BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

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In the Matter of:

CANE CREEK PHARMACY, INC. (Permit Nos. 5443 and 5784)

CONSENT ORDER OF DISCIPLINE

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46.2008. This Conference was scheduled for August 26, 2009 and, after appropriate notice, was heard on that day by Board member Robert McLaughlin, Jr. at the offices of the Board. The Respondent Cane Creek Pharmacy, Inc. (Permit Nos. 5443 and 5784 (hereinafter, "Respondent" or "Cane Creek") was present, through its pharmacist-manager and owner, and was represented by Counsel Mark Kurdys. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and a related respondent and her counsel were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent was, at all relevant times referred to herein, located at 66 Reta Road, Fairview, North Carolina and the holder of Permit No. 5443, issued by the Board. Respondent is currently located at 785 Cane Creek Road, Fletcher, North Carolina and the holder of Permit No. 5784, issued by the Board. Respondent is and was, at all relevant times referenced to herein, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. The Board finds that, between approximately October 2007 and December 2008, Respondent failed to maintain an adequate system of inventory record-keeping and control to prevent and detect the diversion of controlled substances and failed to maintain inventories and records, as required by state and federal law.

4. Although Respondent's pharmacist manager for the period from October 2007 to October 2008 maintains she had completed all required inventories and that documentation thereof was present when her service as pharmacist-manager ended in October 2008, upon inspection in December 2008, Respondent did not maintain required inventories and records, including:

 Invoices for pharmaceuticals, including but not limited to records of ordering or returns of schedule III through schedule V controlled substances, from August 2006 to March 2007;

ii. Records of biennial inventories from 2001, 2003, 2005 or 2007;

iii. A current policy and procedure manual.

5. Although Respondent's pharmacist manager for the period form October 2007 to October 2008 denies it, the Board finds that at least some of the inventories and records that were missing from the pharmacy in December 2008 had been missing since at least the time that the current pharmacist-manager was employed with Respondent, in April 2008.

6. In or around November 2007, Respondent failed to assure that certain controlled substances were safe and secure within the pharmacy. As a result, one of Respondent's employees diverted from Respondent about 36 dosage units of controlled substances, including 20 dosage units of Percocet (a schedule II controlled substance), 8 dosage units of Diazepam (a schedule IV controlled substance), 5 dosage units of Darvocet (a schedule IV controlled substance) and 3 dosage units of Xanax (a schedule IV controlled substance).

7. After the November 2007 arrest, Respondent reported the loss to the DEA, but Respondent did not report the loss to the Board, as required by law.

8. While Respondent contends otherwise, the Board finds that, between at least April 2008 and December 2008, Respondent's physical facility failed to satisfy the requirements of North Carolina law. Respondent lacked sufficient floor space to ensure sanitation and quality of the product dispensed, lacked sufficient security to ensure that prescription drugs and controlled substances remained safe and secure within the pharmacy, and did not maintain equipment sufficiently to ensure the safety, sterility and purity of the products dispensed.

9. At various times during 2008, Respondent employed four technicians who were not registered with the Board as required by law.

10. On various dates in December 2008, Respondent scheduled more than two technicians to work under the supervision of one pharmacist without Board authorization. In addition, on various dates in December 2008, an excessive number of prescriptions was filled

without a sufficient number of pharmacists at such a rate as to pose a danger to public health and safety.

11. The investigation revealed no incidents of mid-filled prescriptions and no incident where a patient's heath or safety was adversely impacted by the deficiencies described above.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

Respondent's conduct, as set out in the findings of fact above, constitutes grounds for discipline pursuant to N.C. Gen. Stat. § 90-85.38 because Respondent's acts were in violation of N.C. Gen. Stat. §§ 90-85.15A(b) and (c), 90-85.21(a), 90-85.25(b), 90-85.38(b), 90-85.40(a), (c) and (f), 90-106 and 90-108; and 21 N.C.A.C. 46. 1601, 46. 1803, 46. 1804, 46. 1811, 46. 2501, and 46. 2502(a) and (d).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of Respondent, the Board enters the following:

CONSENT ORDER OF DISCIPLINE

1. Respondent's pharmacy permit (Permit No. 5784) is hereby SUSPENDED for thirty (30) days. The suspension shall be stayed for a period of five (5) years. The stay is conditioned upon Respondent's compliance with the terms of this Consent Order. If at the end of the five (5) year period, Respondent has violated no terms of this Consent Order, Respondent shall not be required to serve the thirty (30) day suspension;

2. Within forty-five (45) days from the date of this order, Respondent shall submit to the Executive Director (a) a policies and procedures manual and (b) a securities manual. Those

manuals shall be adequate, in the discretion of the Executive Director, to ensure that there are adequate procedures in place, at a minimum, for (a) record-keeping and control to prevent and detect the diversion of controlled substances, (b) ensuring the sanitation, security and quality of the product dispensed, (c) ensuring the licensure of all pharmacists and registration of all technicians, (d) ensuring the adequate supervision of technicians, and (c) ensuring an adequate number of pharmacists for the volume of drugs dispensed.

- 3. For a period of five (5) years from the date of this order:
 - Respondent will notify the Board within fifteen (15) days of the date of employment of any person who, as any part of his or her job, has been employed to perform technical functions to assist the pharmacist in preparing and dispensing prescription medications;
 - b. Respondent will notify the Board within fifteen (15) days of the change in status of any existing employee who, as any part of his or her job, begins to perform technical functions to assist the pharmacist in preparing and dispensing prescription medications;
 - c. Respondent will maintain a perpetual inventory on all schedule II controlled substances;
 - d. No less frequently than every 12 months, Respondent will perform an inventory on all controlled substances;
 - e. Respondent will maintain, in a format that is readily retrievable upon request by the Board, the items in subsections (c) and (d) above; and
 - f. Respondent will be subject to random inspection by the investigators from the Board.

4. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs;

5. Respondent shall violate no rules and regulations of the Board;

6. If Respondent fails to comply with the terms or conditions of this Consent Order,

Respondent may be subject to additional disciplinary action by the Board.

This the 22^{bn} day of 0 down, 2009.

NORTH CAROLINA BOARD OF PHARMACY

, th By: ambbell, IV Jack W. Executive Director

Cane Creek Pharmacy, Inc. Permit No. 5784, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order. The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter. The undersigned further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action. The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board. The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Consent Order, and represents that it enters this Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel.

The undersigned certifies that its agent executing this Consent Order is duly authorized to accept the Consent Order on behalf of the permit holder and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

CANE CREEK PHARMACY, INC. (Permit No. 5784)

Cane Creek Pharmany, Inc. Date Oct 16, 2009 By: Roge C- Elman & Title: Presiden t

NORTH CAROLINA

Buncombe COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person(s) personally appeared before me this day, and each acknowledged the due execution of the foregoing document: $\underline{Roger C. Floren, T}$

Date: 10/16/09



Cathy J. Merrill Notary Public

My commission expires: $\frac{9/18}{10}$

REJECTED BY:

Date_____ CANE CREEK PHARMACY, INC. (Permit No. 5784)