IN THE MATTER OF	*	**BEFORE THE MARYLAND**
JOHN ANTHONY WOLK **License Number: 09874**	*	**STATE BOARD OF**
	*	**PHARMACY**
AUSTIN PHARMACY **Permit Number: P01511**	*	
AUSTIN PHARMACY & MEDICAL SUPPLIES **Permit Number: P05668**	*	
The Respondents	*	**Case Number: 19-403**

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

CONSENT ORDER

On or about July 15, 2020, the Maryland State Board of Pharmacy (the "Board") charged: John Anthony Wolk, Pharmacist (License Number: 09874); Austin Pharmacy (Permit Number: P01511); and Austin Pharmacy & Medical Supplies (Permit Number: P05668) (the "Respondents") with violations of the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occupations ("Health Occ.") §§ 12-101 *et seq*. (2014 Repl. Vol. and 2019 Supp.) and the regulations adopted by the Board at Code of Md. Regs. ("COMAR") 10.34.01 *et seq*. The Charges issued to each Respondent are attached and incorporated into this Consent Order as Attachments 1, 2, and 3.

On September 16, 2020, a Case Resolution Conference ("CRC") was held via teleconference. As a resolution of this case, the Respondent agreed to enter into this Consent Order.

FINDINGS OF FACT

1. The Board hereby adopts the "Allegations of Fact" sections of the Charges (Attachments 1, 2, and 3) as findings of fact with respect to each respective Respondent.

2. In addition, the Board finds that the Respondents have ceased the practice of sterile compounding of any prescription drugs.

CONCLUSIONS OF LAW

The Board hereby concludes as a matter of law that Respondents' conduct, as described in the Findings of Fact, constitutes violations of the Act as cited in the "Grounds for Discipline" sections of the Charges (Attachments 1, 2, and 3) with respect to each respective Respondent.

ORDER

Based on the foregoing, it is by the Board hereby:

ORDERED that Mr. Wolk is REPRIMANDED; and it is further

ORDERED that from the effective date of this Consent Order, the Respondents shall be placed on PROBATION for a minimum period of ONE (1) YEAR, and continuing until the following terms and conditions are satisfied:

1. The Respondents shall immediately remediate all compliance issues raised in the three sets of charges issued in this case;

2. During the probationary period, each quarter a Board-assigned inspector shall conduct an unannounced inspection of one of the Respondent Pharmacies. (Therefore, each Respondent Pharmacy shall be inspected twice per year.) The inspections shall include an examination of the Respondents' updated manuals, policies, and processes that reflect remediation efforts undertaken pursuant to this Consent Order (including the requirement that only licensed

pharmacists may have access to the Pharmacy area). The Board-assigned inspector shall provide inspection reports to the Board within ten (10) business days of the date of each inspection and may consult with the Board regarding the findings of the inspections;

3. The Respondents are fined in the total amount of $10,000 (TEN THOUSAND DOLLARS), of which $5,000 (FIVE THOUSAND DOLLARS) is immediately STAYED, pending the successful completion of the terms of the Consent Order, and waived permanently upon successful completion of probation. The remaining $5,000 (FIVE THOUSAND DOLLARS) is due within 90 (ninety) calendar days of the execution of the Consent Order;

4. Within 90 (ninety) calendar days of the execution of the Consent Order, Mr. Wolk shall submit documentation to the Board that he has successfully completed a Board-approved in-person (or, if in-person courses are not practicable due to the current State of Emergency, then online) two (2) credit hour course in pharmacy ethics, which may not be applied toward his license renewal continuing education requirements; and

5. The Respondents shall, at all times, practice pharmacy and conduct pharmacy operations in accordance with the Maryland Pharmacy Act and related statutes and regulations.

And it is further:

ORDERED that if the Respondents wish to perform sterile compounding of prescription drugs in the future, to include repackaging Lupron kits into different doses, the Respondents shall first successfully complete the following conditions:

A. Mr. Wolk shall submit documentation to the Board that he has successfully completed a Board-approved in-person (or, if in-person courses are not practicable due to the State of Emergency, then online) six (6) credit hour course in USP 797 guidelines for sterile compounding;

B. Mr. Wolk shall provide written notice to the Board that the Respondents intend to perform sterile compounding of prescription drugs and request the appropriate Board inspection of the Respondent's premises; and

C. The Respondents shall be subject to the appropriate Board inspection, which shall demonstrate the Respondents' compliance with USP 797 guidelines for sterile compounding.

And it is further:

ORDERED that the Respondents shall at all times cooperate with the Board, its agents or employees, and with the Board-assigned inspector, in the monitoring, supervision and investigation of the Respondents' compliance with the terms and conditions of this Consent Order; and it is further

ORDERED that the Respondents shall be responsible for all costs incurred under this Consent Order; and it is further

ORDERED that after a minimum of one (1) year from the effective date of this Consent Order, the Respondents may submit a written petition to the Board requesting termination of probation. After consideration of the petition, the probation may be terminated through an order of the Board. The Board shall grant termination if the Respondents have fully and satisfactorily complied with all of the probationary terms and conditions and there are no pending investigations or outstanding complaints related to the findings of fact in this Consent Order; and it is further

ORDERED that if the Respondents allegedly fail to comply with any term or condition of probation or this Consent Order, the Respondents shall be given notice and an opportunity for a hearing. If there is a genuine dispute as to a material fact, the hearing

shall be an evidentiary hearing before the Board. If there is no genuine dispute as to a material fact, the Respondent shall be given a show cause hearing before the Board; and it is further

ORDERED that after the appropriate hearing, if the Board determines that the Respondents have failed to comply with any term or condition of probation or this Consent Order, the Board may impose further disciplinary sanctions on the Respondents, permissible under the Act and the regulations adopted by the Board; and it is further

ORDERED that this document constitutes an Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. Code Ann., General Provisions, §§ 4-101 through 4-601 (Repl. Vol. 2014 & 2019 Supp.).

