IN THE MATTER OF

CO-OP PHARMACY

* BEFORE THE

MARYLAND BOARD

BOARD BOARD Pharm

Respondent-Pharmacy

* OF PHARMACY

PERMIT No: P01086

Case No.: PI-13-071/13-471

CONSENT ORDER

On March 20, 2013, the State Board of Pharmacy (the "Board") charged **CO-OP PHARMACY** ("the Respondent-Pharmacy"), Permit No.: P01086, the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl. Vol. and 2012 Supp.). The Board issued Amended Charges on May 18, 2012.

Specifically, the Board charged the Respondent-Pharmacy with the following provisions of the Act under H. O. § 14-404:

H.O. §12-403 Required Standards.

- (b) *In general.* Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
 - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board; [and]
 - (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under 12-313 or a registered pharmacy technician under 12-6B-09 of this title[.]

The pertinent provisions of Code Md. Regs ("COMAR"), tit. 10, § 34.10 provide as follows:

.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

- (a) United States Code, Title 21,
- (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
- (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
- (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and
- (e) COMAR 10.19.03:

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist[.]

COMAR 10.19.03.07C:

Purpose of Issue of Prescription

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501 - 5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of the law relating to controlled dangerous substances.

COMAR 10.19.03.09A:

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription

signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

On May 22, 2013, the Respondent-Pharmacy appeared before members of the Board and the Board's counsel for a Case Resolution Conference (CRC) to discuss the potential resolution of the Charges by consent. At the conclusion of the CRC, the Respondent-Pharmacy agreed to enter into this Consent Order to resolve the pending charges and to avoid the expense and time of proceeding to an administrative hearing. The Respondent-Pharmacy and the Board agreed to the inclusion of Findings of Fact and Conclusions of Law as required by the Board, and with the terms and conditions set forth herein.

FINDINGS OF FACT

- 1. The Respondent-Pharmacy is licensed to operate a retail pharmacy in the State of Maryland under permit number P01086. The Respondent-Pharmacy was first licensed on June 6, 1984. The Respondent-Pharmacy's permit is currently active and will expire on December 31, 2013.
- 2. At all times relevant, the Respondent-Pharmacy was operating a retail pharmacy at 121 Centerway, Greenbelt, Maryland 20770.
- 3. On or about November 8, 2012, the Board conducted an annual inspection of the Respondent-Pharmacy which revealed that the Respondent-Pharmacy filled a large number of prescriptions for controlled dangerous substances ("CDS") for out-of-state patients.

- 4. During the inspection, the Board's inspector observed 24 prescriptions dated November 2, 2012 through November 7, 2012 for out-of-state patients from Physician A in Gaithersburg, Maryland.¹ The patients were from Ohio, Kentucky, Florida and West Virginia. All of the prescriptions were for CDS.
- 5. The Board's inspector reviewed CDS schedule II prescription numbers 12100 through 12199 and noted the following:
 - a. Twenty-four of the prescriptions were written by Physician A for patients in states other than Maryland (Ohio, Kentucky, Florida and West Virginia);
 - b. Prescription numbers 12113 (oxycodone 15 mg #120) and 12114 (oxycodone² 30 mg #210) were for the same patient in Ohio. The patient paid \$420 for the oxycodone 30 mg and a \$10 co-pay for the oxycodone 15 mg;
 - c. Prescription numbers 12118 (methadone³ 10 mg #180), 12119 (oxycodone 15 mg #120) and 12120 (oxycodone 30 mg #210) were for the same patient in Kentucky. The total cost to the patient was \$576;
 - d. The Board's inspector observed that Physician A prescribed Alprazolam⁴ 2 mg for most patients, in addition to the narcotics.

¹ On or about November 15, 2012, the Maryland Board of Physicians summarily suspended Physician A's license to practice medicine after it determined that his prescribing practices constituted a substantial likelihood of a risk of serious harm to the public health, safety and welfare. Physician A also permanently relinquished his license to practice medicine in Florida for while he was under investigation for inappropriate prescribing practices.

² Oxycodone is an opioid analgesic and a schedule II CDS.

³ Methadone is an opioid analgesic and a schedule II CDS.

⁴ Alprazolam (brand name: Xanax) is an benzodiazepine and a schedule IV CDS.

- 6. The Board's inspector also reviewed prescription numbers 385322 and 385323, which were from Physician B of Miami, Florida. Both prescriptions were for Xanax 2 mg and for different patients in Ohio.
- 7. Prescriptions numbers 12898 (oxycodone 15 mg #180) and 12899 (oxycodone 30 mg #180) were also prescribed by Physician B for the same patient in Ohio and were paid for in cash (\$180 and \$360, respectively).
- 8. Prescription numbers 12116 (oxycodone 30 mg # 210) and 12117 (oxycodone 15 mg #120) were prescribed by Physician A for the same patient in Ohio and were paid for in cash (\$420 and \$120, respectively).
- 9. The Board's inspector learned that two patients travel from Ohio to the Respondent-Pharmacy each month on the same day. They fill prescriptions for alprazolam 2 mg, oxycodone 30 mg and oxycodone 15 mg.
- 10. On the Community Pharmacy Inspection Report dated November 8, 2012, the pharmacist ("Pharmacist A") who assisted with the inspection stated that the Respondent-Pharmacy does not fill original prescriptions received via the Internet and does not fill mail order prescriptions.
- 11. On or about February 1, 2013, the Board conducted a follow-up inspection of the Respondent-Pharmacy. The Board Inspector obtained a dispensing report for prescriptions from Physician A for 2012, which revealed the following:
 - a. The Respondent-Pharmacy filled 1179 prescriptions from Physician A between May 17, 2012 and November 15, 2012;

