IN THE MATTER OF	*	**BEFORE THE**
GWYNN OAK PHARMACY	*	**MARYLAND BOARD**
PERMIT No: P07413	*	**OF PHARMACY**
Respondent	*	**Case No.: 19-061**

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

CONSENT ORDER

On August 17, 2022, the Maryland Board of Pharmacy ("the Board") charged **GWYNN OAK PHARMACY** ("the Respondent-Pharmacy"), Permit No.: **P07413**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.).

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;

(2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

. . . .

(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;

. . . .

(11)(i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

1. To prepare and dispense prescriptions properly; and

2. To otherwise operate a pharmacy; and

(ii) Shall:

. . . .

2. Be kept in a clean and orderly manner;

§ 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[.]

§ 12-6C-03. Permit required.

(a) *Wholesale distributors* – A wholesale distributor[1] shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution in the State.

The Board also charged the Respondent-Pharmacy with violating the following pertinent provisions of Code Md. Regs ("COMAR"):

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[.]

. . . .

[1] A wholesale distributor "means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices," which includes "a pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5% of the pharmacy's annual sales." § 12-6C-01(v)(1), (2)(xii); COMAR 10.34.22.02(B)(23)(a), (b)(xii). *See also* § 12-406(b)(1)(i). Wholesale distribution "means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient." § 12-6C-01(u)(1); COMAR 10.34.22.02(B)(22)(a).

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.

. . . .

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.

. . . .

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for detoxification treatment or maintenance treatment.

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.

. . . .

D. Labeling of Substances (21 CFR §1306.14).

(1) The pharmacist filling a written or emergency oral prescription for a controlled dangerous substance listed in Schedule II shall affix to the package a label showing the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in this prescription or required by law. It is further provided that the label of a drug listed in Schedules II, III, IV, and V of Criminal Law Article, §§5-403-5-406, Annotated Code of Maryland, shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient. When the size of the label space requires a reduction in type,

the reduction shall be made to a size no smaller than necessary and in no event to a size smaller than six-point type.

. . . .

(3) When dispensed to or for a patient, the label of a drug listed in Schedules II, III, IV, or V shall contain a clear and concise warning that it is a crime to transfer the drug to any person other than the patient.

COMAR 10.19.03.09. Controlled Substances Listed in Schedules III, IV, and V.

A. Requirement of Prescriptions Listed in Schedules III, IV, and V (21 CFR §1306.21).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

COMAR 10.34.37.03. Requirements for Wholesale Distribution.

A. General Requirements.

(1) A full service pharmacy may conduct wholesale distribution provided that the wholesale distribution business does not exceed 5 percent of the full service pharmacy's annual sales.

On November 9, 2022, the Respondent, pro se, 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 October 20, 2016 under permit number P07413. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. A pharmacist licensed in the State of Maryland (the "Pharmacist-Owner") is the Respondent-Pharmacy's owner and sole pharmacist.

3. On March 21, 2017, the Chief of the Enforcement Division ("Chief of the Enforcement Division") for the Office of Controlled Substances Administration ("OCSA") conducted a change of location inspection of the Respondent-Pharmacy. During the inspection, the Chief of the Enforcement Division noted the following concerns:

   a. Invoices showed large quantities of CDS ordered for a small pharmacy that fills very few prescriptions – only 5-7 a day, according to the Respondent. The large quantities included 13 bottles of 100 each of oxycodone, 30mg in four weeks; lorazepam 0.5mg and 1mg, 500 of each; diazepam, 10mg 500ct; alprazolam 1mg 1000ct; alprazolam 2mg 3x500ct; clonazepam 1mg and 2mg 500ct; and clonidine 0.2mg 500ct and 0.3mg 4x100ct.

b. During the inspection, the pharmacist received one phone call on his cellphone because he does not have a landline in the pharmacy. The pharmacist answered the call stating, "Yes, hello?" rather than identifying the pharmacy's name.

c. Schedule II CDS were ordered using a controlled substance ordering system, but a record was not created of the quantity of each item received, the date received, or electronically linked to the original order. Nor was there an archive of the same.

d. The quantity and date of Schedule II CDS surrendered for disposal was not written when using DEA Form 222.