12-11-2020
Date

Deena Speights-Napata, Exec. Dir.
on behalf of
Kevin Morgan, Board President

CONSENT

By this Consent, I, John Anthony Wolk, on behalf of the Respondents, agree and accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest or seek judicial appeal of the Findings of Fact, Conclusions of Law, or the Order. For purposes of licensure only 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 my own 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 sign this Consent Order after having consulted with counsel, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its effect.

12/7/20
Date

John Anthony Wolk, Pharmacist
On behalf of the Respondents

NOTARY

STATE OF Maryland

CITY/~~COUNTY~~ OF: Baltimore

I HEREBY CERTIFY that on this 7th day of December 2020, before me, a Notary Public of the State and County aforesaid, personally appeared[1] John Anthony Wolk, and gave oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS, my hand and Notary Seal.

BRUCE M. LUCHANSKY
Notary Public-Maryland
Baltimore City
My Commission Expires
7/25/22

Notary Public

My commission expires: 7/25/22

[1] During the current State of Emergency, and in compliance with the Governor's emergency orders, notarization may be accomplished remotely.

ATTACHMENT 1

IN THE MATTER OF	*	**BEFORE THE**
JOHN ANTHONY WOLK	*	**MARYLAND BOARD**
LICENSE No: 09874	*	**OF PHARMACY**
Respondent	*	**Case No.: 19-403**

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

CHARGES UNDER THE MARYLAND PHARMACY ACT

The Maryland Board of Pharmacy ("the Board") hereby charges **JOHN ANTHONY WOLK** (the "Respondent"), License Number **09874**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.) and certain provisions of the Board's regulations found at Md. Code Regs. ("COMAR").[1]

The pertinent provisions of the Act provide as follows:

§ 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 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:

. . . .

(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;

[1] Further, the Board's Regulations incorporate by reference the standards set forth in publication United States Pharmacopeia publication 797 ("USP 797") and United States Pharmacopeia publication 795 ("USP 795"). *See* COMAR 10.34.19.02(A)-(B).

. . . .

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

§ 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) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

. . . .

(23) Subject to § 12-510 of this title, may provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian who intends to dispense the compounded nonsterile preparations or compounded sterile preparations in accordance with § 2-313(c) of the Agriculture Article.

§ 12-6C-03. Permit required.

(a) A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution[2] in the State.

The pertinent provisions of COMAR 10.34 and COMAR 10.19.03 provide as follows:

COMAR 10.34.05.02. Prescription Area.

A. The pharmacy permit holder shall:

. . . .

(2) Provide a means of securing the prescription area;

(3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services;

. . . .

(5) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.

B. The pharmacist shall:

(1) Secure the prescription area and its contents in order that the pharmacy permit holder or the pharmacy permit holder's agent may:

(a) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

(b) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open;

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[2] "Wholesale distribution" means "the distribution of prescription drugs or prescription devices to persons other than a consumer or patient." Md. Code Ann., Health Occ. § 12-6C-01(u)(1).

(2) Have sole possession of a means of access to the pharmacy, except in emergencies[.]

COMAR 10.34.05.05. Security Responsibility.

A. The pharmacy permit holder is responsible for ensuring that pharmacists, employees, and others who enter the pharmacy:

(1) Know and abide by the requirements of this chapter;

(2) Maintain those measures necessary to ensure this chapter's enforcement[.]

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:

. . . .

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code of Maryland;

. . . .

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

. . . .

(3) Engage in unprofessional conduct.

COMAR 10.19.03.08. Controlled Substances Listed in Schedule II.

. . . .

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.

The pertinent provisions of Health-General Article provide as follows:

Md Code, Health - General, § 21-221. Prescription drug labeling.

(a) A drug that is dispensed under a prescription shall bear a label that states:

. . . .

(4) The name of the prescriber[.]

ALLEGATIONS OF FACT[3]

The Board bases these charges on the following facts that it has reason to believe are true:

1. At all times relevant hereto, a corporation operated by the Respondent, a pharmacist (hereinafter the "Respondent Pharmacist-Owner"), owned and operated two

[3] The allegations set forth in this document are intended to provide the Respondent with notice of the alleged charges. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent in connection with these charges.

pharmacies with locations in Baltimore County, Maryland ("Respondent-Pharmacy #1" and "Respondent-Pharmacy #2").[4]

2. At all times relevant hereto, the Respondent Pharmacist-Owner had a license to practice pharmacy in the State of Maryland under license number 09874. The Respondent Pharmacist-Owner was originally licensed on or about July 27, 1982. The Respondent Pharmacist-Owner's license expires on July 31, 2020.

3. At all times relevant hereto, Respondent-Pharmacy #1 had a permit to operate as a pharmacy in the State of Maryland. Respondent-Pharmacy #1 was originally issued a permit on or about July 17, 1989. Respondent-Pharmacy #1's permit expires on May 31, 2020.

4. At all times relevant hereto, Respondent-Pharmacy #2 had a permit to operate as a pharmacy in the State of Maryland. Respondent-Pharmacy #2 was originally issued a permit on or about March 30, 2012. Respondent-Pharmacy #2's permit expires on May 31, 2020.

5. At all times relevant, neither Respondent-Pharmacy #1 nor Respondent-Pharmacy #2 has held a permit to practice sterile compounding.

6. On or about June 18, 2019, the Board received a complaint involving Respondent-Pharmacy #1, Respondent-Pharmacy #2, and the Respondent Pharmacist-Owner, which alleged the Respondent Pharmacist-Owner and the pharmacies engage in

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

the unlicensed practice of sterile compounding, and all staff, including non-pharmacists, have access to the pharmacies via keys and alarm codes.

7. On July 24, 2019, Board inspectors ("Board Inspector #1" and "Board Inspector #2") conducted annual inspections of Respondent-Pharmacy #1 and Respondent-Pharmacy #2.

