BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:	)
	)
HEALTH INNOVATIONS PHARMACY, INC.	)
	)
(Permit No. 7705)	)

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 September 12, 2016 and, after appropriate notice, was heard on that day by Board Member J. Andrew Bowman at the office of the Board. Respondent Health Innovations Pharmacy, Inc. (hereinafter "Respondent" or "Pharmacy") was present and represented by its pharmacist-manager, Timothy H. Clark, and by its counsel, Michael C. Allen. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff 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. 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 by its consent. 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 Health Innovations Pharmacy, Inc., located at 295 Pinehurst Avenue, Building 2, Southern Pines, North Carolina, is, and since December 18, 2000, has been, the holder of Permit No. 7705.

COMPOUNDING AND OTHER PHARMACY MANAGEMENT VIOLATIONS

3. On February 11, 2015, the Board's investigators inspected the Pharmacy. On February 23-27, 2015, investigators from the United States Food and Drug Administration ("FDA") performed related inspections of the Pharmacy. The inspections revealed numerous violations of the Pharmacy Practice Act and its regulations with respect to the Pharmacy's compounding practices. These violations are detailed in the Board's Pharmacy Inspection Report, dated February 11, 2015; the Board's Sterile Compounding Pharmacy Inspection Report, also dated February 11, 2015; the FDA's Form 483, dated February 27, 2015; and the FDA Warning Letter, dated July 8, 2016, all of which are incorporated herein by reference.

4. In addition to the compounding violations, the Board's investigators also found other violations, including the fact that the Pharmacy's principal compounding technician had worked at the Pharmacy for a number of years without being registered with the Board. On April 20, 2011, the Board had issued a letter warning the Pharmacy specifically, among other things, about the Pharmacy's prior employment of technicians who were not registered with the Board.

5. The Pharmacy did not dispute the accuracy of any findings in the reports of Board's or the FDA's inspections.

6. As a result of the health and safety concerns, during the Board's February 11, 2015 inspection, the Pharmacy agreed to stop all compounding until the Pharmacy's compounding facilities and practices could come into compliance with Board requirements. Furthermore, on February 22, 2015, the Pharmacy recalled all sterile compounded products that had been dispensed in the previous six months.

7. The Board has received no evidence of any contamination in the Pharmacy's sterile compounded products or injury to any patient. No patient or prescriber has complained to the Board or otherwise reported any issues with any of the Pharmacy's sterile compounded products.

8. The Pharmacy cooperated with both the recall of the sterile compounded drugs and the Board's investigation. Furthermore, the Pharmacy permanently ceased any sterile compounding. And subsequent inspections on March 24, 2015 and June 10, 2015, revealed no violations in its non-sterile compounding practices.

DIVERSION AND OTHER CONTROLLED SUBSTANCES VIOLATIONS

9. Between May 1, 2013 and August 29, 2015, approximately 131,000 dosage units of schedule II and III controlled substances were diverted from the Pharmacy. These controlled substances included about 106,000 dosage units of Oxycodone 15 mg, 20 mg, or 30 mg tablets (a schedule II controlled substance), 20,000 dosage units of hydrocodone/APAP (a schedule II or III controlled substance at various times during this period) in combinations including 7.5 or 10 mg of hydrocodone, 4,400 dosage units of alprazolam in various strengths, 660 dosage units of morphine (a schedule II controlled substance) in various strengths, and 100 dosage units of Adderall 5 mg (a schedule II controlled substance). Some or all of these controlled substances

were diverted by a technician who subsequently was sentenced to five years in the federal penitentiary.

10. During the period when this diversion was occurring, the Pharmacy allowed all of its pharmacists and technicians to access the cabinet where schedule II controlled substances were stored. The Pharmacy further performed no inventory control to prevent diversion, other than the Pharmacy's biennial inventories.

11. On March 24, 2015, during the time that this diversion was occurring, Board investigators performed an inspection of the Pharmacy. During this inspection, the Board investigators determined that, on many occasions, the Pharmacy had dispensed schedule II controlled substances based on prescriptions that did not include the prescribers' DEA number, had changed schedule II controlled substance prescription strengths without approval from the prescribers, and had dispensed schedule II controlled substance prescriptions too early.

12. After the diversion was discovered, the Pharmacy filed reports with the Board and the DEA that did not promptly, fully and accurately report the extent of the losses.

13. The Board has been presented with no evidence that, following the discovery of the diversion on August 25, 2015, there have been any further diversions from the Pharmacy.

