IN THE MATTER OF	*	**BEFORE THE MARYLAND**
PATIENT CARE PHARMACY	*	**STATE BOARD**
PERMIT No: P07157	*	**OF PHARMACY**
Respondent	*	**Case No.: 21-248**

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CONSENT ORDER

On October 18, 2023, the Maryland Board of Pharmacy ("the Board") charged **PATIENT CARE PHARMACY** ("the Respondent-Pharmacy"), Permit No.: **P07157**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.).

On December 13, 2023, the Respondent-Pharmacy, along with their attorney, Darci Smith, 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 June 2, 2016. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. The Respondent-Pharmacy is owned by a pharmacist ("Pharmacist-Owner").[1]

3. At all times relevant hereto, the Pharmacist-Owner was licensed to practice pharmacy in the State of Maryland. The Pharmacist-Owner was originally licensed to practice pharmacy in Maryland on or about April 14, 2008. The Pharmacist-Owner's license expires on December 31, 2023.

4. On or about May 10, 2021, the Board received a notice from a wholesale distributor (the "Wholesale Distributor") that they restricted the Respondent-Pharmacy's ability to order controlled substances and added the Respondent-Pharmacy to their "do not ship list." The Wholesale Distributor reported "there was high ratio of controlled substances purchases (26.1% by dosage unit volume) versus non-controlled substances, of which 86.13% is comprised of Mono-buprenorphine."

5. Invoices from the Wholesale Distributor from April 1, 2020 to April 30, 2021, revealed 214 out of 773 medications ordered were buprenorphine.[2]

6. Invoices received from the Respondent-Pharmacy revealed from April 2020 to April 2021 the Respondent-Pharmacy ordered buprenorphine on average approximately ten or more times a month from the Wholesale Distributor.

7. Respondent-Pharmacy asserts that Wholesale Distributor is one of many distributors used by Respondent-Pharmacy and Respondent-Pharmacy orders primarily

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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. The Administrative Prosecutor has provided the information to the Respondent-Pharmacy.

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

buprenorphine from Wholesale Distributor because the prices were more competitive than Respondent-Pharmacy's other distributors, which resulted in the high ratios of controlled substances to non-controlled substances ordered from Wholesale Distributor.

8. On or about June 8, 2023, the Board subpoenaed "[t]he dispensing information (audit log)/drugs for all controlled dangerous substances ("CDS") dispensed by" the Pharmacist-Owner "and their delegates at [the Respondent-Pharmacy]" for the time period of April 1, 2020 to April 30, 2021.

9. By email dated June 28, 2023, the agency reported that the audit trail[3] request had been completed and it yielded no results indicating that the Pharmacist-Owner and his delegates were not checking the PDMP before dispensing the prescriptions at issue. Respondent asserts two other licensed pharmacists employed by the Respondent-Pharmacy checked the PDMP before dispensing medications for which they had reasonable belief may have been issued for reasons other than treatment of an existing medical condition, as evidenced by notations made in the Respondent-Pharmacy's EMR.

10. 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 April 1, 2020 to April 30, 2021.

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[3] An Audit Log is a report containing a log of all PDMP data access by a clinical user under their individual CRISP account or through an approved PDMP integration within their workflow. Clinical users (prescribers, pharmacists, and delegates) can query (search for) PDMP data related to a patient through CRISP products. A record exists when a query was successfully made, regardless of whether data was returned (i.e. a provider can search for a patient in the system and be shown either PDMP prescription data or be told that no data exists for the searched patient demographics; both of these situations would be logged as a successful query).