e. The prescribing practitioners' addresses were not present on all of the back tag labels; nor were they written on the hard copy prescriptions.

f. The dispensed amount of one Tussionex prescription (a Schedule II CDS) was larger than the prescribed amount.

g. "Numerous red flags observed including high strength/quantity of narcotic opioid, same strength/quantity oxycodone for all patients, patients under 40, prescriber long distance."

h. "Suspect fraud" cocktail prescription for clonidine 0.3 #90, alprazolam 2mg #90, oxycodone 10mg #90, and promethazine DM syrup #240ml. The Respondent-Pharmacy was specifically instructed to contact this prescriber to see if the four prescriptions identified were valid and then to email the results to the inspector by April 1, 2017.

i. Out of the 18 Schedule II CDS prescriptions filled, nine were prescribed by one provider ("Provider #1"). All of the patients, except one, received oxycodone 30mg, 120 count for chronic back pain. Seven out of eight of the patients were also prescribed alprazolam 2mg.

j. When the pharmacist was asked about the prescriptions written by Provider #1, the pharmacist said he goes to the doctor's office and picks up the prescriptions, brings them back to the pharmacy, fills the prescriptions and then returns the prescriptions to the doctor's office with the filled prescriptions. He claimed all of the patients wait at the doctor's office.

k. "Questionable validity" of prescriptions from a Virginia child psychiatrist as the clonidine 0.3mg #270 prescriptions were written for a 48-year-old. This was a telephone prescription and did not include an address for the prescriber.

l. Some prescriptions by Provider #2 were suspected as fraudulent or not for a legitimate medical purpose as there were mistakes in the writing of the names of the drugs. Also, one patient was prescribed clonidine 0.3mg #90 with two refills; promethazine 50mg #90 with two refills; and alprazolam 2mg #120 with two refills. All three were paid for in cash. This patient also received a prescription for lisinopril 40mg but did not fill it. A second patient received the same prescriptions: clonidine 0.3mg, promethazine 50mg, and alprazolam 2mg. All three were paid for in cash.

This second patient also received a prescription for lisinopril which was filled through insurance.

m. Prescriptions written by a pulmonologist were suspected as having been outside the scope of his practice since they were for oxycodone 15mg #120 and alprazolam 2mg #90.

n. The Respondent-Pharmacy was specifically instructed "Remember, you have a corresponding responsibility to ensure all CDS RXs you fill are for a legitimate medical purpose by a prescriber ordering in [the] usual scope of practice. Anyone filling or issuing RXs not for [a] legitimate medical purpose and/or not written in [the] usual scope of practice shall be subject to penalties as violations of law relating to CDS. Review COMAR 10.19.03.07c(1)."

4. On January 19, 2018, the Chief of the Enforcement Division for OCSA conducted a regulatory and red flag inspection of the Respondent-Pharmacy. During the regulatory inspection, the inspector noted the following concerns:

a. Permits were not displayed.

b. There were Schedule III – V invoices from other pharmacies. Apparently, CDS was transferred to Respondent-Pharmacy using the original wholesaler's invoice rather than pharmacy to pharmacy invoice.

c. During the routine pharmacy inspection numerous red flags were observed such as in-state long distance practitioner, high strength/quantity of CDS prescriptions written, and many patients

younger than 40 years old were submitting prescriptions for CDS. Due to this, a decision was made to stop the routine pharmacy inspection and move to a red flag inspection.

5. The Chief of the Enforcement Division noted the following concerns for the red flag inspection on January 19, 2018:

a. Two Schedule II CDS packs were reviewed, and multiple red flags were noted in 20 out of 22 prescriptions in pack number 1 and in 98 out of 99 prescriptions in pack number 2. The red flags included common CDS "cocktails," cash, patient long distance, prescriber long distance, patients under 40 years old, and suspect fraudulent.

b. During the Schedule II CDS review, the Chief noted that prescriptions were written on prescription pads with two different provider names but contained "the exact same handwriting." These prescriptions were identified as possibly fraudulent, which Respondent-Pharmacy should have easily observed when the prescriptions were presented.

c. "There were about four CII Rxs observed that were filled as two Rxs using one paper Rx."

d. Three of the four CII counts did not match.

e. The Pharmacist-Owner was informed "Please remember to do your due diligence in ensuring the validity of Rxs . . . . Also remember you have a corresponding responsibility to ensure all CDS Rxs you fill are for a legitimate medical purpose."

