of October 23, 2006, to December 17, 2007, Respondent Cha filled several prescriptions for OxyContin and/or Dilaudid seven or more days early for 14 other patients, and for five of those patients Respondent Cha filled separate prescriptions from two different prescribing physicians. For one of those 14 patients, Respondent Cha filled prescriptions for Dilaudid from four different physicians.

12. From October 23, 2006, to December 17, 2007, Respondents failed to validate correct addresses for all of the involved customers, request and use CURES profiles to determine if customers were abusing controlled substances, and examine customer profiles to determine if customers were requesting prescriptions early or from multiple doctors. There were several red flags created by the behaviors of the involved customers that should have alerted Respondents of the need to take the above-described measures to determine whether the prescriptions in question were legitimate. For example, a large majority of the involved customers lived far from the pharmacy premises; most received prescriptions from a small number of the same physicians; the involved dosages were extremely high and uncommon, yet many of the customers in different medical conditions were prescribed the same high dosages of the same drugs; the frequency within which many customers received early refills; and many of the customers provided more than one address. By failing to take the above measures in light of this suspicious information, Respondents' violated the standard of care in the professional practice of pharmacy.

13. The Board inspector's audit of Respondents' records also revealed that, between October 9, 2006, and December 30, 2007, Respondent Pharmacy purchased 1,397,100 tablets of Dilaudid 4mg and 698,236 tablets of OxyContin 80mg; and that there was an overage of 2,188 tablets of Dilaudid 4mg and a shortage of 10,674 tablets of OxyContin 80mg.

14. Respondents' failure to maintain an accurate inventory of Dilaudid and OxyContin violated the standard of care in the professional practice of pharmacy. Respondents violated the standard of care by not conducting regular and routine counts of controlled substances and dangerous drugs and reporting any discrepancies to the appropriate authorities. In fact, Respondent Cha testified during the hearing that she did not know how she lost count of her inventory.

15. As established by the expert report from Complainant's expert witness, Pharmacist Raffi I. Simonian, the above-described measures that Respondents failed to take in order to determine the validity of the involved prescriptions and an accurate inventory of dangerous drugs at the pharmacy premises are routinely completed by professional pharmacists throughout the state on a daily basis. Those activities are required, not optional.

Respondents' failure to take such measures, in light of several red flags that would have lead a reasonably prudent practitioner to be suspicious, was sufficiently egregious as to constitute gross negligence.

16. It was not established as alleged that Respondents were incompetent with respect to the above described errors and omissions. Pharmacist Simonian neither testified nor concluded in his expert report that Respondents were incompetent.

17. The Board inspector's audit comparing Respondents' purchasing records and wholesalers' disposition records revealed Respondents failed to maintain 13 invoices for OxyContin 80mg and Dilaudid 4mg between October 9, 2006, and December 30, 2007.

Evidence of Mitigation and Aggravation

18. In mitigation, Respondent Cha learned about the PHI forms from a seminar she and an employee attended at the California Korean-American Pharmacists Association. Respondent Cha correctly understood the PHI form complied with HIPPA in terms of sharing customer health information. Her mistaken belief that the PHI form also provided legal authorization for NN and RP to deliver medications to her customers was in good faith.

19. In mitigation, Respondent Cha had been duped by NN and RP, whom she had known and worked with for many years. By Respondent Cha's own admission, she was naive during the events in question, and believed NN's convincing tale that he was committed to assisting HIV patients out of altruism from his experiences with an HIV positive family member. Respondent Cha also naively refused to believe that physicians would purposely participate in diversion schemes for money. The number of early refills, though alarming, was only half as frequent as Board inspectors initially concluded after their inspection and audit. Respondent Cha was given a number of excuses from her customers concerning the need for early refills, such as losing them down the toilet, leaving them while on vacation, forgetting them on a bus, leaving them behind when they moved, etc. At the time, Respondent Cha did not feel comfortable questioning the motives of her customers.

20. In aggravation, Respondent Cha had an incomplete understanding of how the CURES system worked, in that she did not know she could obtain copies of reports documenting patient prescription histories. Such was common knowledge to all pharmacists during the relevant times. Respondent Cha provided no satisfactory explanation for how she lost track of her inventory. She points to an armed robbery in October of 2006 and an overnight burglary in December of 2006. However, the robbery occurred before the audit period and the burglary did not involve Dilaudid or OxyContin. After those events, Respondent Cha apparently did not attempt to determine how the thefts impacted her inventory. The fact that Respondent Cha admitted during the hearing that she had no idea how she lost count of her inventory shows she had no meaningful inventory measures in place at the times in question.

21. In mitigation, it appears that the 13 missing invoices were inadvertently lost. Once made aware of that problem by the Board's inspectors, Respondent Cha obtained copies from the involved manufacturers and timely provided them to the Board.

Evidence of Rehabilitation

22. Respondent Cha has no known criminal record and Respondents have no prior history of discipline or receipt of warnings from the Board. Respondent Cha has been very active in the California Korean-American Pharmacists Association, serving as its president in 2005-2006, and now serving on its board.

23. No evidence of any misconduct since the events in question was submitted. Respondent Cha has opened a pharmacy in Cerritos, which is not involved in this case.

24. Once Respondent Cha became aware of facts indicating that drivers NN and RP probably were diverting large quantities of the drugs they were purportedly delivering to her customers, she has lost her naiveté and has awakened to reality. Respondent Cha thereafter began a conscientious effort to help law enforcement investigate drug diversion schemes involving patients, customers, and physicians. She has met with and provided assistance to the FBI, DHCS, California Bureau of Medi-Cal Fraud and Elder Abuse, the Los Angeles City Attorney's Office, and a consortium of local law enforcement agencies known as the Health Authority Law Enforcement Task Force (HALT). Respondent Cha's assistance has led to the arrest, prosecution and/or conviction of several drug diverters. For her assistance, Respondent Cha has been lauded by numerous members of law enforcement, included two current/past members of HALT who testified in her favor during the hearing. Due to her efforts, Respondent Cha has put herself at risk.

25. After its complaint to the Board, DHCS issued a temporary suspension order (TSO) against Respondents' Medi-Cal provider numbers. However, after completing its investigation of Respondents' practices, DHCS removed the TSO and reinstated Respondents' Medi-Cal provider numbers, effective October 13, 2011.

