IN THE MATTER OF	*	**BEFORE THE**
FAITH PHARMACY LLC	*	**MARYLAND BOARD**
PERMIT No: P06678	*	**OF PHARMACY**
Respondent	*	**Case No.: 20-134**

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

CONSENT ORDER

On February 15, 2023, the Maryland Board of Pharmacy ("the Board") charged **FAITH PHARMACY LLC** ("the Respondent-Pharmacy"), Permit No.: **P06678**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021 Repl. Vol.). The pertinent provisions of the Act provide as follows:

§ 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 [and]

. . . .

(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[.]

§ 12-409. Suspensions and revocations -- Grounds

(a) *In general.* – Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(1) Is conducted so as to endanger the public health or safety;

(2) Violates any of the standards specified in § 12-403 of this subtitle; or

(3) Otherwise is not conducted in accordance with the law.

§ 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:

. . . .

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

The pertinent provisions of COMAR provide as follows:

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.

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 10.34.10.08 Refusing to Dispense a Controlled Substance.

A. If, based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe, or should have reason to believe, that a prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist may not dispense the controlled dangerous substance until the pharmacist:

(1) Consults with the prescriber; and

(2) Verifies the medical legitimacy of the prescription.

COMAR 10.34.20.02. Requirements for Prescription Validity.

A. A valid prescription shall be:

(1) Valid in the professional judgment of the pharmacist responsible for filling the prescription[.]

COMAR 10.34.20.04. Controlled Dangerous Substances.

Transmission and dispensing of controlled dangerous substances shall be in accordance with applicable State and federal statutes and regulations.

On May 10, 2023, the Respondent-Pharmacy 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 agreed to enter into this Consent Order consisting of Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

The Board finds that:

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 December 16, 2014, under permit number P06678. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. A pharmacist licensed in the State of Maryland (the "Pharmacist-Manager")[1] is the Respondent-Pharmacy's owner.

3. By letter dated September 12, 2019, the Board notified the Respondent-Pharmacy that it was not compliant with laws related to medical inventory[2] and imposed a civil monetary penalty of $3,000. Among other things, the Board advised the Respondent-Pharmacy that the Board may perform a follow-up inspection.

4. On October 22, 2019, an inspector for the Board (the "Board Inspector") conducted an annual inspection of the Respondent-Pharmacy.[3] During the inspection, the Board Inspector noted concerns including, but not limited to, multiple red flags during the review of the controlled dangerous substance ("CDS") prescriptions.

5. On February 23, 2022, the Board issued a subpoena to the prescription drug monitoring program ("PDMP") requesting dispensing information for all CDS dispensed by the Respondent-Pharmacy for the time period of August 1, 2019 to February 5, 2022. The PDMP provided the Board a report (the "PDMP Report").

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[1] For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document. Upon written request, the Administrative Prosecutor will provide the information to the Respondent-Pharmacy.

[2] Specifically, the Board found the Respondent-Pharmacy in violation of §12-403(c)(1), §12-403(c)(12), COMAR 10.34.05.02(C)(2)(5) and 10.34.12.

[3] The inspection was conducted pursuant to § 12-413 which permits the Board or agents of the Board to enter any permit holder's pharmacy and inspect for compliance with federal and State laws and regulations.

6. On March 21, 2022, the Board issued a subpoena to PDMP/CRISP[4] requesting the audit log of the CDS dispensed by the Respondent-Pharmacy for the time period of August 1, 2019 to August 31, 2020 (the "Audit Log").

7. On May 9, 2022, the Board issued a subpoena to the Respondent-Pharmacy for complete copies of any, and all, Schedule II – Schedule V CDS dispensed/filled by the Respondent-Pharmacy for the time period of August 1, 2019 to August 31, 2020.

8. A review of the Audit Log revealed that out of 611 immediate-release opioid prescriptions (the "IR Opioid Prescriptions") reported on the PDMP, only 1% of the prescriptions show up on the audit log which indicates the Respondent-Pharmacy rarely checks PDMP/CRISP prior to dispensing the IR Opioid Prescriptions with red flags.

9. In furtherance of its investigation, the Board submitted the PDMP report, Audit Log, and hard copy prescriptions to the Office of Controlled Substances Administration Clinical Pharmacist Inspector ("OCSA Inspector") for review.