6. On January 22, 2018, the Chief of the Enforcement Division for OCSA returned to the Respondent-Pharmacy to check the stock of medication on the shelves and requested printouts of dispensing reports for clonidine 0.3mg, promethazine 50mg, oxycodone 30mg, methadone 10mg, and/or prescriptions issued by Provider #3. This follow-up visit revealed that on December 28, 2017, the owner of the Respondent-Pharmacy "ordered 24 x100 bottles of promethazine 50mg." There were five bottles on the shelf at the time of the follow-up visit with only four prescriptions filled since December 27, 2017 – 330 tabs dispensed (equaling just over 3 bottles of 100). Therefore, there were 15+ bottles (100 each) missing.

7. On June 28, 2018, a Board Inspector and an OCSA inspector ("OCSA Inspector") conducted an annual inspection of the Respondent-Pharmacy.[2] During the inspection, the inspectors noted the following concerns:

a. One return to stock medication was in the pharmacy area without any identifying medication information present.

b. The temperature of the Respondent-Pharmacy during the inspection was 80^0F. The inspectors had the Pharmacist-Owner adjust the temperature during the inspection and recommended that the pharmacy monitor the humidity and temperature.

c. The Respondent-Pharmacy blister packs medications, including methadone, for individual patients. Blister packs of methadone were

[2] The Pharmacist-Owner was the only employee at the time of the inspection.

delivered to a nurse practitioner's office ("Nurse Practitioner's Office") by the Pharmacist-Owner, at which time, *only* the staff from the Nurse Practitioner's Office received the blister packs from the Pharmacist-Owner and signed for receipt of the methadone. According to the Pharmacist-Owner, the nurse practitioner ("Nurse Practitioner") would then dispense the methadone to the patients one at a time. The blister packs that contained medications other than methadone were delivered to the Nurse Practitioner's Office by the Pharmacist-Owner, at which time, the patients *or* the receptionist would sign for the medications.

d. The OCSA Inspector found several physicians' addresses listed on their prescriptions did not match the addresses listed on the labels. Other red flags included "cocktail" prescriptions, prescriptions paid for in cash, long distances between doctor and patient (or between patient and pharmacy), high strength, high quantity, and patients under 40. The OCSA Inspector instructed the Respondent-Pharmacy to make sure they check for red flags when filling prescriptions.

8. On October 11, 2018, the Board issued a subpoena to the Respondent-Pharmacy for copies of any and all methadone prescriptions filled and dispensed by the Respondent-Pharmacy for the time period between June 7, 2017 and October 11, 2018. On October 24, 2018, the Board received copies of forty (40) methadone prescriptions from the Respondent-Pharmacy.

9. The Chief of the Enforcement Division for OCSA reviewed the copies of the forty (40) methadone prescriptions and observed numerous red flags due to elements of the printed paper prescriptions, such as notes on the prescriptions, or lack thereof where there should be notes, suspicious drug, strength, and quantity. Specifically, the following red flags were noted:

a. All forty (40) methadone prescriptions were written by the Nurse Practitioner and there is a misleading heading on each paper prescription stating "Dr. [Nurse Practitioner] CRNP, DNP, FNP, B-C." The Nurse Practitioner, however, is not a medical doctor or a licensed physician.

b. Thirty-nine (39) of the forty (40) methadone prescriptions are written on prescription pads from the Nurse Practitioner's Office, which lists two different locations for the practice. However, for thirty-six (36) out of those thirty-nine (39) prescriptions, there is no indication of which location the patient was seen.

c. One (1) of the prescriptions is written on a prescription pad for a second practice ("Nurse Practitioner Office #2"), which also lists the Nurse Practitioner as the prescribing provider. This prescription lists three (3) different practice locations but does not indicate which location of the practice the patient was seen at. The prescription also inaccurately lists the Nurse Practitioner's NPI number as the license number. The license number is not listed anywhere on the prescription.

d. Each prescription contains a handwritten note stating either "picked up from MD" or "picked up from MD's office" however the Nurse Practitioner is not an MD.