26. Respondents have subsequently reformed their practices. For example, inventories are checked on a daily and weekly basis at the pharmacy; inventories are checked against records of drug receipts and sales; patient profiles and CURES information is now regularly checked; prescribing physicians are more carefully scrutinized; Respondent Cha immediately contacts those at HALT when she becomes suspicious of a customer and/or prescription. In June of 2011, Respondents successfully completed an unannounced inspection by Board inspectors. In 2012, Respondents passed audits conducted by National Audit, a third party auditor for Medicare Part D reimbursements, and HMS Pharmacy Audit Department, on behalf of Blue Shield of California.

27. A number of credible witnesses testified during the hearing concerning Respondent Cha's good character. Those witnesses ranged from a former employee, past and current customers (one of whom is a retired judge with many decades experience in state and

federal courts), and members of the HALT team whom Respondent Cha has helped. All of these witnesses testified that Respondent Cha is honest, caring, sympathetic to customer needs, hard working and yet, by dint of this case and the aforementioned robbery/burglary, more hard-boiled and willing to scrutinize prescriptions as well as the security of her pharmacy.

28. Respondent Cha appeared remorseful and sincere when she testified during the hearing. She testified that she was duped by NN and RP, and that she should have known better. She became upset when she discovered that they lied to and took advantage of her. Respondent Cha has pledged to continue to cooperate with law enforcement to make amends.

Costs

29. The Board has incurred the following costs in the investigation and prosecution of this matter: a) \$66,121.50 of Board inspectors' investigation time; and b) \$87,571.25 of legal services billed to the Board by the Office of the Attorney General (AGO); c) for total costs of \$153,692.75.

30. Records from the AGO indicate that this case was initially handled by two other individuals before being assigned to the current prosecutor, Mr. Brown. The first prosecutor billed \$18,130.50. The second prosecutor billed \$42,764.00. It is highly likely that the first two prosecutors duplicated each other's efforts, and in turn their work has been duplicated by Mr. Brown. Therefore, reducing the AGO costs by the amount billed by the first two prosecutors, i.e., \$60,894.50, is warranted.

31. Based on the above, it was established that the Board has incurred reasonable costs of the investigation and enforcement of this matter in the amount of \$92,798.25.

LEGAL CONCLUSIONS

1. *First Cause for Discipline* (Furnishing Dangerous Drugs to Unauthorized Persons). Respondents Cha and Pharmacy are subject to discipline under Business and Professions Code section 4301, subdivisions (c) and (o),² for unprofessional conduct, in that between October 23, 2006, and December 17, 2007, Respondents gave Schedule II controlled substances to drivers NN and RP on behalf of 714 customers, but it was not established that NN or RP were legally authorized to receive the medications for others, in violation of section 4126.5 and 21 Code of Federal Regulations part 1307.11. Moreover, Respondents provided large quantities of OxyContin 80mg and Dilaudid 4mg to those two individuals on behalf of 714 customers when Respondents had no system in place to ensure that those Schedule II controlled substances were received by the customers, nor have Respondents established that most of those customers received them. (Factual Findings 4-15.)

² Further statutory references are to the Business and Professions Code unless noted.

2. Second Cause for Discipline (Filling of Erroneous or Uncertain Prescriptions and Failure to Assume Co-Responsibility in Legitimacy of a Prescription). Respondents are subject to discipline under section 4301, subdivisions (j) and (o), in conjunction with Health and Safety Code section 11153 and California Code of Regulations, title 16, section 1761, in that, from October 23, 2006, to December 17, 2007, they continuously and excessively filled and dispensed OxyContin and Dilaudid prescriptions under circumstances that would have led a reasonably prudent pharmacist to be suspicious whether the prescriptions served a legitimate medical purpose. Respondent Cha failed to assume her responsibilities of validating correct addresses, requesting and using CURES patient profiles to determine if patients were abusing controlled substances, and examining patient profiles to determine if patients were requesting prescriptions early or from multiple doctors for purposes of drugseeking or diverting drugs for street sales. Respondents' failures were so egregious as to constitute gross negligence in the professional practice of pharmacy. (Factual Findings 4-15.)

3. Third Cause for Discipline (Failure to Meet Requirements for Maintaining an Accurate Inventory). Respondents are subject to disciplinary action pursuant to section 4301, subdivisions (c) and (o), for violating section 4081, subdivision (a), in conjunction with California Code of Regulations, title 16, section 1718, by failing to meet requirements for maintaining an accurate inventory. Respondents' failure to maintain an accurate inventory of Dilaudid and OxyContin fell below the standard of care of a reasonably prudent pharmacist and was so egregious as to constitute gross negligence in the professional practice of pharmacy. (Factual Findings 13-15.)

4. Fourth Cause for Discipline (Failure to Maintain Records- Incomplete Acquisition Record). Respondents are subject to disciplinary action pursuant to section 4081, subdivisions (a) and (b), in conjunction with section 4113, subdivision (b), for failing to meet requirements of maintaining records, in that Respondents failed to maintain 13 invoices pertaining to the acquisition of dangerous drugs and controlled substances. (Factual Finding 17.)

5A. *Disposition*. Since cause for discipline was established, the level of discipline must be determined. In reaching a decision on disciplining a licensee, the Board's Disciplinary Guidelines [Rev. 10/2007] (Guidelines) are considered. (Cal. Code Regs, tit. 16, § 1760.) In this case, Respondents' misconduct is deemed to fall under Category III, which covers violations of sections 4301, subdivision (o), and 4081; Health and Safety Code section 11153; and California Code of Regulations, title 16, section 1761. Those types of violations were established in this case. The minimum discipline recommended in the Guidelines for those violations is five years of probation (for violations involving drug diversion), 90 days actual suspension, and various terms as appropriate; the maximum discipline recommended is revocation.

5B. The Guidelines list 15 factors to be considered in determining the appropriate level of discipline within the various categories. These factors are applied to Respondents as follows:

1. Actual or potential harm to the public. Since a substantial amount of drugs probably were diverted and Respondents received over \$1 million in payments from Medi-Cal, the potential of harm to the public is present.

