IN THE MATTER OF	*	**BEFORE THE MARYLAND**
JAMES G. WALKER, PHARMACIST	*	**BOARD OF PHARMACY**
RESPONDENT	*	
LICENSE NUMBER: 09983	*	**CASE NUMBER: 20-265**

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CONSENT ORDER

On or about April 17, 2024, the Maryland Board of Pharmacy (the "Board") charged **James G. Walker** License Number: **09983** (the "Respondent"), under the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. ("Heath. Occ.") §§ 12-101 *et seq.* (2021 Repl. Vol. & 2023 Supp.). The pertinent provisions of the Act and the Code of Maryland Regulations ("COMAR") state:

> **Health. Occ. §12–313. Denials, reprimands, suspensions, and revocation-Grounds.**
>
> (b) 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 deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:
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> . . . .
>
> (21) Is professionally, physically, or mentally incompetent:
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> . . . .
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> (25) Violates any rule or regulation adopted by the Board[.]

The pertinent provisions of COMAR provide as follows:

> **COMAR 10.19.03.07 Prescriptions.**
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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.

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; and

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

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 10.34.10.04 Competence.

A pharmacy technician, pharmacy intern, or a pharmacist shall:

A. Maintain knowledge of the current pharmacy and drug laws and health and sanitation laws relevant to the practice of pharmacy[.]

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 and

(2) Conveyed:

(b) In a manner that is transmitted to the pharmacy electronically, provided that the prescription is:

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(iii) Maintained by the permit holder in accordance with Regulation .03 of this chapter[.]

COMAR 10.24.20.03 Prescription Record

The pharmacy permit holder shall maintain prescription records in a form that:

A. Is readily and accurately retrievable;

B. Is maintained for at least 5 years from the date of dispensing[.]

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 10.34.26.03 Pharmacy Staff Education.

As part of a pharmacy permit holder's ongoing quality assurance program, the pharmacy permit holder shall:

A. Ensure that each member of the pharmacy staff involved in the medication delivery system receive at least once a year, education regarding the role and responsibility of pharmacy staff in preventing medication errors; and

B. Maintain records for a minimum of 2 years:

(1) Verifying completion of education referred to in §A of this regulation; and

(2) Demonstrating the content of the education.

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent was licensed to practice pharmacy in the State of Maryland. The Respondent was originally issued a license to practice pharmacy in the State of Maryland on or about April 20, 1983. The Respondent's license expires on or about February 28, 2025.

2. The Respondent is the sole owner and pharmacist at a pharmacy (the "Pharmacy") located in Maryland. [1]

3. At all times relevant hereto, the Respondent had no employees working at the Pharmacy.

4. The Respondent was issued a permit to operate the Pharmacy on or about September 5, 2018. The permit expires on or about May 31, 2024.

5. At all times relevant hereto, the Pharmacy operational hours filed with the Board are 10:30 a.m. to 6:30 p.m., Monday through Saturday.

6. Between January 2019 and October 2023, the Office of Controlled Substances Administration ("OSCA") and the Board conducted inspections at the Pharmacy. [2]

July 19, 2019 Inspection

7. On or about July 19, 2019, an OCSA inspector went to the Pharmacy to conduct an inspection. The OCSA inspector arrived at the Pharmacy location at approximately 10:30 a.m. and noticed that the Pharmacy was closed. The OSCA inspector left the Pharmacy location at approximately 10:50 a.m. Before leaving the Pharmacy location, the OCSA inspector attempted to reach the Respondent at the Pharmacy telephone number on file with the Board. A telephone recording informed the OCSA inspector that the Pharmacy phone number was not in service.

[1] For confidentiality and privacy purposes, the name of the Pharmacy in this case is not disclosed in this document.

[2] Inspections set forth in this document were conducted pursuant to Health Occ.§ 12-413 which permits the Board or agents of the Board to enter any pharmacy and inspect for compliance with federal and state laws and regulations.

October 23, 2019 Inspection

8. On or about October 23, 2019, the Board inspectors conducted an inspection of the Pharmacy. Upon arriving at the Pharmacy location, the Board inspectors noticed that the Pharmacy appeared not to be operational. Once inside the Pharmacy, the Board inspectors noticed that the entire Pharmacy including the pharmacy area was dirty and cluttered. The Board inspectors also noticed papers, boxes, and trash throughout.