- b. Of the 1179 prescriptions, 58 were for patients with a Maryland address, while the remaining 1121 prescriptions were for patients with addresses in Kentucky, Florida, West Virginia and Ohio;
- c. Of the 1179 prescriptions, 100 were for non-controlled drugs, while the remaining 1079 prescriptions were for CDS such as oxycodone 30 mg, oxycodone 15mg and Alprazolam 2mg;
- d. Pharmacist A at the Respondent-Pharmacy informed the Board's inspector that some patients presented with pain management contracts from Physician A.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated the following provisions of the Act:

H.O. §12-403 Required Standards.

- (b) *In general.* Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
 - (2) Shall be operated in compliance with the law and with the rules and regulations of the Board; [and]
 - (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under 12-313 or a registered pharmacy technician under 12-6B-09 of this title[.]

The pertinent provisions of Code Md. Regs ("COMAR"), tit. 10, § 34.10 provide as follows:

.01 Patient Safety and Welfare.

A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
 - (f) United States Code, Title 21,
 - (g) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
 - (h) Health Occupations Article, Title 12, Annotated Code of Maryland,
 - (i) Criminal Law Article, Title 5, Annotated Code of Maryland, and
 - (j) COMAR 10.19.03;

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist[.]

COMAR 10.19.03.07C:

Purpose of Issue of Prescription

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501 - 5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of the law relating to controlled dangerous substances.

COMAR 10.19.03.09A:

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

<u>ORDER</u>

ORDERED that the Respondent-Pharmacy's license to operate a pharmacy in the State of Maryland is hereby REPRIMANDED; and it is further

ORDERED that within ninety (90) days the Respondent-Pharmacy shall pay a monetary fine in the amount of **\$8,000** to the Maryland Board of Pharmacy; and it is further

ORDERED that the Respondent-Pharmacy's license to operate a pharmacy in the State of Maryland shall be placed on PROBATION for a period of one (1) year, subject to the following terms and conditions:

- 1. Within thirty (30) days of the date of the Consent Order, the Respondent-Pharmacy shall provide training to all pharmacy staff members regarding valid prescriber-patient relationships and verifying fraudulent prescriptions. The Respondent-Pharmacy shall provide written documentation indicating the successful completion of this training; and
- 2. Within six (6) months after the pharmacy staff members are trained regarding valid prescriber-patient relationships and verifying fraudulent prescriptions, the Board shall conduct an inspection of the Respondent-Pharmacy; and it is further

ORDERED that the Respondent-Pharmacy shall bear all expenses associated with this Order; and it is further

ORDERED that the Respondent-Pharmacy shall at all times cooperate with the Board's monitoring, supervision, and investigation of the Respondent-Pharmacy's compliance with the terms and conditions of this Consent Order; and it is further

ORDERED that after one (1) year from the date of this Consent Order, the Respondent-Pharmacy may submit a written petition to the Board requesting termination of probation. After consideration of the petition, the probation may be terminated, through an order of the Board. The Board shall grant the termination if the Respondent-Pharmacy has fully and satisfactorily complied with all of the probationary terms and conditions and there are no pending complaints related to the charges; and it is further

ORDERED that if the Respondent-Pharmacy violates any of the terms and conditions of Probation and this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board may impose any appropriate sanction under the Act, including an additional probationary term with conditions of probation, reprimand, suspension, revocation and/or a monetary penalty; and it is further

ORDERED that the Respondent-Pharmacy shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for purposes of

public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 et seq.

and COMAR 10.34.01.12.

June 19,2013

Date

Michael N. Souranis, President

State Board of Pharmacy

CONSENT

I, Robert Davis of Co-Op Pharmacy, acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent and for purposes of settlement of Case Number PI-13-071/13-471I accept on behalf of the said Pharmacy to be bound by this Consent Order and its conditions and restrictions. On its behalf I waive any rights it may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which Co-Op Pharmacy would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving Co-Op Pharmacy's right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the language, meaning and

terms of this Consent Order.	I voluntarily sign this Order on behalf of Co-Op Pharamcy,
and understand its meaning ar	nd effect.
6-14-13	Plat Paris

Date

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Robert Davis, General Manager

Co-Op Pharmacy, Respondent-Pharmacy

Reviewed and approved as to form by:	
Robert N. Levin, Esq., Attorney for Co-Op Pharmacy	

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF PRINCE GEORGE'S:

HEREBY CERTIFY that on this // day of _______, 2013 before me, a Notary Public of the foregoing State personally appeared Robert Davis, General Manager of Co-Op Pharmacy, Permit Number P01086, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

Notary Public

My Commission Expires:____

FREDERICK COUNTY
MARYLAND
MY COMMISSION EXPIRES 6-26-201

JOHN MITHELW