2. Actual or potential harm to any consumer. No actual or potential harm to a consumer was proven.

3. Prior disciplinary record, including level of compliance with disciplinary order(s). Respondents have no prior disciplinary record.

4. Prior warnings of record(s), including citation(s) and fine(s). Respondents have no prior record of warnings.

5. *Number and/or variety of current violations*. Four different violations were established, based on core misconduct of Respondents' failure to take and keep accurate inventory and to scrutinize a significant number of suspicious prescriptions.

6. Nature and severity of the act(s), offense(s) or crime(s) under consideration. The acts in question involved serious misconduct.

7. Aggravating evidence. Respondent Cha's apparent lack of understanding how the CURES system worked at the time in question, as well as her inability to explain how she lost count of her inventory, are aggravating facts.

8. *Mitigating evidence*. Respondents presented mitigating evidence, which established that the violations proven in this case did not involve fraudulent, willful or intentional misconduct.

9. *Rehabilitation evidence*. Respondents submitted significant evidence of rehabilitation, including good behavior for the past five years, conscientious and productive assistance with local law enforcement, reformed pharmacy practices which have resulted in reinstatement of their Medi-Cal provider numbers and successfully completing recent audits by various entities, favorable character references, and Respondent Cha's remorseful and sincere testimony during the hearing.

10. Compliance with terms of any criminal sentence. This factor is not applicable.

11. Overall criminal record. No evidence of any conviction was presented.

12. If applicable, evidence of proceedings for case being set aside and dismissed pursuant to section 1203.4 of the Penal Code. This factor is not applicable.

13. *Time passed since the act(s) or offense(s)*. A moderate amount of time has passed since the misconduct concluded in December of 2007.

14. Whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct. Respondents' engaged in gross negligence.

15. Financial benefit to the respondent from the misconduct. Respondents received over \$1 million in payments from Medi-Cal for Dilaudid and OxyContin prescriptions during the relevant time period.

5C. The factors listed above have mixed application to Respondents, in that several go against them and several are in their favor. The overall weight of those factors indicates that Respondents have engaged in serious misconduct but have presented sufficient mitigation and rehabilitation establishing that the public health, safety or welfare will not be adversely affected by their retaining probationary licenses with optional terms calculated to maximize public protection. Since the proven misconduct probably involved drug diversion, a five year probationary period is warranted. However, since Respondent submitted significant evidence of mitigation and rehabilitation, a reduced actual suspension of 30 days is also warranted. (Factual Findings 1-28.)

6. Other Considerations. Section 4307, subdivision (a), provides, in pertinent part, 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, administrator, owner, member, officer, director, associate, or partner and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee. Respondent Cha is the owner/operator of Respondent Pharmacy and she apparently has opened another pharmacy in Cerritos. Under the below probationary conditions, the public will be adequately protected by her remaining in those positions. However, the prohibition of section 4307 shall be applied to any new license application by Respondent Cha or her request to be a pharmacist-in-charge or designated representative at any other facility.

7. *Costs.* Section 125.3 provides that an administrative law judge may order a licentiate who has violated a licensing law to pay the reasonable costs of the investigation and enforcement of the case. Respondents violated provisions of the Pharmacy Law. Pursuant to section 125.3, Respondents should pay the Board its reasonable costs of \$92,798.25 investigating and enforcing this matter. (Factual Findings 29-31.)

ORDER

Respondent Nancy Cha

Original Pharmacist License No. RPH 46617, issued to Respondent Nancy Cha (Respondent), is revoked. However, revocation is stayed and Respondent is placed on probation for five years upon the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent shall report any of the following occurrences to the Board, in writing, within 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 contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;

* a conviction of any crime; or

* discipline, citation, or other administrative action filed by any state and federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

2. Reporting to the Board

Respondent shall report to the Board quarterly. The report shall be made either in person or in writing, as directed. Respondent shall state under penalty of perjury whether there has been compliance with all the terms and conditions of probation. If the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable notice, Respondent shall appear in person for interviews with the Board upon request at various intervals at a location to be determined by the Board. Failure to appear for a scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperation with Board Staff

Respondent shall cooperate with the Board's inspectional program and in the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation. Failure to comply shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

6. Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 3157 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3157, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 3157 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 3157 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, parttime, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the Respondent is an employee, independent contractor or volunteer.

7. Supervision of Interns, Serving as PIC, Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. (See Legal Conclusion No. 6). Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$92,798.25. Respondent shall make monthly payments according to a schedule approved by the Board. There shall be no deviation from that 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.

Whether the filing of bankruptcy by Respondent relieves Respondent of her responsibility to reimburse the Board its costs of investigation and prosecution is a legal matter to be decided by a court of competent jurisdiction.

9. **Probation Monitoring Costs**

Respondent 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.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

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

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may tender his or her 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. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish his or her pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the Board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation.

Should Respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 80 hours per calendar month in California, Respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which Respondent is not practicing as a pharmacist for at least 80 hours, as defined by Business and Professions Code section 4000 <u>et seq</u>. "Resumption of practice" means any calendar month during which Respondent is practicing as a pharmacist for at least 80 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and probation shall automatically be 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 violates probation in any respect, the Board, after giving Respondent 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.

15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

16. Actual Suspension

As part of probation, Respondent is suspended from the practice of pharmacy for 30 days beginning the effective date of this decision.

During suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall Respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the Board.

Subject to the above restrictions, Respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

17. Separate File of Records

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

18. Report of Controlled Substances

Respondent shall submit quarterly reports to the Board detailing the total acquisition and disposition of such controlled substances as the Board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the Board. The report shall be delivered or mailed to the Board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

19. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board. If during the period of probation Respondent serves as a pharmacist-in-charge as permitted herein, Respondent shall retain an independent consultant at her own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at any pharmacy of which she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

20. Remedial Education

Within sixty (60) days of the effective date of this decision, Respondent shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to taking and maintaining accurate inventory, utilizing the CURES program, and otherwise assuming her responsibility as a pharmacist. The program of remedial education shall consist of at least 80 hours, which shall be completed within one year at Respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the Board or its designee.