e. Delivering the medications to the Nurse Practitioner's Office and Nurse Practitioner Office #2 where the office staff signed for the methadone and then partially administer it to the patient while storing the patients' medication onsite at the office "is a [violation] according to COMAR 10.19.03.08D(1) and (3) and 21 CFR § 290.5."

f. "Best practices for a pharmacist include calling practitioners to verify Rxs when they appear different from normal, have information printed at the top that may be incorrect (NPI is incorrectly identified as the license number) or do not indicate at which location the patient was seen. Included in doing their due diligence and best practices, the pharmacist should be calling the practitioner office to determine location where patient was seen and then documenting the call and correct location on the Rx itself. Further, under COMAR 10.19.03.07C(1) and 21 CFR 1306.04(a), pharmacists have a corresponding responsibility to ensure all CDS rxs are for a legitimate medical purpose. This includes calling to verify a Rx if it has incorrect information (such as the NPI identified as the license number) which is a red flag possibly indicating it is a suspect fraudulent rx. Therefore, it is a violation of Maryland's state regulation COMAR 10.19.03.07C(1) and Federal regulation 21 CFR 1306.04(a),

when a pharmacist does not ensure that all (100%) of the CDS rxs they fill are for a legitimate medical purpose. This includes calling the prescriber to ensure legitimacy and noting on the paper rx that a call was made (date and time and name of the person they spoke with) to verify legitimacy."

g. Almost all of the methadone prescriptions are for high quantities. Most are for quantities of 210, 240, 270, or 300, while three are for 90, 120, and 126.

h. All of the methadone prescriptions exceeded the daily MME recommended by the U.S. Centers for Disease Control ("CDC").[3] Most of the patients were prescribed 960 to 1200 MMEs per day. "[T]hough the methadone rxs prescribed by [Nurse Practitioner] note they are for chronic pain (methadone prescribed for pain is the only way to prescribe/dispense methadone from a pharmacy, by law), the doses are in the normal range for treating opioid use disorder (60-120mg) and not chronic pain (10-60mg)."[4] "There appears to be a failure on the part of the pharmacist (a trusted and knowledgeable member of the health care

[3] MME is a value assigned to each opioid to represent its relative potency using morphine as the standard comparison. The CDC Guideline uses MME to establish recommended opioid dosing and currently recommends using precaution when prescribing opioids 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.

[4] Methadone used to treat an individual with a confirmed diagnosis of Opioid Use Disorder can only be dispenses through a SAMHSA certified Opioid Treatment Program ("OTP").

team) who has not questioned the doses, contacted the prescriber, and then noted on the Rxs a justification for doses an average of 10 times more than the recommended 90 MME/day, to prevent overdose and death."

i. Many of the methadone prescriptions were for patients in their late 20s or early 30s, this is a red flag. "When this is seen, a call to the prescriber should be made by the pharmacist to verify the prescription is for a legitimate medical purpose." The pharmacist is "to document any interaction and information obtained from the prescriber but there are no notation's on the rx copies regarding any calls to the prescriber."

j. One of the methadone prescriptions has a patient's address handwritten on the front of the prescription as "MDs office" and "Picked up from MD" is also handwritten on the top corner. On the back of the prescription, on the pharmacy label, the patient's address is listed as one of the locations for the Nurse Practitioner's Office.

k. The prescriptions for Patient 13 had numerous red flags: young age (early 30s), long distance (lives approximately 75 miles from the Nurse Practitioner's Office and the Respondent-Pharmacy), high dose and quantity of methadone prescriptions (1200 MMEs daily), and payment (a discount card with $0 copay).

10. On March 13, 2019, the Chief of the Enforcement Division for OCSA conducted a red flag inspection of the Respondent-Pharmacy. During the inspection, the inspector noted the following concerns:

a. There was no biennial inventory taken since the opening inventory on December 12, 2016.

b. Out of 159 Schedule II CDS prescriptions, 89% had red flags including: cash, high strength/quantity, out of state patients, in-state prescriber long distance, and patients under 40 years old.

c. "OCSA pharmacist inspectors inquired about payment of prescriptions written by [the Nurse Practitioner]. We were told again that prescriptions were filled and delivered to the physician's address (not the address on prescriptions but the address given to us by the pharmacist) and sometimes they are signed for by the secretary and paid for by [the Nurse Practitioner]. Spoke to the pharmacist about this on 1/19/18 and again today, 3/13/19, about filled patient prescriptions not going to the end user but to the office staff."

