IN THE MATTER OF	*	**BEFORE THE**
Tidewater Drug and Health Care	*	**MARYLAND BOARD**
Permit No: P08181	*	**OF PHARMACY**
Respondent	*	**Case No.: 22-051**

* * * * * * * * * * * * *

CONSENT ORDER

On June 15, 2022, the Maryland Board of Pharmacy (the "Board") hereby charges **Tidewater Drug and Health Care** (the "Respondent-Pharmacy"), Permit Number **P08181**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021).

The Board charged the Respondent-Pharmacy with violating the following provisions of the Act:

§ 12-403. Required standards.

. . . .

(c) *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;

. . . .

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title, a registered pharmacy technician under § 12-6B-09 of this title, or a registered pharmacy intern under § 12-6D-11 of this title[.]

§ 12-313. Denials, reprimands, suspensions, and revocations —Grounds

. . . .

(b) *In general* — Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may . . . reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:

. . . .

(2) Fraudulently or deceptively uses a license;

. . . .

(25) Violates any rule or regulation adopted by the Board[.]

The Board also charged the Respondent-Pharmacy with violating the following COMAR provisions:

COMAR 10.34.10.01. 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;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error[.]

. . . .

B. A pharmacist may not:

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

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

COMAR 10.19.03.07. Prescriptions.

. . . .

C. Purpose of Issue of Prescription (21 CFR §1306.04).

(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 violations of the provisions of law relating to controlled dangerous substances.

On December 14, 2022, the Respondent-Pharmacy, along with their attorney, Jamaal Stafford, Esquire, and Kelly Cooper, Administrative Prosecutor, attended a Case Resolution Conference ("CRC") with members of the Board in an effort to resolve the pending charges in lieu of an evidentiary hearing. As a result of the CRC, the Respondent-Pharmacy and the State agreed to enter into this Consent Order consisting of Findings of

Fact, Conclusions of Law, and Order.

I. FINDINGS OF FACT

The Board finds:

1. At all times relevant hereto, the Respondent-Pharmacy had a permit to operate as a pharmacy in the State of Maryland. The Respondent-Pharmacy was originally issued a permit on or about March 19, 2020. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. The Respondent-Pharmacy is owned by two pharmacists ("Respondent #1" and "Respondent #2").

3. At all times relevant hereto, Respondent #1 was licensed to practice pharmacy in the State of Maryland. Respondent #1 was originally licensed to practice pharmacy in Maryland on or about July 2, 2007. Respondent #1's license expires on October 31, 2022.

4. At all times relevant hereto, Respondent #2 was licensed to practice pharmacy in the State of Maryland. Respondent #2 was originally licensed to practice pharmacy in Maryland on or about February 21, 1990. Respondent #2's license expires on March 31, 2023.

5. On March 22, 2021, the Office of Controlled Substances Administration ("OCSA") conducted a regulatory inspection of the Respondent-Pharmacy. The inspection revealed the following:

a. A large number of prescriptions for buprenorphine[1] 8mg, all of which were filled for self-pay and were for patients from West Virginia. Many of the patients came in groups from the same towns in West Virginia. Most of the prescriptions were prescribed by one physician ("Physician"). The prescriptions were sent via E-scribe or fax. All of the prescriptions sent via fax were accompanied by an additional sheet by the Physician stating that the patient could not receive the combination buprenorphine/naloxone because of the reaction to naloxone.

6. On June 17, 2021, OCSA conducted a red flag inspection of the Respondent-Pharmacy. As part of the inspection, three packs of Schedule III through Schedule V Controlled Dangerous Substances were reviewed, which revealed that 33.2% of the prescriptions across all three packs contained red flags, but a review of just the third pack of CDS, which was the only pack to contain CDS filled after the last OCSA regulatory inspection, revealed the percentage of red flags decreased to 15.2% of prescriptions.

[1] Buprenorphine is a partial opioid agonist used to treat opiate addiction. It is a Schedule III CDS.

7. On August 3, 2021, the Board's Inspector conducted an annual inspection of the Respondent-Pharmacy. The inspection revealed the following:

a. Multiple items in the over-the-counter section outside of the pharmacy area with "Rx Only" signage or products with "Caution: Federal Law restricts this device to sale by or on the order of a physician" listed on the products. The Board Inspector brought these products to the attention of the pharmacist on duty at the time (the "Pharmacist"), and the Pharmacist immediately removed all of the products from the over-the-counter area.

b. Five (5) prescriptions were discovered with high strength and/or high quantity.

c. Two (2) prescriptions were filled for cash.

d. For one (1) prescription the patient's address on the prescription did not match the back tag.

e. Three (3) prescriptions were from physicians located in the District of Columbia approximately 40 miles from the Respondent-Pharmacy.

f. One (1) prescription is from a physician located in Virginia approximately 38 miles from the Respondent-Pharmacy.

g. One (1) telephone prescription did not have a date of issuance present on the prescription.

II. CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provisions of the Act:

§ 12-403. Required standards.

. . . .

(c) *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;

. . . .

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title, a registered pharmacy technician under § 12-6B-09 of this title, or a registered pharmacy intern under § 12-6D-11 of this title[.]

§ 12-313. Denials, reprimands, suspensions, and revocations —Grounds

. . . .

(b) *In general* — Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may . . . reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:

. . . .

(2) Fraudulently or deceptively uses a license;

. . . .

(25) Violates any rule or regulation adopted by the Board[.]

The Board also concludes that the Respondent-Pharmacy violated the following COMAR provisions:

COMAR 10.34.10.01. 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;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error[.]

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B. A pharmacist may not:

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

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

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C. Purpose of Issue of Prescription (21 CFR §1306.04).

(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 violations of the provisions of law relating to controlled dangerous substances.

III. ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 17th day of January, 2023, by the affirmative vote of a majority of the members of the Board then serving:

ORDERED that the Respondent-Pharmacy's permit to practice pharmacy in the State of Maryland is **REPRIMANDED**; and it is further

ORDERED that the Respondent-Pharmacy's permit shall be placed on **Probation** for a period of at least **ONE (1) YEAR**, subject to the following terms and conditions:

1. During the probationary period, the Board, at its discretion, may conduct random inspections of the Respondent-Pharmacy;

2. During the probationary period, the Board, shall obtain quarterly reports from the prescription drug monitoring program (PDMP) for the Respondent-Pharmacy;

3. Within thirty (30) days of the effective date of the Consent Order the Respondent-Pharmacy shall submit the name of a Board-approved

consultant to the Board for review of the Respondent-Pharmacy's updated Controlled Dangerous Substance dispensing policy and procedures with a focus on buprenorphine products. Within ninety (90) days of the effective date of the Consent Order the Respondent-Pharmacy shall submit the finalized Controlled Dangerous Substance dispensing policy and procedures with a focus on buprenorphine products to the Board for approval. Within one hundred and twenty (120) days of the effective date of the Consent Order the Respondent-Pharmacy shall retrain all staff on the revised policies and procedures and submit written documentation indicating the successful completion of the retraining to the Board;

4. 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, provided that it has been fully compliant with this Consent Order and has no outstanding complaints filed against it;

ORDERED that the Respondent-Pharmacy shall pay a monetary **fine in the amount of THREE THOUSAND ($3,000) DOLLARS** within the probationary period of the Consent Order, payable by certified check or money order to The Maryland State Board of Pharmacy and sent to:

Wells Fargo Bank
Attn: State of MD – Board of Pharmacy
Lockbox 2051
401 Market Street,
Philadelphia, PA 19106

Please reference Case Number 22-051 on your check or money order to ensure proper assignment to your case; and it is further

ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and it is further

ORDERED that the Respondent-Pharmacy shall bear the cost(s) of complying with the Consent Order; and it is further

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

ORDERED that failure to comply with the terms and conditions of the Consent Order, including failure to pay the monetary fine in full by the deadline, constitutes a violation of the Consent Order and 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; and it is further

ORDERED that the Consent Order shall be a public document pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq*. (2019).

1-17-23
Date

Deena Speights-Napata, M.A.
Executive Director, for
Jennifer L. Hardesty, President
State Board of Pharmacy

CONSENT

I, Joseph W. Penzenstadler and Mark Barbino, owners of Tidewater Drug and Health Care, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of Tidewater Drug and Health Care, to be bound by this Consent Order and its conditions and restrictions. On its

behalf, I waive any rights Tidewater Drug and Health Care. 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 Tidewater Drug and Health Care would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its 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 Tidewater Drug and Health Care's right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order 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 Tidewater Drug and Health Care and understand its meaning and effect.

1/11/2023
Date

Joseph W. Penzenstadler, Owner
Tidewater Drug and Health Care

1/11/2023
Date

Mark Barbino, Owner
Tidewater Drug and Health Care

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Charles

I hereby certify that on this 11 day of January, 2023, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared Charles **Joseph W. Penzenstadler and Mark Barbino**, and made an oath in due form that the foregoing Consent was their voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Notary Public

My Commission Expires: Oct 23, 2024

BNYONKA BROWN
Notary Public-Maryland
Charles County
My Commission Expires
October 23, 2024