Following the completion of each course, the Board or its designee may require the Respondent, at his or her own expense, to take an approved examination to test the Respondent's knowledge of the course. If the Respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require Respondent to take another course approved by the Board in the same subject area.

Respondent C & N Pharmacy, Inc.

Original Pharmacy Permit No. PHY 47337, issued to Respondent C & N Pharmacy, Inc., to do business as Burbank Medical Pharmacy (Respondent), is revoked. However, revocation is stayed and Respondent is placed on probation for five years upon 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 contendere 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 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 his or her 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 \$92,798.25. Respondent owner shall make monthly payments according to a schedule approved by the Board. There shall be no deviation from that 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. Whether the filing of bankruptcy by Respondent owner relieves her responsibility to reimburse the Board its costs of investigation and prosecution is a legal matter to be decided by a court of competent jurisdiction.

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 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'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 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 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.

14. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

15. Report of Controlled Substances

Respondent owner shall submit quarterly reports to the Board detailing the total acquisition and disposition of such controlled substances as the Board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the Board. The report shall be delivered or mailed to the Board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

16. Suspension

Respondent C & N Pharmacy, Inc., doing business as Burbank Medical Pharmacy, is suspended for a period of 30 days beginning the effective of this decision.

Respondent shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

17. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the Board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of suspension ordered by this decision.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, 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 closure of the licensed entity.

DATED: January 22, 2013

ERIC SAWYER Administrative Law Judge Office of Administrative Hearings

1 2 3 4 5 6 7 8		RE THE
9	DEPARTMENT OF C	PHARMACY ONSUMER AFFAIRS
10	· · · · · · · · · · · · · · · · · · ·	CALIFORNIA
11	In the Matter of the First Amended Accusation Against:	Case No, 3157
12	C & N PHARMACY, INC. dba BURBANK	OAH No. 2011010422
13	MEDICAL PHARMACY, NANCY CHA, PHARMACIST-IN- CHARGE	FIRSTAMENDED ACCUSATION
14	2701 West Alameda Avenue Burbank, CA 91505	ACCUSATION
15	Original Pharmacy Permit License No. PHY 47337	
16	and	
17	NANCY CHA	
18	17104 Maria Avenue Cerritos, CA 90703	
`19	Original Pharmacist License No. PRH 46617	
20	Respondents.	
21 22	* ************************************	
22	Complainant alleges:	
24		TIES
.25		s this First Amended Accusation solely in her
26	official capacity as the Executive Officer of the l	
27	Affairs.	
28	111	
		1
. I	First Amend	ed Accusation

On or about April 12, 2006, the Board of Pharmacy issued Original Pharmacy Permit 2. 1 License Number PHY 47337 to C & N Pharmacy, Inc. to do business as Burbank Medical 2 Pharmacy (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at 3 all times relevant to the charges brought herein and will expire on April 20, 2013, unless renewed. 4 Nancy Cha was the President and Pharmacist-in-Charge since April 12, 2006. 5 3. On or about August 19, 1993, the Board of Pharmacy issued Original Pharmacist 6 License No. RPH 46617 to Nancy Cha (Respondent Cha). The Original Pharmacist License was 7 in full force and effect at all times relevant herein and will expire on August 31, 2013, unless 8 renewed. 9 JURISDICTION 10 4. This First Amended Accusation is brought before the Board of Pharmacy (Board), 11 Department of Consumer Affairs, under the authority of the following laws. All section 12 references are to the Business and Professions Code unless otherwise indicated. 13 5. Section 118, subdivision (b), of the Code provides that the 14 suspension/expiration/surrender/cancellation of a license shall not deprive the 15 Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period 16 within which the license may be renewed, restored, reissued or reinstated. 17 Section 4011 of the Code provides that the Board shall administer and enforce both 6. 18 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances 19 Act [Health & Safety Code, § 11000 et seq.]. 20Section 4300(a) of the Code states that every license issued by the Board may be 7. 21 22 suspended or revoked. Section 4402(a) of the Code provides that any license that is not renewed within three 8. 23 years following its expiration may not be renewed, restored, or reinstated and shall be canceled by 24 operation of law at the end of the three-year period. 2511126 111 27III28 2 First Amended Accusation

1	STATUTORY PROVISIONS
2	9. Section 4081 of the Code states, in pertinent part:
3	"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs
4	or dangerous devices shall be at all times during business hours open to inspection by authorized
5	officers of the law, and shall be preserved for at least three years from the date of making. A
6	current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary
7	food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
8	institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
9	registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
10	Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
-11	Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
12	"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal
13	drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee, for
14	maintaining the records and inventory described in this section."
15	10. Section 4105 of the Code provides, in pertinent part, that all records or other
16	documentation of the acquisition and disposition of dangerous drugs and dangerous devices by
17	any entity licensed by the board shall be retained on the licensed premises in a readily retrievable
18	form for a period of three years from the date of making.
19	11. Section 4113, subdivision (b) of the Code states:
20	"The pharmacist-in-charge shall be responsible for a pharmacy's compliance with
21	all state and federal laws and regulations pertaining to the practice of pharmacy."
22	12. Section 4126.5 of the Code provides, in pertinent part, that a pharmacy may furnish
23	dangerous drugs only to: (1) A wholesaler owned or under common control by the wholesaler
24	from whom the dangerous drug was acquired; (2) The pharmaceutical manufacturer from whom
25	the dangerous drug was acquired; (3) A licensed wholesaler acting as a reverse distributor; (4)
26	Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could
27	result in the denial of health care; (5) A patient or to another pharmacy pursuant to a prescription
28	
	3