8. The inspection conducted by Board Inspector #1 of Respondent-Pharmacy #1 revealed the following:

a. Respondent-Pharmacy #1 does not perform sterile compounding, but does perform non-sterile compounding.

b. Unlicensed personnel had access to the pharmacy only when a pharmacist is present.

c. Viagra 25mg suppositories were stored in the refrigerator. The suppositories were made at Respondent-Pharmacy #2, not Respondent-Pharmacy #1, however, Respondent-Pharmacy #1 did not have compounding logs nor did they have prescription orders available – the suppositories were received in anticipatory batching.

d. Respondent-Pharmacy #1 does not maintain a perpetual inventory of Schedule II CDS.

e. A review of the Schedule II CDS revealed discrepancies between the prescriptions and the pharmacy's labels, including: three prescriptions were not filled under the prescribing physician and three prescriptions

had a doctor's address that did not match the address on the pharmacy's label.

9. The inspection conducted by Board Inspector #2 of Respondent-Pharmacy #2 revealed the following:

a. Respondent-Pharmacy #2 does not perform sterile compounding, but does perform non-sterile compounding.

b. A NuAire hood was present in the pharmacy that the pharmacist stated was not in use.

c. The pharmacy area does not have the same hours as the store front. The store front shares the same alarm system as the pharmacy area. There are three doors to access the pharmacy area – one door leads to the store front, one door leads to the stock room, and one door leads to the nurse's office. All three doors with access to the pharmacy area have locks on the outside of the doors, however, Board Inspector #2 observed a nurse enter the pharmacy area with a key.[5] Board Inspector #2 noted that she asked the pharmacy manager how she ensures unlicensed personnel (*e.g.*, nurses) were not in the pharmacy area when the pharmacy was closed if unlicensed personnel had keys, however, the pharmacy manager "could not answer the question."

[5] The pharmacist reported that the nurses do not perform pharmacy duties.

d. Two outdated medications were discovered in the inventory and were pulled during the inspection.

e. Expired vaccines were observed in the crisper compartment of the medication refrigerator and a box of expired Schedule II CDS was observed on the floor of the pharmacy.

10. Respondent-Pharmacy #1 provided the Board with a written response to the allegations contained in the complaint. In their written response, Respondent-Pharmacy #1 stated, in part: 1) "[s]taff have access to the pharmacy area where medications are stored only when a licensed pharmacist is on duty;" 2) the store manager has a key to access the main business area in case of emergency but in the last ten years she has not had to enter the building without a pharmacist being present; and 3) "[s]everal years ago, on a few occasions when we used a laminar flow hood, we did compound microdose leupron trigger shots. Compounding regulations have changed since then and there is no compounding of microdose leŭpron to any extent today. In fact, we have no compounding services in this locations."

11. As part of the Board's investigation, the Board issued subpoenas to Respondent-Pharmacy #1 requiring them to submit to the Board, copies of "any purchasing, compounding, and prescription records for any Lupron filled, compounded or purchased by [Respondent-Pharmacy #1] and [Respondent-Pharmacy #2] from July 24, 2014, to date" and "[c]opies of all hard copy prescriptions for any Lupron dispensed/sold by [Respondent-Pharmacy #1] and [Respondent-Pharmacy #2], from January 2018, to date."

12. In response to the Board's subpoenas, the Respondent Pharmacist-Owner, Respondent-Pharmacy #1, and Respondent-Pharmacy #2, submitted copies of dispensing records, purchase records, and prescriptions, which revealed the following:

a. The purchasing records revealed the only Lupron[6] medications the pharmacies purchased from 2017 to 2019 were leuprolide 2wk 14 mg/2.8 ml kits and leuprolide 1 mg/2 ml 14 days MDV kits.

b. From 2017-2019, the Respondent Pharmacist-Owner and the pharmacies dispensed several prescriptions for Lupron, including, but not limited to, Leuprolide two week kits, Leuprolide triggers, and Leuprolide microdoses.

c. A comparison of the hardcopy prescriptions and the dispensing records revealed for numerous cases, the Respondent dispensed a different dose to patients than had been prescribed to the patients.

d. In numerous other cases, the Respondent dispensed to patients a different dose than what it had purchased from the wholesaler, indicating that the Respondent was engaging in non-permitted sterile compounding.

[6] Leuprolide (brand name Lupron) is a synthetic gonadotropin-releasing hormone that is often prescribed for prostate cancer, endometriosis, precocious puberty, as well as in vitro fertilization (IVF) cycles. In IVF, leuprolide is prescribed as either 1) a two-week kit containing a 2.8 ml multi-dose vial of leuprolide and 14 disposable syringes for daily subcutaneous injection, 2) microdoses, or 3) a single-dose trigger. When a pharmacy dispenses microdoses or a single-dose trigger, the pharmacy engages in sterile compounding by taking the full-strength leuprolide and diluting it to the strength and volume specified by a physician.

e. For example, on January 19, 2018, a physician prescribed a patient Lupron trigger 4 mg; however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL. Then, on January 31, 2018, a physician prescribed a patient Lupron Microdose 50 mcg/0.2 cc, however, the pharmacy dispensed Leuprolide 4 mg/0.8 mL trigger. A third example occurred on May 13, 2019, when a physician prescribed a patient Lupron Microdose 50 mcg/0.2 mL, however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL.

VIOLATIONS OF THE ACT

13. By violating the following regulations of the Board, the Respondent Pharmacist-Owner violated Health Occ. § 12-313(b)(15) & (25).

14. Pursuant to Health Occ. § 12-313(b)(25), the pertinent violations include the following:

a. By permitting nursing staff to have keys to the nurse's office which leads directly into the pharmacy area, Respondent-Pharmacy #2 permitted unlicensed personnel to have access to the pharmacy area when the pharmacy area was closed and/or while a pharmacist was not immediately available on the premises to provide pharmacy services, consequently, the Respondent Pharmacist-Owner violated COMAR 10.34.10.01(A)(1)(c), COMAR 10.34.05.02(A)(2)-(3), (A)(5), (B)(1)(a)-(b), and (B)(2), and COMAR 10.34.05.05(A)(1)-(2).

b. By receiving Viagra suppositories at Respondent-Pharmacy #1, which were compounded at Respondent-Pharmacy #2, without complying with the required standards governing non-sterile compounding in USP 795, including maintaining compounding logs, the Respondent Pharmacist-Owner violated COMAR 10.34.19.02(B) and COMAR 10.34.10.01(A)(1)(c) and (B)(1).