14. On May 18, 2016, the Pharmacy entered into a Memorandum of Agreement with the DEA. Among other things, that Memorandum of Agreement prohibits the Pharmacy from dispensing Schedule II controlled substances for a period of three (3) years.

DEVICE AND MEDICAL EQUIPMENT VIOLATIONS

15. On June 10, 2015, the Board's investigators inspected the device and medical equipment ("DME") operations at the Pharmacy. The inspection revealed a number of violations of the Pharmacy Practice Act and its regulations, including failing to keep the DME operations in

clean, orderly and sanitary conditions, and failure to keep a number of records required for DME operations.

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.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes § 90-85.38(b) because Respondent's acts were in violation of North Carolina General Statutes §§ 90-85.15A(a1), (b) and (c), 90-85.25(b), 90-85.28, 90-85.29, 90-85.38(a)(6), (7) and (9) and (b), 90-85.40(b) and (f), 90-106, 90-108, 106-122; 106-133, 106-134, 106-134.1, 106-135, and 106-140.1; 21 N.C.A.C. 46 .1601(a), 46 .1801, 46 .1802, 46 .1804(a) and (c), 46 .1805, 46 .1809, 46 .1810, 46 .2501, 46 .2502(a), (d), (e) and (k), 46 .2601(b), 46 .2604, 46 .2606, 46 .2607, 46 .2611, and 46 .2801; 21 U.S.C. §§ 331, 351, 352, 353, 353a, 355, 827, 829 and 842; 21 C.F.R. §§ 201.17, 201.18, 211.25, 211.28, 211.42, 211.46, 211.48, 211.56, 211.58, 211.63, 211.65, 211.67, 211.80, 211.84, 211.87, 211.100, 211.103, 211.110, 211.113, 211.122, 211.130, 211.134, 211.137, 211.142, 211.150, 211.160, 211.165, 211.166, 211.167, 211.170, 211.180, 211.182, 211,184, 211.186, 211.188, 211.192, 211.194, 211.196, 1301.71, 1301.76, 1304.21, 1306.05, 1306.12 and 1306.22.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The permit of Respondent HEALTH INNOVATIONS PHARMACY, INC. (Permit No. 7705) is hereby PERMANENTLY SUSPENDED. That suspension shall be STAYED INDEFINITELY, under the following conditions:

a. Respondent Health Innovations Pharmacy, Inc. shall comply with all of the terms of the Memorandum of Agreement with the United States Department of Justice, Drug Enforcement Administration ("DEA"), dated May 18, 2016 (the "MOA"). The MOA is hereby incorporated by reference in this Consent Order. Furthermore, by virtue of this Consent Order, all of the Terms and Conditions in the MOA shall survive the termination of the MOA and shall continue indefinitely. No sooner than May 18, 2019 (unless the MOA is earlier terminated by the DEA), Health Innovations Pharmacy, Inc. may petition the Board to have some or all of those Terms and Conditions lifted. The Board is not obligated to lift any of those Terms and Conditions in the MOA, and will do so only if Health Innovations Pharmacy, Inc. demonstrates that lifting any Term or Condition would be consistent with the public health, safety and welfare.

b. Respondent Health Innovations Pharmacy, Inc. shall not engage in any sterile compounding and shall not dispense any sterile compounded products.

c. Respondent Health Innovations Pharmacy, Inc. shall violate no laws governing the practice of pharmacy or the distribution of drugs, medical devices or medical equipment; and

d. Respondent Health Innovations Pharmacy, Inc. shall violate no rules or regulations of the Board.

2. Respondent Health Innovations Pharmacy, Inc. shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation regarding compliance with the provisions of this Consent Order.

4. If Respondent Health Innovations Pharmacy, Inc. fails to comply with any terms or conditions of this Order, the period of stay described above shall be lifted and the Board shall activate the permanent suspension of its permit.

This the 13th day of October, 2016.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

Health Innovations Pharmacy, Inc., the holder of permit number 7705, 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 Health Innovations Pharmacy, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

HEALTH INNOVATIONS PHARMACY, INC.
(Permit No. 7705)

Timothy H Clark Date 10-14-16

By: Timothy H. Clark

Title: President

STATE OF NC

Moore COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day and acknowledged the due execution of the foregoing document: Timothy H. Clark.

Date: 10-14-16

Misty Bruce
Notary Public

MISTY BRUCE
NOTARY PUBLIC
Moore County
North Carolina
My Commission Expires February 8, 2017

My commission expires: 2-8-17

REJECTED BY:

HEALTH INNOVATIONS PHARMACY, INC.
(Permit No. 7705)

_____ Date_____

By: Timothy H. Clark

Title: President