First Amended Accusation

or as otherwise authorized by law; (6) A health care provider that is not a pharmacy but that is 1 2 authorized to purchase dangerous drugs; or (7) Another pharmacy under common control. "Common control" means the power to direct or cause the direction of the management and 3 policies of another, by ownership, voting rights, contract, or other means. 4 13. Section 4301 of the Code provides, in pertinent part, that the Board shall take action 5 against any holder of a license who is guilty of "unprofessional conduct," defined to include, but 6 not be limited to, any of the following: 7 8 "(b) Incompetence, 9 "(c) Gross negligence. 10 "(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) 11 of Section 11153 of the Health and Safety Code. 12 "(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) 13 of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining 14 whether the furnishing of controlled substances is clearly excessive shall include, but not be 15 limited to, the amount of controlled substances furnished, the previous ordering pattern of the 16 customer (including size and frequency of orders), the type and size of the customer, and where 17and to whom the customer distributes its product. 18 19 "(i) The violation of any of the statutes of this state, or any other state, or of the United 20 States regulating controlled substances and dangerous drugs. 21 22 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 23 violation of or conspiring to violate any provision or term of this chapter or of the applicable 24 federal and state laws and regulations governing pharmacy, including regulations established by 25 the board." 26 11127III28

1	14. Section 4332 of the Code states;
2	"Any person who fails, neglects, or refuses to maintain the records required by
3	Section 4081 or who, when called upon by an authorized officer or a member of the board, fails,
4	neglects, or refuses to produce or provide the records within a reasonable time, or who willfully
5	produces or furnishes records that are false, is guilty of a misdemeanor."
6	15. California Code of Regulations, title 16, section 1717, states in part:
7	"(a) No medication shall be dispensed on prescription except in a new container which
8	conforms with standards established in the official compendia. Notwithstanding the above, a
9	pharmacist may dispense and refill a prescription for non-liquid oral products in a clean
10	multiple-drug patient medication package (patient med pak), provided:
11	(1) a patient med pak is reused only for the same patient;
12	(2) no more than a one-month supply is dispensed at one time; and
13	(3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place."
14	16. California Code of Regulations, title 16, section 1718, states:
15	"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
16	Code shall be considered to include complete accountability for all dangerous drugs handled by
17	every licensee enumerated in Sections 4081 and 4332.
18	"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
19	available for inspection upon request for at least 3 years after the date of the inventory."
20	17. California Code of Regulations, title 16, section 1761, states:
21	"(a) No pharmacist shall compound or dispense any prescription which contains any
22	significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any
23	such prescription, the pharmacist shall contact the prescriber to obtain the information needed to
24	validate the prescription.
25	"(b) Even after conferring with the prescriber, a pharmacist shall not compound or
26	dispense a controlled substance prescription where the pharmacist knows or has objective reason
27	to know that said prescription was not issued for a legitimate medical purpose."
28	111
	5
J.	First Amended Accusation

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 registration in a manner consistent with the public health, safety, or welfare."

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

Title 21, Code of Federal Regulations, title 16, section 1307.21 (hereinafter "21 20. 14 C.F.R. § 1307.21") provides in pertinent part that any person in possession of any controlled 15 substance and desiring or required to dispose of such substance may request assistance from the 16 Special Agent in Charge of the Drug Enforcement Administration (DEA) in the area in which the 17 person is located for authority and instructions to dispose of such substance. In the event of a 18 properly-made request, the Special Agent in Charge shall authorize and instruct the applicant to 19 dispose of the controlled substance by transfer to a person registered under the Drug Enforcement 2021 Act and authorized to possess the substance, by delivery to an agent of the DEA, by destruction in the present of an agent of the DEA or other authorized person, or by other appropriate means. 22

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

26 111

1

2

3

4

5

6

7

- 27 111
- 28 1/1

1	
1	CONTROLLED SUBSTANCES / DANGEROUS DRUGS
2	22. Section 4021 of the Code states:
3	"Controlled substance' means any substance listed in Chapter 2 (commencing with Section
4	11053) of Division 10 of the Health and Safety Code."
5	23. Section 4022 of the Code states, in pertinent part:
б	"Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use,
7	except veterinary drugs that are labeled as such, and includes the following:
8	"(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without
9	prescription,' 'Rx only,' or words of similar import.
10	
11	(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
12	prescription or furnished pursuant to Section 4006."
13	24. Health and Safety Code section 11153 states, in pertinent part:
14	"(a) A prescription for a controlled substance shall only be issued for a legitimate medical
15	purpose by an individual practitioner acting in the usual course of his or her professional practice.
16	The responsibility for the proper prescribing and dispensing of controlled substances is upon the
17	prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the
18	prescription. Except as authorized by this division, the following are not legal prescriptions: (1)
19	an order purporting to be a prescription which is issued not in the usual course of professional
20	treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of
21	controlled substances, which is issued not in the course of professional treatment or as part of an
22	authorized narcotic treatment program, for the purpose of providing the user with controlled
23	substances, sufficient to keep him or her comfortable by maintaining customary use."
24	•••
25	25. Dilaudid - a trade name for the narcotic substance hydromorphone, is classified as a
26	Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision
27	(b)(1)(k), and is a dangerous drug within the meaning of Business and Professions Code section
28	4022.
	7
	First Amended Accusation

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

CHARGES AND ALLEGATIONS

7 27. On December 3, 2007, the Board received a written complaint from the California
8 Department of Healthcare Services (DHCS). The complaint stated that on November 1, 2007,
9 DHCS completed an unannounced visit at Respondent Pharmacy which revealed only Dilaudid
10 4mg (43 prescriptions) and OxyContin 80mg (42 prescriptions) were dispensed that day. Review
11 of the patient and physician addresses revealed none of the patients or physicians either lived or
12 practiced in the Burbank area.

28. On or about January 9, 2008, Board inspectors conducted a routine inspection of
Respondent Pharmacy and collected records. Respondent Cha was interviewed during the
inspection, she stated that she worked with drivers NH¹ and RP, who are patient representatives
that drop-off and pick-up patient medications.

29. Board inspectors requested Respondent Cha provide them with the records indicating
NH and RP serve as patient representatives. Respondent Cha provided Board inspectors with 714
files in which NH had 321 patients and RP had 393 patients. Respondent Cha stated she did not
have any information on RP except her phone number. Respondent Cha stated the Respondent
pharmacy contacts patients after NH and RP pick-up the medications for them to verify that the
patients had received their prescriptions. Respondent Cha did not have any records or
documentation indicating patient phone verification.

- 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
- 27 28

6

Initials are used to protect the privacy of the drivers.