c. By receiving Viagra suppositories at Respondent-Pharmacy #1, which were compounded at Respondent-Pharmacy #2 without a patient-specific prescription, and without falling into the exceptions delineated in Health Occ. § 12-510, the Respondent Pharmacist-Owner violated COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

d. By dispensing leuprolide trigger and leuprolide microdoses, Respondent-Pharmacy #1, Respondent-Pharmacy #2, and the Respondent Pharmacist-Owner engaged in the practice of sterile compounding without a permit to practice sterile compounding and without complying with the standards set forth in USP 797 governing sterile compounding, and therefore the Respondent Pharmacist-Owner violated COMAR 10.34.19.02(A) and COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

e. By dispensing leuprolide to patients in doses that differed from the doses prescribed, Respondent-Pharmacy #1, Respondent-Pharmacy #2, and the Respondent Pharmacist-Owner engaged in the

practice of sterile compounding without a permit to practice sterile compounding and without complying with the standards set forth in USP 797 governing sterile compounding, and therefore the Respondent Pharmacist-Owner violated COMAR 10.34.19.02(A) and COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

f. By dispensing leuprolide to patients in doses that differed from the doses prescribed, Respondent-Pharmacy #1 Respondent-Pharmacy #2, and the Respondent Pharmacist-Owner violated COMAR 10.34.19.02, COMAR 10.34.10.01(B)(1), and (B)(3).

g. By failing to maintain a perpetual inventory of Schedule II CDS at Respondent-Pharmacy #1, the Respondent Pharmacist-Owner violated COMAR 10.34.10.01(B)(1) and (B)(3).

h. By filling Schedule II CDS under a different physician than was listed on the prescription at Respondent-Pharmacy #1, the Respondent Pharmacist-Owner violated COMAR 10.34.10.01(A)(1)(b), COMAR 10.19.03.08(D)(1), and Health - General, § 21-221(a)(4).

i. By committing the violations described herein, as well as, failing to ensure that employees abide by the requirements of applicable law, the Respondent Pharmacist-Owner violated COMAR 10.34.05.05(A)(1)-(2).

15. By providing compounded non-sterile preparations, specifically Viagra 25 mg suppositories to Resident-Pharmacy #1, which were compounded at Respondent-

Pharmacy #2, without a patient-specific prescription and without falling into the exceptions delineated in Health Occ. § 12-510, the Respondent Pharmacist-Owner violated § 12-403(c)(23) of the Act.

16. By distributing non-sterile compounded medications, specifically Viagra 25 mg suppositories to Resident-Pharmacy #1, which were compounded at Respondent-Pharmacy #2, without a wholesale distributor permit and without qualifying as an exception to the permit requirement, the Respondent Pharmacist-Owner violated § 12-6C-03(a) of the Act.

17. By failing to store prescriptions or nonprescription drugs or devices properly and safely subject to the regulations of the Board at Respondent-Pharmacy #2, including that the pharmacy stored outdated medications, including expired Schedule II CDS, and expired vaccines, the Respondent Pharmacist-Owner violated § 12-403(c)(12) of the Act.

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, the Board finds that the Respondent Pharmacist-Owner has violated the Act, the Board may reprimand, place on probation, suspend, or revoke the Respondent Pharmacist-Owner's pharmacy license pursuant to Health Occ. § 12-313, and/or may impose a monetary penalty pursuant to Health Occ. § 12-314.

NOTICE OF CASE RESOLUTION CONFERENCE[7]

A Case Resolution Conference in this matter is scheduled for Wednesday, September 9, 2020, at 2:00 p.m. at the Board's office, 4201 Patterson Avenue, Baltimore,

[7] Due to the current pandemic, Board hearings may be held remotely by teleconference.

Maryland 21215. If this matter is not resolved on terms accepted by the Board, an evidentiary hearing will be scheduled.

7-15-2020
Date

Deena Speights-Napata, M.A.
Executive Director

For

Kevin Morgan, Pharm.D.
President
Maryland Board of Pharmacy

ATTACHMENT 2

IN THE MATTER OF	*	**BEFORE THE**
AUSTIN PHARMACY	*	**MARYLAND BOARD**
Respondent	*	**OF PHARMACY**
Permit Number: P01511	*	**Case Number: 19-403**

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

CHARGES UNDER THE MARYLAND PHARMACY ACT

The Maryland Board of Pharmacy ("the Board") hereby charges **AUSTIN PHARMACY** (the Respondent, hereinafter "Respondent-Pharmacy #1"), Permit Number **P01511**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.) and the Board's regulations found at Md. Code Regs. ("COMAR") 10.34.01 *et seq.*[1] The pertinent provisions of the Act provide as follows:

Health Occ. § 12-409. Suspensions and revocations – Grounds

(a) In general. -- Subject to the hearing provisions of Section 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 Section 12-403 of this subtitle; or

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

Health Occ. § 12-410. Penalty instead of suspension or in addition to suspension or revocation

[1] Further, the Board's Regulations incorporate by reference the standards set forth in publication United States Pharmacopeia publication 797 ("USP 797") and United States Pharmacopeia publication 795 ("USP 795"). *See* COMAR 10.34.19.02(A)-(B).

(a) Imposition of penalty. -- If after a hearing under Section 12-411 of this subtitle the Board finds that there are grounds under Section 12-409 of this subtitle to suspend or revoke a permit, the Board may impose a penalty not exceeding $10,000:

(1) Instead of suspending the permit; or

(2) In addition to suspending or revoking the permit.

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;

. . . .

(23) Subject to § 12-510 of this title, may provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian who intends to dispense the compounded nonsterile preparations or compounded sterile preparations in accordance with § 2-313(c) of the Agriculture Article.

Health Occ. § 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 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:

. . . .

(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 pertinent provisions of COMAR 10.34 and COMAR 10.19.03 provide as follows:

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:

. . . .

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland;

(c) Health Occupations Article, Title 12, Annotated Code of Maryland;

. . . .

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

. . . .

(3) Engage in unprofessional conduct.