d. "OCSA performed a regulatory and red flag inspection on 1/19/18. During this time an abundant amount of education was given especially in regards to red flags. Despite the amount of education given there continues to be red flags observed. In actuality since our last visit on 1/19/18, the amount of red flags has increased. Please keep in mind that a pharmacist has a corresponding responsibility to ensure every CDS

prescription is written for a legitimate medical purpose. Also, please look for red flags when filling a CDS prescription as they can indicate the prescription may not be written for a legitimate medical purpose."

e. "Please remember that patients filled prescriptions are to be given to them directly not to their prescriber the office start of the prescriber."

11. On May 28, 2019, the Board Inspector and the Board Inspector Supervisor conducted an annual inspection of the Respondent-Pharmacy and noted:

a. The Pharmacist-Owner could not provide two consecutive years of having received annual training on medication errors.

b. The Respondent-Pharmacy was still filling and delivering methadone in blister packs to the Nurse Practitioner's Office.[5] The address listed on the electronic prescriptions did not match the address listed for the Nurse Practitioner's Office listed on the back tag label.

c. One Schedule II[6] CDS revealed that the physician address on the hardcopy prescription did not match the address on the pharmacy back tag label.

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[5] According to the Pharmacist-Owner, the blister cards are delivered to the patient, physician or secretary immediately, while the patient is still at the physician's office. The physician does not give the patient all the methadone supply for 30 days if the patient is being titrated off. Only 2 weeks of the methadone are dispensed at a time, and the patient has to go to the physician for the other 2 weeks that have been filled by the pharmacy and left at the physician's office.

[6] A Schedule II medication "consists of each controlled dangerous substance: (1) listed in [Md. Code Ann., Crim. Law § 5-403]; (2) added to Schedule II by the Department under § 5-202(b) of [Title 5 of the Criminal Law Article]; or (3) designated as a Schedule II controlled dangerous substance by the federal government unless the Department objects under § 5-202(f) of [Title 5 of the Criminal Law Article]." Md. Code Ann.,

d. There were five outdated medications in the pharmacy area, one return to stock vial without an expiration date, and four medications about to expire in May 2019.

e. Forty-five (45) Schedule II CDS prescriptions were reviewed and revealed:

   i. Four (4) were for methadone and were paid for in cash;

   ii. Four (4) prescriptions revealed that the prescriber and the patient were located an usually far distance from one another;

   iii. Two (2) prescriptions were for a high quantity of methadone (e.g., 180 and 240 tablets, respectively), and were paid for in cash.

f. Schedule III and V prescriptions[7] were mixed in with the regular prescriptions, and one prescription for Suboxone did not have the DEA X registration number for the prescription on the electronic prescription and on the back tag label.

g. The Respondent-Pharmacy did not have running hot water, but the Respondent-Pharmacy contacted a repair company and had the hot water fixed later that day.

Crim. Law § 5-403(a). Schedule II substances include opiate substances such as oxycodone and hydrocodone, which are highly addictive. Crim. Law § 5-403(b).

[7] Schedule III - V controlled dangerous substances are set forth in Md. Code Ann., Crim. Law §§ 5- 404 and 5-405 and are highly addictive.

h. After the inspection was completed and signed by the Pharmacist-Owner, the Pharmacist-Owner stated that the methadone prescriptions paid for in cash were paid by the physician because the patient could not afford the prescriptions.

12. On August 23, 2019, 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 from June 9, 2018 to August 21, 2019. The Board received copies of the prescriptions on September 6, 2019.