1	Board inspector conducted a drug audit of Respondent Pharmacy's acquisition and disposition of
2	tablets of Dilaudid 4mg and tablets of OxyContin 80mg. The audit result indicated an overage of
3	2,188 tablets of Dilaudid 4mg and 10,800 tablets of OxyContin 80mg were unaccounted for.
4	FIRST CAUSE FOR DISCIPLINE
5	(Furnishing Dangerous Drugs to Unauthorized Persons)
6	As to Respondents Cha and Pharmacy
7	31. Respondents Cha and Pharmacy are subject to discipline under Code section 4301(b)
8	and/or 4301(c) and/or 4301(o) in that between October 23, 2006 to December 17, 2007,
9	Respondent Cha gave Schedule II controlled substances to drivers NH and RP, who represented a
10	total of 714 patients. Respondent Cha did not have any information about RP other than her
11	phone number. No documents existed showing a family relationship to the patients, nor
12	information on how both drivers were paid for their services. Respondent Cha had no
13	documentation reflecting the patients actually received the medication. NH and RP are not
14	licensed reverse distributors nor are they otherwise entities to which Respondents are/were
15	authorized to furnish dangerous drugs and/or controlled substances pursuant to Code section
16	4126.5 and/or 21 C.F.R. § 1307.11.
17	32. Respondents Cha and Pharmacy are subject to discipline under Code sections 4301(b)
18	and/or 4301(c) in that, as described in Paragraph 31 above, large quantities of OxyContin 80mg
19	and Dilaudid 4mg were given to two persons and Respondents did not have any information on
20	RP other than her phone number and with no system in place to ensure that the large quantities of
21	Schedule II controlled substances were not diverted for illegal street use, acts constituting
22	incompetence and/or gross negligence in the professional practice of pharmacy.
23	SECOND CAUSE FOR DISCIPLINE
24	As to Respondents Cha and Pharmacy
25	(Filling of Erroneous or Uncertain Prescriptions and Failure to Assume Co-Responsibility in
26	Legitimacy of a Prescription)
27	33. Respondents Cha and Pharmacy are subject to discipline under Code sections 4301(j)
28	and/or 4301(0) in conjunction with H&S Code section 11153 and California Code of Regulations,
	9
	First Amended Accusation

1	title 16, section 1761, in that from October 23, 2006 to December 17, 2007, Respondent Cha						
2	continuously and excessively filled and dispensed OxyContin and Dilaudid prescriptions without						
3	a legitimate medical purpose, clearly falling below the standard of care of a reasonable prudent						
4	pharmacist. The circumstances are as follows:						
5	a. From 11/10/2006 to 6/19/2007, Respondent Cha filled 8 prescriptions early for 7 or						
6	more days for patient MB ² .						
7	b. From 12/13/2006 to 12/17/2007, Respondent Cha filled 22 prescriptions for 7 or						
8	more days early for patient WC.						
9	c. From 4/2/2007 to 6/1/2007, Respondent Cha filled 5 prescriptions early and filled						
10	separate prescriptions from 2 different doctors for patient KH.						
11	d. From 11/15/2006 to/11/2007, Respondent Cha filled prescriptions for Dilaudid 4mg						
12	from Doctors Alva Marsh, Felix Cedraro, Dr. Samuel Sanchez and Daniel Pearce with no regard						
13	as to filling the prescriptions early for patient TH. This patient did obtain these prescriptions						
14	from 4 other pharmacies; Respondent Cha did not assume her co-responsibility in obtaining a						
15	Controlled Substance Utilization Review and Evaluation System (CURES) report.						
16	e. From 1/4/2007 to 6/21/2007, Respondent Cha filled 4 prescriptions 7 or more days						
17	early also for 2 separate doctors for patient TJ.						
18	f. From 11/14/2006 to 8/11/2007, Respondent Cha filled 18 prescriptions 7 or more						
19	days early for patient JM.						
20	g. From 12/8/2006 to 12/10/2007, Respondent Cha filled 13 prescriptions 7 or more						
21	days early for patient MM.						
22	h. From 11/21/2006 to 2/20/2007, Respondent Cha filled 2 prescriptions for Dilaudid 7						
23	or more days early for patient AO from 2 separate doctors.						
24	i. From 1/12/2007 to 9/1/2007, Respondent Cha filled 14 prescriptions for OxyContin 7						
25	or more days early for patient RP.						
26							
27	² Initials are used to protect the privacy of the patients. Full names will be provided						
28	following a request for discovery.						
	10						
	First Amended Accusation						
1	j. From 12/1/2006 to 8/20/2007, Respondent Cha filled 12 prescriptions for OxyContin						
----	---	--	--	--	--	--	--
2	80mg 7 or more days early for patient MP.						
3	k. From 2/7/2007 to 12/17/2007, Respondent Cha filled 11 prescriptions for OxyContin						
4	80mg 7 or more days early for patient CP.						
5	1. From 1/15/2007 to 8/27/2007, Respondent Cha filled 16 prescriptions for OxyContin						
6	80mg 7 or more days early for patient JS.						
7	m. From 11/16/2006 to 10/31/2007, Respondent Cha filled 5 prescriptions for						
8	OxyContin 80mg 7 or more days early for patient JS. Respondent Cha also filled 2 prescriptions						
9	each for Dilaudid and OxyContin 80mg on 1/9/2007.						
10	n. From 10/27/2006 to 8/2/2007, Respondent Cha filled 9 prescriptions early for						
11	OxyContin 7 or more days early for patient ES.						
12	o. From 2/21/2007 to 3/1/2007, Respondent Cha filled 1 prescription early for Dilaudid						
13	7 or more days early for patient RS.						
14	p. From 7/23/2007 to 12/10/2007, Respondent Cha filled 6 prescriptions for Dilaudid						
15	4mg7 or more days early for patient TS from 2 separate doctors.						
16	q. From 10/23/2006 to 10/24/2007, Respondent Cha filled 20 prescriptions for Dilaudid						
17	4mg 7 or more days early for patient FT from 2 separate doctors.						
18	r. From 10/23/2006 to 11/5/2007, Respondent Cha filled 17 prescriptions for Dilaudid						
19	4mg 7 or more days early for patient ST from 2 separate doctors.						
20	s. From 11/30/2006 to 4/12/2007, Respondent Cha filled 3 prescriptions for OxyContin						
21	80mg 7 or more days early for patient KK.						
22	34. Respondents Cha is subject to discipline under Code section 4301(d) in conjunction						
23	within H&S Code sections 11153, in that from October 23, 2006 to December 17, 2007,						
24	Respondent Cha failed to assume her corresponding responsibility by validating correct						
25	addresses, requesting and using a CURES patient profile to determine if patients were abusing						
26	controlled substances and failing to examine her patient profiles to determine if patients were						
27	requesting prescriptions early or from multiple doctors.						
28	111						
	, 11						
ļ	First Amended Accusation						

35. Respondents Cha and Pharmacy are subject to discipline under Code sections 4301(b) and/or 4301(c) and/or 4301(o) in that, as described in Paragraphs 33 and 34 above, Respondents' behavior is considered to be incompetence and/or gross negligence in the professional practice of pharmacy.