10. In a report provided to the Board and dated July 12, 2022, the OCSA Inspector noted the following:

a. The Respondent-Pharmacy reported a total of 5,290 CDS prescriptions to PDMP from August 1, 2019 to February 5, 2022.

b. Of the 5,290 CDS prescriptions dispensed, 1,131 (21%) were for immediate-release oxycodone in strengths of either 10mg, 15mg, 20mg or 30mg. Most

[4] CRISP is the State designated health information exchange for Maryland which facilitates the electronic transfer of clinical information, including patient prescribing history, between health information systems in the region.

of the 1,131 oxycodone prescriptions had a daily dosage that met or exceeded 90 morphine milligram equivalents ("MME").[5]

c. Most patients who received these high dose immediate-release oxycodone prescriptions did not receive any long-acting opioids as part of their regimen.

d. The Respondent-Pharmacy dispensed high dose opioids to 17 patients who were 40 years old and younger on a chronic basis.

e. The pharmacy dispensed prescriptions written by prescribers who have histories of Board actions or restrictions involving their CDS prescribing.

f. Patients sharing the same address received the same or similar CDS prescriptions.

g. One patient received oxycodone, then Suboxone on a later date, and then oxycodone again.

h. Patients regularly received opioids combined with benzodiazepines.

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:

[5] The US Centers for Disease Control (CDC) recommends that daily opioid dosages should rarely meet or exceed 90 MME. This is due to a statistically increased risk of fatal overdose for patients on these doses compared to patients on lower doses.

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board [and]

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(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[.]

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A. A valid prescription shall be:

(1) Valid in the professional judgment of the pharmacist responsible for filling the prescription[.]

COMAR 10.34.20.04. Controlled Dangerous Substances.

Transmission and dispensing of controlled dangerous substances shall be in accordance with applicable State and federal statutes and regulations.

III. ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 21st day of June, 2023, by the affirmative vote of a majority of the members of the Board then serving:

ORDERED that the Respondent-Pharmacy is **REPRIMANDED**; and it is further

ORDERED that the Respondent-Pharmacy's permit shall be placed on **PROBATION** for **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 sixty (60) days of the effective date of the Consent Order the Respondent-Pharmacy shall submit a standard operating procedure regarding Controlled Dangerous Substance prescriptions to the Board for review and approval;

4. After Board approval of the standard operating procedure regarding Controlled Dangerous Substance prescriptions, the Respondent-Pharmacy shall re-train all pharmacy staff members on the approved procedure. Such training shall occur within ninety (90) days of the effective date of the Consent Order and yearly thereafter for the duration of the probationary period. The Respondent-Pharmacy shall provide written documentation indicating the successful completion of these trainings;

5. The Respondent-Pharmacy shall pay a monetary **fine in the amount of $5,000**, payable within the one (1) year period of probation;

ORDERED that the Respondent-Pharmacy shall practice 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 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 this Consent Order shall be a public document pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq*. (2022).

6-21-23
Date

Deena Speights-Napata, M.A.
Executive Director, for
Neil Leikach, R.Ph., M.Sc., President
State Board of Pharmacy

CONSENT

I, Adekunle Onalaja, Agent for the Respondent-Pharmacy, acknowledge that the Respondent-Pharmacy has had the opportunity to consult with legal counsel before signing this document. By this Consent, the Respondent-Pharmacy accepts, to be bound by this Consent Order and its conditions and restrictions. The Respondent-Pharmacy waives any rights the Respondent-Pharmacy may have had to contest the Findings of Fact and Conclusions of Law.

The Respondent-Pharmacy acknowledges the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which the Respondent-Pharmacy 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.

The Respondent-Pharmacy acknowledges the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. The Respondent-Pharmacy also affirms that the Respondent-Pharmacy is waiving the right to appeal any adverse ruling of the Board that might have followed any such hearing.

The Respondent-Pharmacy signs this Consent Order without reservation, and the Respondent-Pharmacy fully understands and comprehends the language, meaning and terms of this Consent Order. The Respondent-Pharmacy voluntarily signs this Order and understands its meaning and effect.

06-09-23.
Date

Agent for the Respondent-Pharmacy

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Baltimore

I hereby certify that on this 9th day of June, 2023, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared Adekunle Onalaja [Agent for the Respondent Pharmacy], 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: May 18 2025

JASON WANCOWICZ
Notary Public - State of Maryland
Baltimore County
My Commission Expires May 18, 2025