13. On October 16, 2019, 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 January 1, 2017 to August 21, 2019. On or about February 3, 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. There were a total of 2,212 prescriptions reported to PDMP by the Respondent-Pharmacy from January 1, 2017 to August 21, 2019.

b. Of the 2,212 CDS prescriptions dispensed, 994 (45%) were prescribed by the Nurse Practitioner. The prescriptions issued by the Nurse Practitioner were primarily for Suboxone and methadone.

c. There were some patients who were dispensed both methadone and Suboxone at different times from the Nurse Practitioner.[8]

d. Of the 2,212 CDS prescriptions dispensed, 611 (28%) were for high dose immediate-release opioid medications. These prescriptions were usually dispensed in quantities of 90 tablets or greater as a month's supply. Most of the opioid prescriptions had daily dosages equivalent to or exceeding 90 milligrams of morphine equivalents ("MME"). The methadone prescriptions had dosages in ranges of 320 MME to 1,200 MME daily.[9]

e. Of the 2,212 CDS prescriptions dispensed, only one prescription was for a long acting opioid.

f. Many of the patients receiving chronic high dose opioids from the Respondent-Pharmacy were between 30 and 40 years old.

g. Many patients received prescriptions for both opioids and benzodiazepines written by the same prescriber and dispensed at the Respondent-Pharmacy.

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[8] Suboxone is indicated for treatment of opioid abuse. Methadone may only be used for opioid abuse treatment in a clinic setting and is only appropriate and legal to prescribe for dispensing from a pharmacy for the treatment of pain by an appropriate provider.

[9] 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.

14. On June 26, 2020, the Board Inspector conducted an annual inspection of the Respondent-Pharmacy. During the inspection, the inspector noted the following:

a. The Pharmacy "blister packs medications for 1 or 2 independent patients as a courtesy to help with medication management. This pharmacy blister packs methadone for 1 patient when the prescription is sent to the pharmacy. This pharmacy offers a delivery service to patients and will deliver directly to the patients home residence or deliver medications to 1 patient while the patient is at [the Nurse Practitioner's] office; was informed by the pharmacist that all patients sign a delivery log when the medications is delivered to patient (home residence or at [the Nurse Practitioner's] Office)."

15. On October 1, 2020, the Board Inspector conducted a follow-up inspection to conduct a narcotic audit. The following discrepancies were noted:

a. There were two (2) additional Hydromorphone 8 mg tablets in inventory than had been prescribed for dispensing;

b. There were 36 additional Oxycodone 5 mg tablets in inventory; and

c. There was a shortage of 2,110 tablets of Methadone 10 mg.

16. On May 17, 2022, a Board Inspector ("Board Inspector #2") conducted an annual inspection of the Respondent-Pharmacy and noted the following:

a. The Respondent-Pharmacy was not clean and orderly.

b. Schedule II CDS medications were stored in various cardboard boxes throughout the Respondent-Pharmacy. When asked to count the four

Schedule II CDS medications for the narcotic audit, it was observed that the generic Adderall tablets were removed from a cardboard box.

c. During the audit of four (4) Schedule II CDS medications, a discrepancy was found between the on-hand inventory and the perpetual inventory for Oxycodone 15 mg tablets. The Pharmacist-Owner explained that two prescriptions had not yet been added to the perpetual log book and that those quantities were mistakenly added to the perpetual inventory.

d. A dispensing report for all CDS from May 11, 2022 to May 17, 2022, was provided after the inspection. None of the prescriber X DEA numbers were associated with the appropriate prescriptions on the dispensing report.

e. The Pharmacist-Owner reported that the pharmacy no longer blister packs as a courtesy to patients, but will deliver as a courtesy.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law the following:

By filling prescriptions that displayed numerous red flags and/or were likely fraudulent, the Respondent-Pharmacy filled prescriptions that were not issued for a legitimate medical purpose in violation of Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(A)(2), and/or 10.34.10.01(B)(1)-(3), and/or COMAR 10.19.03.07(B)(1)(a) and/or 10.19.03.07(b), and/or 10.19.03.07(C)(1).

By dispensing methadone to staff at the Nurse Practitioner's Office and/or dispensing medication that exceeds the recommended MME, the Respondent-Pharmacy dispensed narcotic drugs for both detoxification treatment and/or pain treatment, and dispensed Methadone in a non-clinic setting, in violation of COMAR 10.19.03.07(C)(3), § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(A)(2), and/or 10.34.10.01(B)(1)-(3).

By failing to create and/or maintain a record of the quantity of CDS ordered and date received, the Respondent-Pharmacy violated Health Occ.§ 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(B)(1).

By failing to accurately document the prescribing practitioner's address on all of the back tag labels and on the prescriptions, the Respondent-Pharmacy violated Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(B)(1), and/or COMAR 10.19.03.08(D)(1).

