IN THE MATTER OF	*	**BEFORE THE**
MARK A. BARBINO, R.PH	*	**MARYLAND BOARD**
License No: 18402	*	**OF PHARMACY**
Respondent	*	**Case Nos.: 20-172, 20-287, & 22-051**

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

CONSENT ORDER

On June 15, 2022, the Maryland Board of Pharmacy ("the Board") hereby charges **MARK A. BARBINO, R.PH** ("the Respondent"), License No.: **18402**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021 Repl. Vol.).

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

> **§ 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 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, along with his 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 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 was licensed to practice pharmacy in the State of Maryland. The Respondent was originally licensed to practice pharmacy in Maryland on or about July 2, 2007. The Respondent's license expires on October 31, 2022.

2. At all times relevant hereto, the Respondent has owned a pharmacy in Maryland ("Respondent-Pharmacy #1") and has also been the pharmacist-in-charge at another pharmacy in Maryland ("Respondent-Pharmacy #2").

Disciplinary History

3. On November 17, 2010, the Respondent surrendered his Maryland pharmacy license. As part of the surrender the Respondent admitted that if the Board had issued charges against the Respondent the Board could find by a preponderance of the evidence that he violated the Maryland Pharmacy Act by "falsifying prescriptions for controlled dangerous substances, specifically Oxycodone, from approximately November 2008 through July 2009;" "in return for filling false prescriptions presented by others, I would receive a certain number of the pills for my own use;" and the Respondent "pled guilty to three misdemeanors: (a) conspiracy to commit grand theft, (b) conspiracy to distribute Oxycodone, and (c) obtaining controlled dangerous substances by fraud."

4. On September 17, 2012, the Board executed a Consent Order of Reinstatement, which reinstated the Respondent's license and placed it on probation for a minimum of five (5) years subject to conditions.[1]

5. On April 19, 2017, the Board issued an Order Terminating Probation, which terminated the probationary terms and conditions.

[1] On November 25, 2013, the Board issued an Order of Modification, which modified the terms of the Respondent's probation.

Respondent-Pharmacy #1

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

7. Respondent-Pharmacy #1 is co-owned by the Respondent and another pharmacist ("Respondent #2").

8. On March 22, 2021, the Office of Controlled Substances Administration ("OCSA") conducted a regulatory inspection of Respondent-Pharmacy #1. The inspection revealed the following:

a. A large number of prescriptions for buprenorphine 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.

9. On June 17, 2021, OCSA conducted a red flag inspection of Respondent-Pharmacy #1. 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.

10. On August 3, 2021, the Board's Inspector conducted an annual inspection of Respondent-Pharmacy #1. 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 Respondent-Pharmacy #1.

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

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

Respondent-Pharmacy #2

11. At all times relevant hereto, Respondent-Pharmacy #2 had a permit to operate as a pharmacy in the State of Maryland. Respondent-Pharmacy #2 was originally issued a permit on or about June 15, 2000. Respondent-Pharmacy #2's permit expires on May 31, 2024.

12. At all times relevant hereto, the Respondent has been the pharmacist-in-charge at Respondent-Pharmacy #2.

13. Respondent-Pharmacy #2 is owned by Respondent #2.

14. On March 22, 2018, Board Inspector #1 conducted an annual inspection of Respondent-Pharmacy #2. The inspection revealed that Respondent-Pharmacy #2 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.

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

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

16. On December 10, 2019, Board Inspector #3 conducted an annual inspection of Respondent-Pharmacy #2. 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 (4) prescriptions the patient's address on the hard copy did not match the pharmacy's label; two (2) prescriptions were from out of state prescribers in Virginia; one (1) prescription had an address on the hard copy that did not match the prescriber's address on the pharmacy's label; and for one (1) 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 (11) 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.

17. On December 18, 2019, the Board issued a Subpoena Duces Tecum to Respondent-Pharmacy #2 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 Respondent-Pharmacy #2, from January 2, 2019 to December 24, 2019, Respondent-Pharmacy #2 filled:

a. 2,078 prescriptions for buprenorphine

b. 203 prescriptions for suboxone[3]

c. 156 prescriptions for zubsolv[4]

d. only 680 prescriptions were for Maryland residents

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

[3] 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.

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

18. On March 13, 2020, OCSA conducted a regulatory inspection of Respondent-Pharmacy #2. 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.

19. On April 20, 2020, the Board received a Prescription Drug Monitoring Program (PDMP) report for Respondent-Pharmacy #2 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 Respondent-Pharmacy #2 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 for 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.

20. 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:

§ 12-313. 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 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[.]

. . . .

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's license shall be placed on **Probation** for a period of at least **TWO (2) YEARS**, subject to the following terms and conditions:

1. Within the first twelve (12) months of the probationary period, the Respondent shall successfully complete twelve (12) Board-approved continuing education credits – six (6) credits in medication assisted therapy and six (6) credits in red flags and the corresponding responsibility for pharmacists. This requirement is in addition to the continuing education credits necessary for license renewal;

2. Within thirty (30) days of the effective date of the Consent Order, the Respondent submit to the Board for review and approval the name and curriculum vitae of a pharmacist mentor for review and consultation on Controlled Dangerous Substances dispensing;

3. The Respondent shall meet in person quarterly with the Board-approved pharmacist mentor;

4. During the period of probation, the Respondent's Board-approved pharmacist mentor shall provide the Board with quarterly reports addressing the Respondent's practice;

5. After **TWO (2) YEARS** from the date of this Consent Order, the Respondent may submit a written petition to the Board requesting termination of probation, provided that he has been fully compliant with this Consent Order and has no outstanding complaints filed against him; and it is further

ORDERED that the Respondent 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 Numbers 20-172, 20-287, and 22-051 on the check or money order in order to ensure proper assignment to your case; and it is further

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

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

ORDERED that the Respondent shall at all times cooperate with the Board in the monitoring, supervision, and investigation of his 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, Mark Barbino, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, to be bound by this Consent Order and its conditions and restrictions. I waive any rights I 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 I 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 my 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 and understand its meaning and effect.

1/11/2023
Date

Mark Barbino, ~~R.Ph.~~, 18402

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 **Mark Barbino**, 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