9. During the inspection, the Respondent informed the Board inspectors that the Pharmacy had been closed since April 29, 2019. The Respondent explained that on April 28, 2019, Baltimore City Fire Department personnel, when battling a fire at an adjacent property, broke down the front and back entrances of the Pharmacy.[3]

10. The Respondent told the Board inspectors that he was notified by his alarm company on April 28, 2019, that the front and back doors of the Pharmacy had been breached.

11. The Respondent told the Board inspectors that he went to the Pharmacy on the on day following the fire and discovered that the front and back doors to the Pharmacy were damaged and left wide open, and all prescription drugs, computers, phones, refrigerators, and other non-pharmacy items had been stolen from the Pharmacy.

[3] The fire at the adjacent property occurred the night of April 28, 2019.

12. The Respondent also told the Board inspectors that he was in the process of reopening for business and had only filled one prescription for Atorvastatin because he had no computer access.

13. The Board inspectors noted in the inspection report that the Respondent failed to notify the Board, OCSA, and/or the Drug Enforcement Agency ("DEA") that the Pharmacy had not been operational since April 28, 2019 and prescription drugs including controlled dangerous substances ("CDS") were stolen from the Pharmacy.

14. Board inspectors also noted in the inspection report that the Respondent did not report the thefts to the police.

January 23, 2020 Inspection

15. On or about January 23, 2020, an OCSA inspector went to the Pharmacy to conduct an inspection. The OCSA inspector arrived at the Pharmacy location at approximately 9:15 a.m. and noticed that the Pharmacy was closed.

16. The OCSA inspector attempted to reach the Respondent at the phone number listed on the Pharmacy door and on file with the Board but was unable to do so. The OCSA inspector left the Pharmacy location, but returned to the Pharmacy location at approximately 3:30 p.m. The OCSA inspector noticed that the Pharmacy remained closed even though the Pharmacy hours on file Board are 10:30 a.m. to 6:30 p.m., Monday through Saturday.

January 27, 2020 Inspection

17. On or about January 27, 2020, the OCSA inspectors conducted an inspection of the Pharmacy. During the inspection, the OCSA inspectors discovered that the Respondent did not have an opening CDS inventory report.

18. During the inspection, the Respondent told the OSCA inspectors that the Pharmacy was closed from April 28, 2019 to October 23, 2019. The Respondent also told the OCSA inspectors that he filled 3 prescriptions since he reopened the Pharmacy. The Respondent filled prescriptions for atorvastatin and hydrochlorothiazide.

PDMP Report

19. On or about September 8, 2020, the Board issued a subpoena duces tecum to the Maryland Prescription Drug Monitoring Program ("PDMP") for information regarding CDS dispensed by the Respondent between September 1, 2018 to September 3, 2020.

20. The Board received a report from PDMP that revealed the following:

a. Between April 4, 2020 and September 3, 2020, the Respondent dispensed approximately 35 CDS prescriptions to patients with addresses in Delaware, North Carolina, Kentucky, and West Virginia.

b. All the patients paid for prescriptions in cash or by credit card.

c. Most of the prescriptions dispensed were for Buprenorphine 8 mg. tablets. Prescriptions for Oxycodone 10 mg tablets and Acetaminophen-Codeine were also dispensed.

21. After reviewing the PDMP report of the Respondent's CDS dispensing, the Board requested that Board inspectors conduct a follow-up investigation of the Pharmacy to include a CDS audit.[4]

November 19, 2020 Inspection

22. On or about November 19, 2020, the Board inspectors conducted an inspection of the Pharmacy requested by the Board. During the inspection, the Board inspectors audited CDS schedule III and IV medications dispensed by the Respondent from May 1, 2020 to November 19, 2020.[5]

23. During the inspection, the Board investigators reviewed the Respondent's CDS dispensing reports and found Diazepam 10 mg over by 9 pills and Buprenorphine 8mg tablets was over by 734 pills.[6] The CDS dispensing reports revealed that the Respondent dispensed 119 prescriptions. 107 of the prescriptions dispensed by the Respondent were for Buprenorphine 8 mg tablets.[7]

24. The Respondent told Board inspectors that he had policies in place for verifying CDS prescriptions before they were dispensed. The Respondent indicated that most prescriptions were faxed to the Pharmacy by the prescriber. He further indicated that he would contact the prescriber if a CDS prescription was questionable. The Respondent also told Board investigators that he reported to the PDMP two times per day.[8]

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[4] A virtual inspection was conducted by a Board inspector on May 20, 2020. However, a CDS audit was not conducted.
[5] The Respondent had Schedule II CDS medications in inventory, but none was dispensed during this period.
[6] The Respondent maintained a book for perpetual inventory for CDS medications.
[7] Diazepam is a Schedule IV CDS and Buprenorphine is a Schedule III CDS.
[8] Schedule II-IV CDS are required to be reported to the PDMP.