The Respondent-Pharmacy filled prescriptions which included inaccuracies or missing information, as set forth herein, and thus committed violations of Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(A)(2), and/or 10.34.10.01(B)(1)-(3), and/or COMAR 10.19.03.07(B)(1).

By dispensing a greater amount of Schedule II CDS than prescribed, on more than one occasion, the Respondent-Pharmacy violated §§ 12-403(c)(1), 12-403(c)(1)(9), 12-

409(a)(1)-(3), and/or 12-313(b)(25), COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(B)(1)-(3), and/or COMAR 10.19.03.08(A)(1).

By continuing to fill prescriptions including obvious red flags, despite being instructed on at least three occasion that the Respondent-Pharmacy has a corresponding responsibility to ensure all prescriptions filled are for a legitimate medical purpose, the Respondent-Pharmacy violated Health Occ. § 12-403(c)(1) and/or 12-403(c)(9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(A)(2), and/or 10.34.10.01(B)(1)-(3), and/or COMAR 10.19.03.07(C)(1).

By failing to create and maintain invoices for the transfer of CDS between pharmacies, the Respondent-Pharmacy violated Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(B)(1)-(3).

By filling multiple prescriptions written on one paper prescription, the Respondent-Pharmacy violated Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or (B)(1)-(3), and/or COMAR 10.19.03.08(A)(1), and/or COMAR 10.19.03.09(A)(1).

By failing to maintain an accurate count of Schedule II CDS and failing to accurately account for over 15 missing bottles of promethazine, the Respondent-Pharmacy violated Health Occ.§ 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1) and/or 10.34.10.01(B)(1)-(3).

By maintaining the temperature of the pharmacy at 80^0F, not having running hot water, and not maintaining the cleanliness of the pharmacy, the Respondent-Pharmacy

violated Health Occ. § 12-403(c)(1), (c)(2), (c)(9), (c)(11)(1)-(2), (c)(11)(ii)(2), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or COMAR 10.34.10.01(A)(1).

By repeatedly blister packing methadone and delivering the blister packs to the staff at the Nurse Practitioner's Office for the staff to distribute to patients, the Respondent-Pharmacy engaged in wholesale distribution without a permit, in violation of Health Occ. § 12-403(c)(1) and/or (9), and/or § 12-409(a)(1)-(3), and/or § 12-313(b)(25), and/or § 12-6C-03(a), and/or COMAR 10.34.10.01(A)(1) and/or (B)(1)-(3), and/or COMAR 10.19.03.08(D)(1) and (3), and/or COMAR 10.34.37.03(A)(1).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 8th day of December 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 **THREE (3) 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 obtain quarterly reports from the prescription drug monitoring program (PDMP) for the Respondent-Pharmacy;

3. 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;

4. During the period of probation, the Respondent-Pharmacy shall be monitored by a Board-approved supervisor;

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

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

7. 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) and calculations of morphine milligram equivalents (MME);

8. 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;

9. After **THREE (3) 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 19-061 – Gwynn Oak 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).

12-8-22
Date

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

CONSENT

I, Oluwayomi Akinbodi, owner of Gwynn Oak 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 Gwynn Oak Pharmacy, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Gwynn Oak 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 Gwynn Oak 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 Gwynn Oak 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 Gwynn Oak Pharmacy and understand its meaning and effect.

12/5/22

Date

Oluwayomi Akinbode, Owner
Gwynn Oak Pharmacy

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Baltimore

I hereby certify that on this 5th day of December 2022, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **Oluwayomi Akinbode**, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

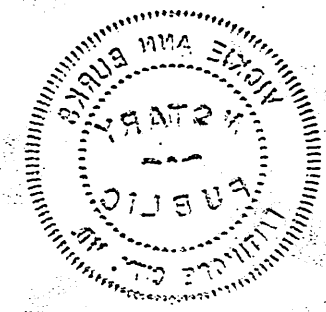
AS WITNESSETH my hand and notarial seal.

Vickie Ann Burks

Notary Public

VICKIE ANN BURKS
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires October 23, 2023

My Commission Expires: Oct 23, 2023


VICKIE ANN BURKE
NOTARY
PUBLIC