COMAR 10.19.03.08. Controlled Substances Listed in Schedule II.

. . . .

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.

The pertinent provisions of Health-General Article provide as follows:

Md Code, Health - General, § 21-221. Prescription drug labeling.

(a) A drug that is dispensed under a prescription shall bear a label that states:

. . . .

(4) The name of the prescriber[.]

ALLEGATIONS OF FACT[2]

The Board bases these charges on the following facts that it has reason to believe are true:

[2] The allegations set forth in this document are intended to provide the Respondent with reasonable notice of the asserted facts. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent in connection with these charges.

1. At all times relevant hereto, a corporation operated by a pharmacist (the "Pharmacist-Owner")[3] owned and operated two pharmacies with locations in Baltimore County, Maryland ("Respondent-Pharmacy #1" and "Pharmacy #2").

2. At all times relevant hereto, the Pharmacist-Owner had a license to practice pharmacy in the State of Maryland. The Pharmacist-Owner was originally licensed on or about July 27, 1982. The Pharmacist-Owner's license expires on July 31, 2020.

3. At all times relevant hereto, Respondent-Pharmacy #1 had a permit to operate as a pharmacy in the State of Maryland under permit number P01511. Respondent-Pharmacy #1 was originally issued a permit on or about July 17, 1989. Respondent-Pharmacy #1's permit expires on May 31, 2020.

4. At all times relevant hereto, Pharmacy #2 had a permit to operate as a pharmacy in the State of Maryland. Pharmacy #2 was originally issued a permit on or about March 30, 2012. Pharmacy #2's permit expires on May 31, 2020.

5. At all times relevant, neither Respondent-Pharmacy #1 nor Pharmacy #2 has held a permit to practice sterile compounding.

6. On or about June 18, 2019, the Board received a complaint involving Respondent-Pharmacy #1, Pharmacy #2, and the Pharmacist-Owner, which alleged the Pharmacist-Owner and the pharmacies were engaging in the unlicensed practice of sterile

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

compounding. The Complaint also alleged that staff, including non-pharmacists, had independent access to the pharmacies via keys and alarm codes.

7. On or about July 24, 2019, Board inspectors ("Board Inspector #1" and "Board Inspector #2") conducted annual inspections of Respondent-Pharmacy #1 and Pharmacy #2.

8. The inspection Board Inspector #1 of Respondent-Pharmacy #1 conducted revealed the following:

a. Respondent-Pharmacy #1 did not perform sterile compounding, but did perform non-sterile compounding.

b. Unlicensed personnel had access to the pharmacy only when a pharmacist is present.

c. Viagra 25mg suppositories were stored in the refrigerator. The suppositories were made at Pharmacy #2, not Respondent-Pharmacy #1; however, Respondent-Pharmacy #1 did not have compounding logs nor did it have prescription orders available – the suppositories were received in anticipatory batching.

d. Respondent-Pharmacy #1 did not maintain a perpetual inventory of Schedule II Controlled Dangerous Substances ("CDS").

e. A review of the Schedule II CDS revealed discrepancies between the prescriptions and the pharmacy's labels, including: three prescriptions were not filled under the prescribing physician and three prescriptions

had a doctor's address that did not match the address on the pharmacy's label.

9. Respondent-Pharmacy #1 provided the Board with a written response to the allegations contained in the complaint. In its written response, Respondent-Pharmacy #1 stated, in part: 1) "[s]taff have access to the pharmacy area where medications are stored only when a licensed pharmacist is on duty;" 2) the store manager has a key to access the main business area in case of emergency but in the last ten years she has not had to enter the building without a pharmacist being present; and 3) "[s]everal years ago, on a few occasions when we used a laminar flow hood, we did compound microdose leupron trigger shots. Compounding regulations have changed since then and there is no compounding of microdose leupron to any extent today. In fact, we have no compounding services in this locations."

10. As part of the Board's investigation, the Board issued subpoenas to Respondent-Pharmacy #1 requiring them to submit to the Board, copies of "any purchasing, compounding, and prescription records for any Lupron filled, compounded or purchased by [Respondent-Pharmacy #1] and [Pharmacy #2] from July 24, 2014, to date" and "[c]opies of all hard copy prescriptions for any Lupron dispensed/sold by [Respondent-Pharmacy #1] and [Pharmacy #2], from January 2018, to date."

11. In response to the Board's subpoenas, the Pharmacist-Owner, Respondent-Pharmacy #1, and Pharmacy #2, submitted copies of dispensing records, purchase records, and prescriptions, which revealed the following:

a. The purchasing records revealed the only Lupron [4] medications/dosages the pharmacies purchased wholesale from 2017 to 2019 took the form of (1) leuprolide 2wk 14 mg/2.8 ml kits and (2) leuprolide 1 mg/2 ml 14 days MDV kits.

b. From 2017-2019, the Pharmacist-Owner and the pharmacies dispensed several varieties of dosages for Lupron that were different from the dosages they had ordered wholesale, including, but not limited to, the Leuprolide two-week kits, Leuprolide triggers, and Leuprolide microdoses.

c. A comparison of the hardcopy prescriptions and the dispensing records revealed for numerous cases, the Respondent dispensed a different dose to patients than had been prescribed to the patients.

d. In numerous other cases, the Respondent dispensed to patients a different dose than what it had purchased from the wholesaler,

[4] Leuprolide (brand name Lupron) is a synthetic gonadotropin-releasing hormone that is often prescribed for prostate cancer, endometriosis, precocious puberty, as well as *in vitro* fertilization (IVF) cycles. In IVF, leuprolide is prescribed as either 1) a two-week kit containing a 2.8 ml multi-dose vial of leuprolide and 14 disposable syringes for daily subcutaneous injection, 2) microdoses, or 3) a single-dose trigger. When a pharmacy dispenses microdoses or a single-dose trigger, the pharmacy engages in sterile compounding by taking the full-strength leuprolide and diluting it to the strength and volume specified by a physician.

indicating that the Respondent was engaging in non-permitted sterile compounding.

e. For example, on January 19, 2018, a physician prescribed a patient Lupron trigger 4 mg; however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL. Then, on January 31, 2018, a physician prescribed a patient Lupron Microdose 50 mcg/0.2 cc, however, the pharmacy dispensed Leuprolide 4 mg/0.8 mL trigger. A third example occurred on May 13, 2019, when a physician prescribed a patient Lupron Microdose 50 mcg/0.2 mL, however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL.