25. In the inspection report, the Board inspectors noted red flag concerns regarding the Respondent's dispensing of the CDS prescriptions. Those red flag concerns were as follows: (1) 107 Buprenorphine prescriptions were dispensed to patients living in Delaware, Kentucky, North Carolina, Pennsylvania, and West Virginia; (2) 6 Buprenorphine prescriptions were dispensed to different patients with the same West Virginia address; and (3) all CDS prescriptions on the Respondent's dispensing report were cash or credit card payments.

26. The Board inspectors also noted concerns in the inspection report that the Respondent had tobacco products for sale in the pharmacy area of the Pharmacy.

December 5, 2022 OCSA Report

27. In furtherance of the Board's investigation, the Board provided the PDMP report for the Respondent's CDS dispensing and hard copies of prescriptions for Buprenorphine from May 1, 2021 to January 31, 2022, to an OCSA Clinical Pharmacist Inspector ("Clinical Pharmacist Inspector") for review.

28. In a report provided to the Board and dated December 5, 2022, the Clinical Pharmacist Inspector noted the following concerns and red flags:

PDMP report

a. The Respondent reported a total of 2306 CDS prescriptions to PDMP from May 1, 2021 to January 31 2022.

b. Of the 2306 CDS prescriptions dispensed, 2066 (90%) were for Buprenorphine 8 mg, and were dispensed in quantities of 60 to 100 tablets.

c. Every prescription in the PDMP report was dispensed as a self-pay.

d. The Respondent dispensed Buprenorphine to patients who lived hundreds of miles from the Pharmacy. (97%) of the prescriptions were dispensed to patients with a West Virginia address; (2%) of the prescriptions were dispensed to patients with a Maryland address; and (1%) of the prescriptions were dispensed to patients with an address a Delaware, Pennsylvania, Virginia, North Carolina, or Ohio.

e. Patients with the same address were dispensed Buprenorphine. Most of these patients had a West Virginia address.

f. 90% of the Buprenorphine 8mg tablets prescriptions were prescribed from three medical offices. Only one of these medical offices was located near the Pharmacy. One thousand and one hundred (1,111) Buprenorphine prescriptions were prescribed by medical practitioners whose medical offices were 32 miles from the Pharmacy.

g. Most of the prescriptions dispensed by the Respondent were prescribed by prescribers who had disciplinary actions and/or restrictions taken against their license because of CDS prescribing practices.

h. Patients were dispensed 1 or 2 mg of Alprazolam with Buprenorphine.

i. The method of transmission of the prescriptions was not accurately reflected in the PDMP report.

Hard Copy Prescriptions

j. No indication on hard copy prescriptions for Buprenorphine 8 mg tablets that the PDMP had been accessed by the Respondent before prescriptions were dispensed.

k. 25 prescriptions for Buprenorphine 8 mg tablets were not listed in the PDMP report.

September 29, 2023 Inspection

29. On or about September 29, 2023, a Board inspector conducted an inspection of the Pharmacy. The Board inspector noted in the inspection report that the Pharmacy was not clean and orderly. The Board inspector observed medications, boxes, and trash throughout all areas of the Pharmacy, including in the pharmacy area.

30. During the inspection, the Board inspector also found 31 expired medications.

31. The Board inspector noted in the inspection report that the Respondent did not have two (2) continuous years of records of training on medication errors and an ongoing quality assurance program for reporting medication errors.

October 5, 2023 Inspection

32. On or about October 5, 2023, an OCSA inspector conducted an inspection of the Pharmacy. During the inspection, the OCSA inspector noticed that the Pharmacy was extremely cluttered and disorganized. The OCSA inspector observed an assortment of paper, trash and debris scattered throughout the Pharmacy, including in the pharmacy area.