11. On or about March 10, 2022, OCSA's Clinical Pharmacist Inspector ("Clinical Pharmacist Inspector") reviewed the PDMP report and provided the Board with their analysis, which notes the following:

a. Of 129,115 total prescriptions filled by Respondent-Pharmacy from April 1, 2020 to April 30, 2021, 20,216 were prescriptions were for controlled substances;

b. 8,593 were for opioid prescriptions;

c. 1,482 were immediate release oxycodone in strengths of 10mg, 15mg, 20mg, or 30mg – most were dispensed in quantities of 90 or greater as a month's supply;

d. 1,627 were for monoproduct buprenorphine 8mg tablets – most were dispensed in quantities of 60 to 90 tablets; and

e. There were red flags noted among the 1,627 monoproduct buprenorphine prescriptions dispensed including:

i. 1,057 were prescribed by just three different prescribers;

ii. 1,305 were dispensed as self-pay prescriptions;

iii. 1,166 were dispensed to patients with out of state addresses;[4]

iv. pharmacy-prescriber-patient location triangle;[5]

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[4] Of the total buprenorphine 8mg prescriptions, 1,027 (63%) were dispensed to patients with addresses in West Virginia.

[5] Pharmacy-prescriber-patient location triangle refers to patients and prescribers located a long distance from the pharmacy. For example, one patient traveled 363 miles to a medical office, and then went to the Respondent-Pharmacy which was 45 miles from the patient's address – the total distance traveled in this triangle is 773 miles.

v. more than one family member receiving same CDS; and

vi. more than one person at same address receiving same CDS.

f. There were also red flags noted among other CDS prescriptions dispensed including: 250 out of 1,472 (17%) high dose oxycodone immediate release were for patients 40 years old or younger, and many of the high dose opioid prescriptions were prescribed by providers with past disciplinary actions regarding CDS prescribing.

12. The Board subpoenaed hardcopies of buprenorphine prescriptions from the Respondent-Pharmacy from April 1, 2020 through April 30, 2021. In response, the Board received a total of 1,213 hardcopy prescriptions. Out of the 1,213 hardcopy prescriptions, only two prescriptions had annotations on them, both stating CRISP verified last fill. Respondent-Pharmacy asserts that certain notes were made in the Respondent-Pharmacy's EMR. The prescriptions failed to contain annotations indicating valid clinical rationale in accordance with CDC guidelines for the dispensing of mono-product buprenorphine instead of the combination product buprenorphine containing naloxone.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy is subject to discipline in accordance with Health Occ. § 12-313(b)(25); Health-Gen. § 21-2A-04.2(e)(1)-(2); COMAR 10.34.10.01(A)(1)-(A)(2), (B)(1)-(3); COMAR 10.34.20.02(A)(1); and COMAR 10.19.03.07(C)(1) and/or (E).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 25th day of January 2024, 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 **EIGHTEEN (18) MONTHS**, 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. During the probationary period, the Board, shall conduct quarterly inspections of 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. During the period of probation, the Respondent-Pharmacy shall be monitored by a Board-approved supervisor;

6. The Respondent-Pharmacy shall receive approval from the Board for the supervisor within sixty (60) days of the effective date of the consent order;

7. The Respondent-Pharmacy shall meet in person quarterly with the Board-approved supervisor;

8. The Board approved supervisor shall consult with the Respondent-Pharmacy on the pharmacy operation and work with the Respondent-Pharmacy to develop policies regarding Controlled Dangerous Substances ("CDS") which should include, among other things, inquires of the prescription drug monitoring program (PDMP);

9. During the period of probation, the Respondent-Pharmacy's Board-approved supervisor shall provide the Board with quarterly reports addressing the Respondent-Pharmacy's practice;

10. After **EIGHTEEN (18) MONTHS** 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 $5,000**, 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 21-248 – Patient Care 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).

1-25-24
Date

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

CONSENT

I, Vaibhav Patel, owner of Patient Care 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 Patient Care Pharmacy, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Patient Care Pharmacy 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 Patient Care 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.

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 Patient Care Pharmacy'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 Patient Care Pharmacy and understand its meaning and effect.

1/18/2024
Date

Vaibhav Patel, Owner
Patient Care Pharmacy

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Anne Arundel

I hereby certify that on this 18 day of January 2024, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **Vaibhav Patel**, 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

KATE EDWARDS
Notary Public
Anne Arundel County
Maryland
My Commission Expires Dec. 5, 2027

My Commission Expires: 12/5/27

Maryland Board of Pharmacy