VIOLATIONS OF THE ACT

12. By engaging in the conduct described above, Respondent-Pharmacy #1 violated Health Occ. § 12-409(1), (2) & (3).

13. Pursuant to Health Occ. § 12-409(2), Respondent-Pharmacy #1 violated Health Occ. § 12-403(c)(1) & (9).

14. Pursuant to Health Occ. § 12-403(c)(9), the Respondent-Pharmacy #1 participated in activities that are grounds for Board action against a licensed pharmacist under Health Occ. § 12-313, specifically Health Occ. § 12-313(b)(15) & (25), as described below in more detail.

a. By receiving Viagra suppositories which were compounded at Pharmacy #2, without complying with the required standards governing non-sterile compounding in USP 795, including

maintaining compounding logs, Respondent-Pharmacy #1 violated COMAR 10.34.19.02(B), COMAR 10.34.10.01(A)(1)(c) and (B)(1).

b. By receiving Viagra suppositories which were compounded at Pharmacy #2 without a patient-specific prescription, and without falling into the exceptions delineated in Health Occ. § 12-510, Respondent-Pharmacy #1 violated COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

c. By dispensing leuprolide trigger and leuprolide microdoses, Respondent-Pharmacy #1 and Pharmacy #2 engaged in the practice of sterile compounding without a permit to practice sterile compounding and without complying with the standards set forth in USP 797 governing sterile compounding, and thereby Respondent-Pharmacy #1 violated COMAR 10.34.19.02(A) and COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

d. By dispensing leuprolide to patients in doses that differed from the doses prescribed, Respondent-Pharmacy #1 violated COMAR 10.34.19.02, COMAR 10.34.10.01(B)(1), and (B)(3).

e. By failing to maintain a perpetual inventory of Schedule II CDS, Respondent-Pharmacy #1 violated COMAR 10.34.10.01(B)(1) and (B)(3).

f. By filling Schedule II CDS under a different physician than was listed on the prescription, Respondent-Pharmacy #1 violated COMAR

10.34.10.01(A)(1)(b), COMAR 10.19.03.08(D)(1), and Health - General § 21-221(a)(4).

15. By participating in activities described herein with Pharmacy #2 and the Pharmacist-Owner, which are grounds for action against the Pharmacist-Owner under Health Occ. § 12-313, including § 12-313(b)(15) & (25), § 12-403(c)(23), COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3), Respondent-Pharmacy #1 violated § 12-403(c)(9) of the Act.

NOTICE OF POSSIBLE SANCTIONS

If, after an evidentiary hearing, the Board finds that Respondent-Pharmacy #1 has violated the Act, the Board may impose a sanction on Respondent-Pharmacy #1's pharmacy permit pursuant to Health Occ. § 12-409 and/or may impose a monetary penalty pursuant to Health Occ. § 12-410.

NOTICE OF CASE RESOLUTION CONFERENCE[5]

A Case Resolution Conference in this matter is scheduled for Wednesday, September 9, 2020, at 12:00 p.m. at the Board's office, 4201 Patterson Avenue, Baltimore,

[5] Due to the current pandemic, Board hearings may be held remotely by teleconference.

Maryland 21215. If this matter is not resolved on terms accepted by the Board, an evidentiary hearing will be scheduled.

7-15-2020
Date

Deena Spelghts-Napata, M.A.
Executive Director

For

Kevin Morgan, Pharm.D.
President
Maryland Board of Pharmacy

ATTACHMENT 3

IN THE MATTER OF	*	**BEFORE THE**
AUSTIN PHARMACY & MEDICAL SUPPLIES	*	**MARYLAND BOARD**
	*	**OF PHARMACY**
Respondent	*	**Case Number: 19-403**
PERMIT Number: P05668		

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

CHARGES UNDER THE MARYLAND PHARMACY ACT

The Maryland Board of Pharmacy ("the Board") hereby charges **AUSTIN PHARMACY & MEDICAL SUPPLIES** ("Respondent-Pharmacy #2"), Permit Number **P05668**, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.) and certain provisions of the Board's regulations found at Md. Code Regs. ("COMAR") 10.34.01 *et seq.*.[1] The pertinent provisions of the Act provide as follows:

Health Occ. § 12-409. Suspensions and revocations – Grounds

(a) In general. -- Subject to the hearing provisions of Section 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 Section 12-403 of this subtitle; or

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

Health Occ. § 12-410. Penalty instead of suspension or in addition to suspension or revocation

[1] Further, the Board's Regulations incorporate by reference the standards set forth in publication United States Pharmacopeia publication 797 ("USP 797") and United States Pharmacopeia publication 795 ("USP 795"). *See* COMAR 10.34.19.02(A)-(B).

(a) Imposition of penalty. -- If after a hearing under Section 12-411 of this subtitle the Board finds that there are grounds under Section 12-409 of this subtitle to suspend or revoke a permit, the Board may impose a penalty not exceeding $10,000:

(1) Instead of suspending the permit; or

(2) In addition to suspending or revoking the permit.

§ 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) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

. . . .

(23) Subject to § 12-510 of this title, may provide compounded nonsterile preparations or compounded sterile preparations without a patient-specific prescription to a licensed veterinarian who intends to dispense the compounded nonsterile preparations or compounded sterile preparations in accordance with § 2-313(c) of the Agriculture Article.

§ 12-6C-03. Permit required.

(a) A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution[2] in the State.

The pertinent provisions of COMAR 10.34 and COMAR 10.19.03 provide as follows:

COMAR 10.34.05.02. Prescription Area.

A. The pharmacy permit holder shall:

. . . .

(2) Provide a means of securing the prescription area;

(3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services;

. . . . .

(5) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.

