IN THE MATTER OF	*	**BEFORE THE**
Accokeek Drug and Health Care Inc.	*	**MARYLAND BOARD**
Permit No: P02491	*	**OF PHARMACY**
Respondent	*	**Case No.: 20-172 & 20-287**

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

CONSENT ORDER

On June 15, 2022, the Maryland Board of Pharmacy (the "Board") charged **Accokeek Drug and Health Care Inc.** (the "Respondent-Pharmacy"), Permit Number **P02491**, 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 June 15, 2000. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. The Respondent-Pharmacy is owned by a pharmacist ("Respondent #2").

3. At all times relevant hereto, Respondent #1 was the pharmacist in charge at the Respondent-Pharmacy. 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, 2018, Board Inspector #1 conducted an annual inspection of the Respondent-Pharmacy. The inspection revealed that the Respondent-Pharmacy did not have hot running water at the time of the inspection and there was a discrepancy involving one tablet of Hydrocodone/APAP 5/325 mg for the perpetual inventory.

6. On April 16, 2019, Board Inspector #2 conducted an annual inspection of the Respondent-Pharmacy. The inspection revealed multiple prescriptions for buprenorphine[1] were filled for West Virginia residents and paid for with cash.

7. On December 10, 2019, Board Inspector #3 conducted an annual inspection of the Respondent-Pharmacy. The inspection revealed the following:

a. The generic manufacturer's name did not print on the sample label given during the inspection.

b. Discrepancies were noted in the perpetual inventory system for Oxycodone/APA 10/325 mg and Methylphenidate 10 mg.

c. Schedule II CDS were not separated from Schedule III-V CDS in the biennial inventory.

d. There were items in the over-the-counter section outside of the pharmacy area with "Rx Only" listed on the products. The items included Tracheostomy Clean and Care Trays, Catheter Stabilization Devices, and Urethral PVC Catheters.

e. The review of Schedule II CDS revealed for four prescriptions the patient's address on the hard copy did not match the pharmacy's label; two prescriptions were from out of state prescribers in Virginia; one prescription had an address on the hard copy that did not match the prescriber's address on the

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

pharmacy's label; and for one prescription the patient's and the prescriber's address on the hard copy did not match the addresses on the pharmacy's label.

f. The review of Schedule III-V CDS revealed eleven prescriptions were for "out of state patient and prescriber (WV) for Buprenorphine, billed to cash" and one prescription was from an out-of-state prescriber in Virginia.

8. On December 18, 2019, the Board issued a Subpoena Duces Tecum to the Respondent-Pharmacy for a "copy of any and all dispensing reports for Buprenorphine for the time period of January 1, 2019, to date." According to the dispensing report received from the Respondent-Pharmacy, from January 2, 2019, to December 24, 2019, the Respondent-Pharmacy filled:

a. 2,078 prescriptions for buprenorphine

b. 203 prescriptions for suboxone[2]

c. 156 prescriptions for zubsolv[3]

d. only 680 prescriptions were for Maryland residents

[2] Suboxone contains a combination of buprenorphine and naloxone, it is a partial opioid agonist used to treat opiate addiction. It is a schedule III CDS.

[3] Zubsolv contains a combination of buprenorphine and naloxone. Zubsolv is a Schedule III CDS used to treat opioid addiction.

e. 1757 prescriptions were for non-Maryland residents (Alabama, Florida, Kentucky, North Carolina, Ohio, South Carolina, Virginia, and West Virginia)

f. Of the 1757 prescriptions for non-Maryland residents, 1731 of those prescriptions were paid for in cash

9. On March 13, 2020, the Office of Controlled Substances Administration ("OCSA") conducted a regulatory inspection of the Respondent-Pharmacy. The inspection revealed the following:

a. Approximately 100 schedule III-V prescriptions from February 4, 2020 to February 11, 2020, were examined. Around 35% of the Schedule III-V prescriptions were for buprenorphine 8 mg and were dispensed to West Virginia patients for cash.

b. The pharmacy manager on duty as well as the owner was educated on how filling prescriptions in this manner will be viewed as red flags.

10. On April 20, 2020, the Board received a Prescription Drug Monitoring Program (PDMP) report for the Respondent-Pharmacy and forwarded it to OCSA for

review. After conducting a review of the PDMP report, OCSA made the following observations:

a. 2,674 of all 11,586 CDS prescriptions (23%) filled at the Respondent-Pharmacy were for a buprenorphine-containing product.

b. 1,957 (73%) of those buprenorphine-containing products were for residents of West Virginia.

c. Every prescription for a West Virginia resident was for buprenorphine 8mg tablets.

d. 98% of the West Virginia prescriptions were self-pay by the customer.

e. Members of the same household or family obtained prescriptions from the same group of providers and got their prescriptions filled at the Respondent-Pharmacy.

11. The Board's compliance unit analyzed 2,381 hardcopy prescriptions of buprenorphine from January 1, 2019 to March 31, 2020, and discovered that a majority of the prescriptions were for West Virginia patients paying with cash. Specifically, more than 80% of the prescriptions for buprenorphine were for West Virginia patients.

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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COMAR 10.19.03.07. Prescriptions.

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

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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 shall be **SUSPENDED** for a period of **TWO (2) YEARS**, with all two (2) years **STAYED**, subject to the following terms and conditions:

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

2. During the stayed suspension 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 **TWO (2) YEARS** from the date of this Consent Order, the Respondent-Pharmacy may submit a written petition to the Board requesting termination of the stayed suspension, 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 TEN THOUSAND ($10,000) 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 Numbers 20-172 and 20-287 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, owner of Accokeek Drug and Health Care Inc., acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of Accokeek Drug and Health Care

Inc., to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Accokeek Drug and Health Care Inc. 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 Accokeek Drug and Health Care Inc. 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 Accokeek Drug and Health Care Inc.'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 Accokeek Drug and Health Care Inc. and understand its meaning and effect.

1/11/2023
Date

Joseph W. Penzenstadler, Owner
Accokeek Drug and Health Care Inc.

NOTARY

STATE OF Mayland

COUNTY/CITY OF: Charles

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