

IN THE MATTER OF

*** BEFORE THE**

LUSBY PHARMACY

*** MARYLAND BOARD**

PERMIT No: P08070

*** OF PHARMACY**

Respondent

*** Case No.: 20-489**

*** * * * ***

CONSENT ORDER

On June 15, 2022, the Maryland Board of Pharmacy (“the Board”) charged **LUSBY PHARMACY** (“the Respondent-Pharmacy”), Permit No.: **P08070**, under the Maryland Pharmacy Act, (the “Act”) Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021 Repl. Vol.).

The Board charged the Respondent-Pharmacy with violating the following pertinent provisions of Health Occ.:

§ 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;

....

- (15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

....

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

The Board also charged the Respondent-Pharmacy with violating the following pertinent provisions of Code Md. Regs (“COMAR”), 10.34.10 and COMAR 10.19.03:

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 10.34.20.02. 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.

COMAR 10.19.03.07. Prescriptions.

....

B. Persons Entitled to Issue Prescriptions (21 CFR §1306.03).

- (1) A prescription for a controlled dangerous substance may be issued only by an individual practitioner who is:
 - (a) Authorized to prescribe controlled dangerous substances in the State of Maryland, in which the practitioner is licensed to practice the practitioner's profession; and

- (b) Either registered or exempted from registration pursuant to 21 CFR §1301.22(c) and 21 CFR §1301.23.

....

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.

....

- E. Persons Entitled to Fill Prescriptions. A prescription for controlled dangerous substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

COMAR 10.19.03.08. Controlled Substances Listed in Schedule II.

A. Requirement of Prescription-Schedule II (21 CFR §1306.11).

- (1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in §A(4) of this regulation. Except as noted in §A(5)-(7) of this regulation, a prescription for a Schedule II controlled substance

may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review before the actual dispensing of a controlled substance.

On August 10, 2022, the Respondent-Pharmacy, along with their attorney, Charles E. Walton, Esq., 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, for purposes of compromise and settlement, agreed to enter into this Consent Order consisting of Findings of Fact, Conclusions of Law, and Order.

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 April 17, 2019. The Respondent-Pharmacy's permit expires on May 31, 2024.
2. The Respondent-Pharmacy is owned and managed by a pharmacist ("Pharmacist").
3. At all times relevant hereto, the Pharmacist was licensed to practice pharmacy in the State of Maryland. The Pharmacist was originally licensed to practice pharmacy in Maryland on or about July 28, 2005. The Pharmacist's license expires on July 31, 2023.

4. On or about June 25, 2020, the Board received a complaint raising concerns about the prescription dispensing habits of the Respondent-Pharmacy.

5. After receiving the complaint, the Board initiated an investigation.

6. As part of the Board's investigation, the Board obtained a dispensing report from the prescription drug monitoring program ("PDMP"), hard copies of prescriptions from the Respondent-Pharmacy, obtained a written response from the Pharmacist, and submitted the Board's investigative file to an expert from the Office of Controlled Substances Administration ("OCSA Expert").

7. A review of the PDMP report revealed that out of 1,869 prescriptions dispensed from the Respondent-Pharmacy, the Respondent-Pharmacy filled approximately 142 prescriptions written by a nurse practitioner ("Nurse Practitioner") who was employed at a pain management clinic (the "Facility"). The 142 prescriptions were for Oxycodone, Oxymorphone, Hydromorphone, Methadone, Phentermine, Morphine Sulfate, Pregabalin, and Oxycodone with Acetaminophen.

8. A review of the 142 hardcopy prescriptions written by the Nurse Practitioner from December 24, 2019 to June 4, 2020, revealed that for only 11 (8%) of the prescriptions the Pharmacist verified and documented checking with the doctor's office (the Facility).

9. A review of the 142 hardcopy prescriptions written by the Nurse Practitioner from December 24, 2019 to June 4, 2020, further revealed that there were red flags for many of the prescriptions. The red flags included the following:

- a. 62 (44%) of the Schedule II CDS there was a high quantity, greater than 30 day supply of oxycodone;

- b. 78 (55%) of the Schedule II CDS there was a high quantity, greater than 120 day supply of oxycodone;
- c. 94 (66%) of the Schedule II CDS the MME¹ was greater than 90 mg per day;
- d. 46 (32%) of the prescriptions were paid for in cash;
- e. 114 (80%) of the prescriptions were for long-distance patients; and
- f. 34 (24%) of the prescriptions were for patients under 40 years old.

10. On or about April 13, 2021, the Board received a written response from the Pharmacist. As part of the written response the Pharmacist stated in part:

- a. “I have to change a lot way [*sic*] because of [the Facility].”
- b. “I requested to speak with the prescribing doctor about some patient [*sic*] and she was very defensive and she said she is the manager I insisted she hunged [*sic*] up and call sometimes [*sic*] later with threat after I said I will not fill for patients anymore if I couldn’t talk to the Dr.”