B. The pharmacist shall:

(1) Secure the prescription area and its contents in order that the pharmacy permit holder or the pharmacy permit holder's agent may:

(a) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

(b) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open;

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[2] "Wholesale distribution" means "the distribution of prescription drugs or prescription devices to persons other than a consumer or patient." Md. Code Ann., Health Occ. § 12-6C-01(u)(1).

(2) Have sole possession of a means of access to the pharmacy, except in emergencies[.]

COMAR 10.34.05.05. Security Responsibility.

A. The pharmacy permit holder is responsible for ensuring that pharmacists, employees, and others who enter the pharmacy:

(1) Know and abide by the requirements of this chapter;

(2) Maintain those measures necessary to ensure this chapter's enforcement[.]

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:

. . . .

(c) Health Occupations Article, Title 12, Annotated Code of Maryland;

. . . .

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

. . . .

(3) Engage in unprofessional conduct.

ALLEGATIONS OF FACT[3]

The Board bases these charges on the following facts that it has reason to believe are true:

1. At all times relevant hereto, a corporation operated by a pharmacist (the "Pharmacist-Owner")[4] owned and operated two pharmacies with locations in Baltimore County, Maryland ("Pharmacy #1" and "Respondent-Pharmacy #2").

2. At all times relevant hereto, the Pharmacist-Owner had a license to practice pharmacy in the State of Maryland. The Pharmacist-Owner was originally licensed on or about July 27, 1982. The Pharmacist-Owner's license expires on July 31, 2020.

3. At all times relevant hereto, Pharmacy #1 had a permit to operate as a pharmacy in the State of Maryland. Pharmacy #1 was originally issued a permit on or about July 17, 1989. Pharmacy #1's permit expires on May 31, 2020.

4. At all times relevant hereto, Respondent-Pharmacy #2 had a permit to operate as a pharmacy in the State of Maryland under permit number P05668. Respondent-Pharmacy #2 was originally issued a permit on or about March 30, 2012. Respondent-Pharmacy #2's permit expires on May 31, 2020.

5. At all times relevant, neither Pharmacy #1 nor Respondent-Pharmacy #2 has held a permit to practice sterile compounding.

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[3] The allegations set forth in this document are intended to provide the Respondent with notice of the alleged charges. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent in connection with these charges.

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

6. On or about June 18, 2019, the Board received a complaint involving Pharmacy #1, Respondent-Pharmacy #2, and the Pharmacist-Owner, which alleged the Pharmacist-Owner and the pharmacies engage in the unlicensed practice of sterile compounding, and all staff, including non-pharmacists, have access to the pharmacies via keys and alarm codes.

7. On July 24, 2019, Board inspectors ("Board Inspector #1" and "Board Inspector #2") conducted annual inspections of Pharmacy #1 and Respondent-Pharmacy #2.

8. The inspection conducted by Board Inspector #1 of Pharmacy #1 revealed the following:

a. Viagra 25mg suppositories were stored in the refrigerator. The suppositories were made at Respondent-Pharmacy #2, not Pharmacy #1, however, Pharmacy #1 did not have compounding logs nor did they have prescription orders available – the suppositories were received in anticipatory batching.

9. The inspection conducted by Board Inspector #2 of Respondent-Pharmacy #2 revealed the following:

a. Respondent-Pharmacy #2 does not perform sterile compounding, but does perform non-sterile compounding.

b. A NuAire hood was present in the pharmacy that the pharmacist stated was not in use.

c. The pharmacy area does not have the same hours as the store front. The store front shares the same alarm system as the pharmacy area. There are three doors to access the pharmacy area – one door leads to the store front, one door leads to the stock room, and one door leads to the nurse's office. All three doors with access to the pharmacy area have locks on the outside of the doors, however, Board Inspector #2 observed a nurse enter the pharmacy area with a key.[5] Board Inspector #2 noted that she asked the pharmacy manager how she ensures unlicensed personnel (*e.g.*, nurses) were not in the pharmacy area when the pharmacy was closed if unlicensed personnel had keys, however, the pharmacy manager "could not answer the question."

d. Two outdated medications were discovered in the inventory and were pulled during the inspection.

e. Expired vaccines were observed in the crisper compartment of the medication refrigerator and a box of expired Schedule II CDS was observed on the floor of the pharmacy.

10. Pharmacy #1 provided the Board with a written response to the allegations contained in the complaint. In their written response, Pharmacy #1 stated, in part: 1) "[s]taff have access to the pharmacy area where medications are stored only when a licensed pharmacist is on duty;" 2) the store manager has a key to access the main business area in

[5] The pharmacist reported that the nurses do not perform pharmacy duties.

case of emergency but in the last ten years she has not had to enter the building without a pharmacist being present; and 3) "[s]everal years ago, on a few occasions when we used a laminar flow hood, we did compound microdose leupron trigger shots. Compounding regulations have changed since then and there is no compounding of microdose leupron to any extent today. In fact, we have no compounding services in this locations."

11. As part of the Board's investigation, the Board issued subpoenas to Pharmacy #1 requiring them to submit to the Board, copies of "any purchasing, compounding, and prescription records for any Lupron filled, compounded or purchased by [Pharmacy #1] and [Respondent-Pharmacy #2] from July 24, 2014, to date" and "[c]opies of all hard copy prescriptions for any Lupron dispensed/sold by [Pharmacy #1] and [Respondent-Pharmacy #2], from January 2018, to date."

12. In response to the Board's subpoenas, the Pharmacist-Owner, Pharmacy #1, and Respondent-Pharmacy #2, submitted copies of dispensing records, purchase records, and prescriptions, which revealed the following:

a. The purchasing records revealed the only Lupron[6] medications the pharmacies purchased from 2017 to 2019 were leuprolide 2wk 14 mg/2.8 ml kits and leuprolide 1 mg/2 ml 14 days MDV kits.