33. During the October 5, 2023 inspection, the OCSA inspector reviewed the prescriptions that the Respondent filled from October 3, 2023 to October 5, 2023. During this period, the Respondent filled 26 Buprenorphine 8mg tablets prescriptions.

34. During the inspection, the OCSA inspector also noticed several red flags regarding CDS prescriptions dispensed by Respondent from September 30, 2023-October 5, 2023. Those red flags included the following: (1) high quantity

Buprenorphine 8mg tablets dispensed; (2) all the patients were self-pay; and (3) majority of the patients were from out of state, most from West Virginia.

35. The OCSA inspector also reviewed approximately 12 prescriptions dispensed by the Respondent between September 30, 2022 and October 4, 2022. The OCSA inspector noted in the inspection report that these prescriptions had been prescribed by a prescriber whose prescribing privileges were suspended during this period.

36. The Respondent's conduct as set forth above is in violation of Health Occ. §12-313 (b) (21) and (25); COMAR 10.19.03.07 C (1); COMAR 10.34.10.01A (1), (2), and (3) and B (1), (2) and (3); COMAR 10.34.10.04 A; COMAR 10.34.10.08 A (1) and (2); COMAR 10.34.20.02 A(1) and (2)b(iii); COMAR 10.34.20.03 A and B; COMAR 10.34.20.04; and COMAR 10.34.26.03 A and B (1) and (2) .

CONCLUSIONS OF LAW

The Board concludes that the Respondent is in violation of Health Occ. §12-313 (b) (21) and (25); COMAR 10.19.03.07 C (1); COMAR 10.34.10.01A (1), (2), and (3) and B (1), (2) and (3); COMAR 10.34.10.04 A; COMAR 10.34.10.08 A (1) and (2); COMAR 10.34.20.02 A(1) and (2)b(iii); COMAR 10.34.20.03 A and B; COMAR 10.34.20.04; and/or COMAR 10.34.26.03 A and B (1) and (2).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, a majority of a quorum of the Board hereby:

ORDERED that the Respondent's license is hereby **SUSPENDED for a period of one (1) year and said Suspension is Stayed**; and it is further

ORDERED the Respondent's license shall return placed on **PROBATION** FOR **(3) YEARS** subject to the following terms and conditions:

1. The Respondent shall pay a monetary fine in the amount of five thousand dollars ($5000). The $5000 shall be paid **before the termination of the probationary period.**

2. Within ninety (90) of the date of this Order, the Respondent shall successfully complete twelve (12) Board-approved continuing education credits ("CEU"). Six (6) CEU's shall be in effective medication treatment and Six (6) CEU's shall be in pharmacist corresponding responsibility in preventing CDS diversion and misuse. The CEU required under this Order shall not count toward the CEU's requirement for license renewal; and it is further

ORDERED that the Respondent shall bear the cost of complying with this Order; 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 at all times fully cooperate with the Board in its monitoring, supervision, and investigation of the Respondent's compliance with the terms and conditions of this Order; and it is further

ORDERED that the Respondent's failure to fully cooperate with the Board shall be deemed a violation of the terms of probation and a violation of this Order; and it is further

ORDERED that in the event the Board finds for any good faith reason that the Respondent has violated any of the conditions of suspension herein, or in the event that the Board finds for any good faith reason that the Respondent has committed a violation of Title 12 of the Health Occupations Article or regulations adopted thereunder, the Board may take further disciplinary action, to include summary suspension, against the Respondent's license, provided that the Respondent is given notice and an opportunity for a hearing; and it is further

ORDERED that after **ONE (1) YEAR** from the date of this Order, the Respondent may submit a written petition to the Board requesting that the Board terminate probation, provided that the Respondent has fully complied with all conditions of this Order and there are no pending complaints against the Respondent; and it is further

ORDERED that this is a final order of the Maryland Board of Pharmacy and as such is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., General Prov. Art., §4-333.

Krisopher Rusinko, Pharm.D.
President
Maryland Board of Pharmacy
7/23/2024

CONSENT

I, James G. Walker, 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.

7-9-24

Date

James G. Walker

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Baltimore

I hereby certify that on this 09 day of 07, 2024, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **James G. Walker**, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Amanda Sanders

Notary Public

My Commission Expires: 03/31/2027

AMANDA SANDERS
Notary Public - State of Maryland
Baltimore County
My Commission Expires Mar 31, 2027