1

2

3

4

5

6

7

20

21

22

28

THIRD CAUSE FOR DISCIPLINE

As to Respondents Cha and Pharmacy

(Failure to Meet Requirements for Maintaining an Accurate Inventory)

8 36. Respondents are subject to disciplinary action pursuant to Code sections 4301(b)
9 and/or 4301(c) and/or 4301(o) for violating Code section 4081(a) conjunction with California
10 Code of Regulations, title 16, section 1718, for failing to meet requirements for maintaining an
11 accurate inventory. The circumstances are as follows:

a. Between October 9, 2006 to December 30, 2007, Respondent Pharmacy purchased
1,397,100 tablets of Dilaudid 4mg and 698,236 tablets of OxyContin 80mg. The Board
inspector's audit of Respondent Pharmacy indicated an overage of 2,188 tablets of Dilaudid 4mg
and 10,800 tablets of OxyContin 80mg were unaccounted for.

37. Respondents Cha and Pharmacy are subject to discipline under Code sections 4301(b)
and/or 4301(c) and/or 4301(o) in that Respondents' failure to maintain an accurate inventory of
Dilaudid and OxyContin falls below the standard of care of a reasonable prudent pharmacist and
is considered to be incompetence and/or gross negligence.

FOURTH CAUSE FOR DISCIPLINE

As to Respondents Cha and Pharmacy

(Failure to Maintain Records - Incomplete Acquisition Record)

38. Respondents are subject to disciplinary action pursuant to Code sections 4081(a)
and/or 4081(b) in conjunction with Code section 4113(b), for failing to meet requirements for
maintaining records and an accurate inventory. The circumstances are as follows:

a. The Board inspector's audit comparing Respondents' purchasing invoices records and
wholesalers' disposition invoices records revealed Respondents failed to maintain 13 invoices

First Amended Accusation

1	(Invoice No. 797786, 886332, 7624231, 8053054, 8255341, 12706, 133253, 461871, 483146,					
2	518952, 636558, 723307, 849208) between October 9, 2006 to December 30, 2007.					
3	OTHER MATTERS					
4	39. Business and Professions Code section 4307(a) provides, in pertinent part, that any					
5	person whose license has been revoked or is under suspension, or who has failed to renew his or					
6	her license while it was under suspension, or who has been a manager, administer, owner,					
7	member, officer, director, associate, or partner and while acting as the manager, administer,					
8	owner, member, officer, director, associate, or partner had knowledge of or knowingly					
9	participated in any conduct for which the license was denied, revoked, suspended, or placed on					
10	probation, shall be prohibited from serving as a manager, administrator, owner, member, officer,					
11	director, associate, or partner of a licensee.					
12	PRAYER					
13	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,					
14	and that following the hearing, the Board of Pharmacy issue a decision:					
15	1. Revoking or suspending Original Pharmacy Permit No. PHY 47337, issued to C & N					
16	Pharmacy Inc. to do business as Burbank Medical Pharmacy;					
17	2. Revoking or suspending Original Pharmacist License No. RPH 46617, issued to					
18	Nancy Cha.					
19	3. Ordering Burbank Medical Pharmacy and Nancy Cha to pay the Board of Pharmacy					
20	the reasonable costs of the investigation and enforcement of this case, pursuant to Business and					
21	Professions Code section 125.3.					
22	4. Taking such other and further action as deemed necessary and proper.					
23 24	DATED: 11/27/12 Juginia Develet					
25	Executive Officer Board of Pharmacy					
26	Department of Consumer Affairs State of California					
27	Complainant					
28	LA2008600281 51195576.doc					
	13					
ļ	First Amended Accusation					

	·					
1	EDMUND G. BROWN JR., Attorney General					
2	of the State of California GLORIA A. BARRIOS					
3	Supervising Deputy Attorney General MICHEL W. VALENTINE, State Bar No. 153078					
4	Deputy Attorney General IV 300 So. Spring Street, Suite 1702					
	Los Angeles, CA 90013	· · · · · · · · · · · · · · · · · · ·				
5	Telephone: (213) 897-1034 Facsimile: (213) 897-2804					
6	Attorneys for Complainant					
7						
8	BEFORE 3 BOARD OF PH					
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA					
10	SIATE OF CAL	IFORMA				
11	In the Matter of the Accusation Against:	Case No. 3157				
12	C & N PHARMACY,	ACCUSATION				
13	dba BURBANK MEDICAL PHARMACY, NANCY CHA, Pharmacist-in-Charge	ACCUSATION				
14	2701 West Alameda Avenue Burbank, CA 91505	,				
15	Original Pharmacy Permit No. PHY 47337					
16	and					
17	NANCY CHA	· · ·				
18	17104 Maria Avenue Cerritos, CA 90703					
19	Original Pharmacist License No. RPH 46617					
20	Respondents.					
21	· · · · · · · · · · · · · · · · · · ·	• •				
22	Complainant alleges:					
23	PARTIES					
24	1. Virginia Herold (Complainan	t) brings this Accusation solely in her				
25	official capacity as the Executive Officer of the Boa	rd of Pharmacy, Department of Consumer				
26	Affairs.					
27	2. On or about April 12, 2006, t	he Board of Pharmacy issued Original				
28	Pharmacy Permit No. PHY 47337 to C & N Pharma	cy Inc. to do business as Burbank Medical				
	1					

Pharmacy (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect
 at all times relevant to the charges brought herein and will expire on April 1, 2009, unless
 renewed.