¹ Morphine Milligram Equivalence (“MME”) is a value assigned to each opioid to represent its relative potency by using morphine as the standard comparison. The CDC Guideline for Prescribing Opioids for Chronic Pain uses MME to establish a recommended opioid dosing and recommends using precaution when prescribing opioid doses greater than or equal to 50 MME per day and avoiding or carefully justifying a decision to increase opioid doses greater than or equal to 90 MME per day.

- c. “Medication was changed because manufacturer/supplier was out of the 10 mg ER oxymorphone at the time.”²
- d. “Unfortunately, I never reported any of my suspicions but now, will report any suspicious activity form [*sic*] the doctor office if needed.”

11. According to the OCSA Expert’s review of the investigation, the Respondent-Pharmacy and the Pharmacist violated the law pharmacies and pharmacists are required to comply with. Of note, the OCSA Expert found the following:

- a. The Pharmacist did not follow the law when he changed the dose and quantity of oxymorphone ER from 10 mg 60 tablets to 5 mg 120 tablets. A new prescription with the change in strength and quantity should have been obtained before dispensing the substituted product.
- b. The Respondent-Pharmacy dispensed prescriptions prescribed by the Facility even though there were numerous red flags present. The prescriptions were for high dose and quantity oxycodone that were being prescribed from an office in Upper Marlboro that is 49 miles away from the Respondent-Pharmacy. Most of the prescriptions were for patients living in

² A review of the hardcopy prescriptions obtained revealed the Nurse Practitioner wrote a prescription for oxymorphone 10 mg, a quantity of 60 tablets. The prescription is dated May 19, 2020. According to the backtag the Respondent-Pharmacy dispensed 120 tablets of oxymorphone 5 mg.

Lusby, Prince Frederick, Lexington Park, and Leonardtown.

The daily doses of the opioids were at or exceeding 180 MME for many of the prescriptions. About 1/3 of the patients were self-pay for their CDS prescription.

- c. Past inspections conducted by OCSA have documented that the Respondent-Pharmacy has dispensed CDS prescriptions with recognizable red flags for potential abuse and diversion.
- d. The Respondent-Pharmacy should have recognized the red flags and acted appropriately before any legal action had occurred with the Facility.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that by filling numerous Schedule II CDS despite several red flags, the Respondent-Pharmacy violated § 12-403(c)(1) in that the Respondent-Pharmacy violated COMAR 10.34.10.01(A)(1) and/or (A)(2) and/or (B)(1)-(3), COMAR 10.34.20.02(A)(1), COMAR 10.34.20.04, COMAR 10.19.03.07(B)(1) and/or (C)(1) and/or (E), and/or COMAR 10.19.03.08.

The Board further concludes as a matter of law that by altering the prescription written on May 19, 2020, and dispensing a Schedule II CDS in a quantity and dose without a valid prescription, the Respondent-Pharmacy violated § 12-403(c)(1) in that the Respondent-Pharmacy violated COMAR 10.34.10.01(B)(1)-(3), COMAR

10.34.20.02(A)(1), COMAR 10.34.20.04, COMAR 10.19.03.07(B)(1) and/or (C)(1) and/or (E), and/or COMAR 10.19.03.08.

The Board further concludes as a matter of law that by participating in activities, as outlined above, that are a ground for Board action against the Pharmacist, under § 12-313, including § 12-313(b)(2), (15) and/or (25), the Respondent-Pharmacy violated § 12-403(c)(9) of the Act.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 15th day of September 2022, by the affirmative vote of a majority of the members of the Board then serving:

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

ORDERED that the Respondent-Pharmacy's permit shall be placed on **Probation** for a period of at least **TWO (2) YEARS**, 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 conduct quarterly inspections of the Respondent-Pharmacy;
3. During the probationary period, the Board, shall obtain quarterly reports from the prescription drug monitoring program (PDMP) for the Respondent-Pharmacy;
4. The Respondent-Pharmacy shall provide training to all pharmacy staff members regarding valid prescriber-patient relationships and non-scheduled drugs of abuse. 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. Within ninety (90) days of the effective date of the Consent Order the Respondent-Pharmacy shall submit a standard operating procedure regarding Controlled Dangerous Substance prescriptions to a Board or Office of Controlled Substances Administration expert for review and approval;
6. 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 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 \$10,000**, payable within thirty (30) days of the effective date 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 20-489 – Lusby Pharmacy 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;

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

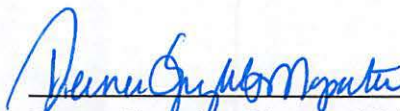
ORDERED that the Respondent-Pharmacy shall at all times cooperate with the Board in the monitoring, supervision, and investigation of its compliance with the terms and conditions of this Order;

ORDERED that the 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;

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

9-15-22

Date



Deena Speights-Napata, MA, Executive
Director
Maryland Board of Pharmacy

CONSENT

I, Taye Ojifinni, owner of Lusby Pharmacy, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of Lusby Pharmacy, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Lusby Pharmacy may have had to contest the Findings of Fact and Conclusions of Law.

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Charles

I hereby certify that on this 9th day of September, 2022, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **Taye Ojifinni**, 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: 8/28/2024