[6] Leuprolide (brand name Lupron) is a synthetic gonadotropin-releasing hormone that is often prescribed for prostate cancer, endometriosis, precocious puberty, as well as in vitro fertilization (IVF) cycles. In IVF, leuprolide is prescribed as either 1) a two-week kit containing a 2.8 ml multi-dose vial of leuprolide and 14 disposable syringes for daily subcutaneous injection, 2) microdoses, or 3) a single-dose trigger. When a pharmacy dispenses microdoses or a single-dose trigger, the pharmacy engages in sterile compounding by taking the full-strength leuprolide and diluting it to the strength and volume specified by a physician.

b. From 2017-2019, the Pharmacist-Owner and the pharmacies dispensed several prescriptions for Lupron, including, but not limited to, Leuprolide two week kits, Leuprolide triggers, and Leuprolide microdoses.

c. A comparison of the hardcopy prescriptions and the dispensing records revealed for numerous cases, the Respondent dispensed a different dose to patients than had been prescribed to the patients.

d. In numerous other cases, the Respondent dispensed to patients a different dose than what it had purchased from the wholesaler, indicating that the Respondent was engaging in non-permitted sterile compounding.

e. For example, on January 19, 2018, a physician prescribed a patient Lupron trigger 4 mg, however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL. Then, on January 31, 2018, a physician prescribed a patient Lupron Microdose 50 mcg/0.2 cc, however, the pharmacy dispensed Leuprolide 4 mg/0.8 mL trigger. A third example occurred on May 13, 2019, when a physician prescribed a patient Lupron Microdose 50 mcg/0.2 mL, however, the pharmacy dispensed Leuprolide 2wk 14 mg/2.8 mL.

VIOLATIONS OF THE ACT

13. By violating the following regulations of the Board, Respondent-Pharmacy #2 violated Health Occ. § 12-409(1), (2) & (3).

14. Pursuant to Health Occ. § 12-409(2), Respondent-Pharmacy #2 violated Health Occ. § 12-403(c)(1) & (9).

15. Pursuant to Health Occ. § 12-403(c)(9), the Respondent-Pharmacy #2 participated in activities that are grounds for Board action against a licensed pharmacist under Health Occ. § 12-313, specifically Health Occ. § 12-313(b)(15) & (25), as described below in more detail.

a. By permitting nursing staff to have keys to the nurse's office which leads directly into the pharmacy area, Respondent-Pharmacy #2 permitted unlicensed personnel to have access to the pharmacy area when the pharmacy area was closed and/or while a pharmacist was not immediately available on the premises to provide pharmacy services, consequently, Respondent-Pharmacy #2 violated COMAR 10.34.10.01(A)(1)(c), COMAR 10.34.05.02(A)(2)-(3), (A)(5), (B)(1)(a)-(b), and (B)(2), and COMAR 10.34.05.05(A)(1)-(2).

b. By compounding and dispensing Viagra suppositories to Pharmacy #1 without a patient-specific prescription, and without falling into the exceptions delineated in Health Occ. § 12-510, Respondent-Pharmacy #2 violated COMAR 10.34.19.02(B), COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

c. By dispensing leuprolide trigger and leuprolide microdoses, Pharmacy #1 and Respondent-Pharmacy #2 engaged in the practice of sterile compounding without a permit to practice sterile compounding

and without complying with the standards set forth in USP 797 governing sterile compounding, and thereby Respondent-Pharmacy #2 violated COMAR 10.34.19.02(A) and COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

d. By dispensing leuprolide to patients in doses that differed from the doses prescribed, Respondent-Pharmacy #2 engaged in the practice of sterile compounding without a permit to practice sterile compounding and without complying with the standards set forth in USP 797 governing sterile compounding, and thereby Respondent-Pharmacy #2 violated COMAR 10.34.19.02(A) and COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3).

e. By dispensing leuprolide to patients in doses that differed from the doses prescribed, Respondent-Pharmacy #2 violated COMAR 10.34.19.02, COMAR 10.34.10.01(B)(1), and (B)(3).

f. By committing the violations described herein, as well as, failing to ensure that employees abide by the requirements of applicable law, Respondent-Pharmacy #2 violated COMAR 10.34.05.05(A)(1)-(2).

16. By providing compounded non-sterile preparations, specifically Viagra 25 mg suppositories to Resident-Pharmacy #1 without a patient-specific prescription and without falling into the exceptions delineated in Health Occ. § 12-510, Respondent-Pharmacy #2 violated § 12-403(c)(23) of the Act.

17. By distributing non-sterile compounded medications, specifically Viagra 25 mg suppositories to Resident-Pharmacy #1 without a wholesale distributor permit and without qualifying as an exception to the permit requirement, Respondent-Pharmacy #2 violated § 12-6C-03(a) of the Act.

18. By failing to store prescriptions or nonprescription drugs or devices properly and safely subject to the regulations of the Board, including that the pharmacy stored outdated medications, including expired Schedule II CDS, and expired vaccines, Respondent-Pharmacy #2 violated § 12-403(c)(12) of the Act.

19. By participating in activities described herein with Pharmacy #1 and the Pharmacist-Owner, which are grounds for action against the Pharmacist-Owner under § 12-313, including § 12-313(b)(25), § 12-403(c)(23), COMAR 10.34.10.01(A)(1)(c), (B)(1), and (B)(3), Respondent-Pharmacy #2 violated § 12-403(c)(9) of the Act.

NOTICE OF POSSIBLE SANCTIONS

If, after an evidentiary hearing, the Board finds that the Respondent-Pharmacy has violated the Act, the Board may impose a sanction on the pharmacy permit pursuant to Health Occ. § 12-409 and/or may impose a monetary penalty pursuant to Health Occ. § 12-410.

NOTICE OF CASE RESOLUTION CONFERENCE[7]

A Case Resolution Conference in this matter is scheduled for Wednesday, September 9, 2020, at 1:00 p.m. at the Board's office, 4201 Patterson Avenue, Baltimore,

[7] Due to the current pandemic, Board hearings may be held remotely by teleconference.

Maryland 21215. If this matter is not resolved on terms accepted by the Board, an evidentiary hearing will be scheduled.

7-15-2020
Date

Deena Speights-Napata, M.A.
Executive Director

For

Kevin Morgan, Pharm.D.
President
Maryland Board of Pharmacy