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

JURISDICTION

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

9

25

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
proceed with a disciplinary action during the period within which the license may be renewed,
restored, reissued or reinstated.

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.].

207.Section 4300(a) of the Code provides that every license issued by the21Board may be suspended or revoked.

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
be canceled by operation of law at the end of the three-year period.

STATUTORY PROVISIONS

26 9. Section 4081 of the Code states, in pertinent part:
27 "(a) All records of manufacture and of sale, acquisition, or disposition of
28 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 1 2 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, 3 pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, 4 laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked 5 certificate, license, permit, registration, or exemption under Division 2 (commencing with 6 Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) 7 of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or 8 dangerous devices.

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

12

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

17

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 12. Section 4126.5 of the Code provides, in pertinent part, that a pharmacy 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

2 ///
3
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:
7

management and policies of another, by ownership, voting rights, contract, or other means.

"(b) Incompetence.

1

8

9

18

21

26

27

28

" "(c) Gross negligence.

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

12 "(e) The clearly excessive furnishing of controlled substances in violation of 13 subdivision (a) of Section 11153 of the Health and Safety Code. Factors to be considered in 14 determining whether the furnishing of controlled substances is clearly excessive shall include, 15 but not be limited to, the amount of controlled substances furnished, the previous ordering 16 pattern of the customer (including size and frequency of orders), the type and size of the 17 customer, and where and to whom the customer distributes its product.

19 "(j) The violation of any of the statutes of this state or of the United States20 regulating controlled substances and dangerous drugs.

22 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or
23 abetting the violation of or conspiring to violate any provision or term of this chapter or of the
24 applicable federal and state laws and regulations governing pharmacy, including regulations
25 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."

4

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.'"

11

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."

17

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.

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or
dispense a controlled substance prescription where the pharmacist knows or has objective reason
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
 registration in a manner consistent with the public health, safety, or welfare."

19. Title 21, Code of Federal Regulations, section 1307.11 (hereinafter "21
C.F.R. § 1307.11") provides in pertinent part that a practitioner who is registered to dispense a
controlled substance may distribute (without being registered to distribute) a quantity of such
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
to receive such controlled substance(s).

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

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

24 25

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."

28

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

""Dangerous drug' or 'dangerous device' means any drug or device unsafe for 2 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 without prescription,' 'Rx only,' or words of similar import. 4

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

8

19

1

5

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 medical purpose by an individual practitioner acting in the usual course of his or her professional 10 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 13 who fills the prescription. Except as authorized by this division, the following are not legal 14 prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course 15 of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment 16 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

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 OxyContin - a brand name formation of oxycodone hydrochloride, is an 26. 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

1

28

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.

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

1

2

 20°

21

(Furnishing Dangerous Drugs to Unauthorized Persons)

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

14 32. Respondents Cha and Pharmacy are subject to discipline under Code.
15 sections 4301(b) and/or 4301(c) in that, as described in Paragraph 31 above, large quantities of
16 OxyContin 80mg and Dilaudid 4mg were given to two persons who Respondents did not have
17 any information about other than their phone numbers and with no system in place to ensure that
18 the large quantities of Schedule II controlled substances were not diverted for illegal street use,
19 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

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

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.

r. From 10/23/2006 to 11/5/2007, Respondent Cha filled 17 prescriptions for
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

above, Respondents' behavior is considered to be incompetence and/or gross negligence in the 1 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 4301(b) and/or 4301(c) and/or 4301(o) for violating Code section 4081(a) conjunction with 7 111 8 California Code of Regulations, title 16, section 1718, for failing to meet requirements for 9 10 maintaining an accurate inventory. The circumstances are as follows: 11 Between October 9, 2006 to December 30, 2007, Respondent Pharmacy a, purchased 1,397,100 tablets of Dilaudid 4mg and 698,236 tablets of OxyContin 80mg. The 12 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. 37. Respondents Cha and Pharmacy are subject to discipline under Code 15 sections 4301(b) and/or 4301(c) and/or 4301(o) in that Respondents' failure to maintain an 16 17 accurate inventory of Dilaudid and OxyContin falls below the standard of care of a reasonable prudent pharmacist and is considered to be incompetence and/or gross negligence. 18 19 FOURTH CAUSE FOR DISCIPLINE 20As to Respondents Cha and Pharmacy (Failure to Maintain Records - Incomplete Acquisition Record) 21 38. 22 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 The Board inspector's audit comparing Respondents' purchasing invoices a. 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,

1 483146, 518952, 636558, 723307, 849208) between October 9, 2006 to December 30, 2007. 2 **OTHER MATTERS** 39. 3 Business and Professions Code section 4307(a) provides, in pertinent part, 4 that any person whose license has been revoked or is under suspension, or who has failed to 5 renew his or her license while it was under suspension, or who has been a manager, administer, owner, member, officer, director, associate, or partner and while acting as the manager, 6 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. 11 PRAYER 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: 14 1. Revoking or suspending Original Pharmacy Permit No. PHY 47337, issued to C & N Pharmacy Inc. to do business as Burbank Medical Pharmacy. 15 16 2. Revoking or suspending Original Pharmacist License No. RPH 46617, 17 issued to Nancy Cha. 18 Ordering Burbank Medical Pharmacy and Nancy Cha to pay the Board of 3. • 19 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to 20 Business and Professions Code section 125.3. 21 4. Taking such other and further action as deemed necessary and proper. 22 DATED: 23 24 25 26 TRGINIA HERO Executive Officer 27 Board of Pharmacy Department of Consumer Affairs 28 State of California 13

			•
· · · · · · · · · · · · · · · · · · ·			
· · ·	1 2	Complainant	
	3		
9 	4	LA2004601406 60351508_3.wpd	
	5	CML (09/24/2004)	
	6		•
	7		
	8		
	9		
	10 11		
	12		
	- 13		
	14		
	15	a	
	16		
	17		•
	18 19		
	20		
	21)
	22		
	23		
	24		
	25 26		
	26 27		
· · ·	28		
		14	