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| **IN THE MATTER OF** | * | **BEFORE THE** |
| **EAST PINES PHARMACY AND MEDICAL EQUIPMENT** | * | **MARYLAND BOARD** |
| | * | **OF PHARMACY** |
| **PERMIT No: P04821** | * | |
| **Respondent** | | **Case No.: 20-057** |

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**CONSENT ORDER**

On November 20, 2019, the Maryland Board of Pharmacy ("the Board") charged **EAST PINES PHARMACY AND MEDICAL EQUIPMENT** Permit No.: **P04821** ("the Respondent-Pharmacy"), under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.) and the Code of Maryland Regulations ("COMAR").

The Board charged the Respondent-Pharmacy with violating the following provisions of the Act:

**§ 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;

. . . .

(11)(ii) Shall:

1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and

2. Be kept in a clean and orderly manner[.]

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

(13) Shall:

. . . .

(iii) Keep additional records as required by the rules and regulations adopted by the Board;

. . . .

(16) Shall provide such personnel, automation, and technology as are necessary to comply with the labeling requirements specified in § 12-505 of this title[.]

**§ 12-505. Labeling requirements for prescription medications.**

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

(b) In addition to any other information required by law, the label shall include:

. . . .

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices which shall be the lesser of:

1. 1 year from the date of dispensing;

2. The month and year when the drugs or devices expire;

3. The appropriate expiration date for repackaged drugs or devices; or

4. A shorter period as determined by the pharmacist[.]

The Board also charged the Respondent-Pharmacy with violating the following COMAR provisions:

**COMAR 10.34.19.06. Special Handling, Packaging, Labeling, and Beyond Use Dating.**

. . . .

B. The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law:

. . . .

(11) The beyond-use/expiration dating and time of the compounded sterile preparation, and if no time is stated, the time is presumed to be at 11:59 p.m. of the stated beyond use date;

. . . .

D. Expiration or Beyond-Use Dating. In the absence of direct testing evidence, as detailed in the Stability Criteria and Beyond Use Dating section of USP 795 Standards, the pharmacist shall use "beyond-use dating" as determined by USP 797 Standards and reference materials as cited in Regulation .16 of this chapter.

**COMAR 10.34.19.07. Record-Keeping Requirements.**

. . . .

B. Compounded Sterile Preparations Records.

(1) For a pharmacy preparing compounded sterile preparations, the following records shall be maintained for at least 5 years:

(a) The training and competency evaluation of employees in sterile preparation procedures;

(b) Refrigerator and freezer temperatures;

(c) Certification of the sterile compounding environment, including ISO 5 workstations and the clean and anterooms;

(d) Other facility quality control logs specific to the pharmacy's policies and procedures, for example, cleaning logs for facilities and equipment[.]

**COMAR 10.34.19.09. Minimum Facility Requirements.**

A. Controlled Environment.

(1) The pharmacy shall have a controlled environment that meets USP 797 Standards.

. . . .

B. Controlled Environment - Clean Room. The permit holder shall ensure that the clean room in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for clean rooms;

. . . .

C. Controlled Environment - Anteroom. The permit holder shall ensure that the anteroom in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for anterooms[.]

**COMAR 10.34.19.10. Minimum Requirements for Equipment.**

. . . .

B. If used, the permit holder shall provide the following equipment that is maintained in working order, calibrated, or certified where appropriate:

. . . .

(3) Electronic balance;

. . . .

(5) Thermometers or other temperature device; and

(6) Incubator.

**COMAR 10.34.19.11. Minimum Requirements for Supplies.**

A pharmacy engaging in compounding sterile preparations shall maintain adequate stock levels of the following supplies according to USP 797 Standards, including but not limited to:

. . . .

C. Disinfectant cleaning agents as specified in USP 797 Standards, including 70 percent sterile isopropyl alcohol;

. . . .

E. Hand washing materials, including antimicrobial skin cleanser;

. . . .

G. Supplies necessary for the aseptic preparation of compounded sterile preparations[.]

**COMAR 10.34.19.12. Minimum Requirements for Policies and Procedures.**

A. The permit holder shall ensure that the pharmacist or the pharmacist's designee shall maintain a policy and procedure manual, reviewed annually, that sets forth in detail the permit holder's standard operating procedures with regard to compounding sterile preparations.

**COMAR 10.34.19.14. Training of Staff, Patient, and Caregiver.**

. . . .

B. The permit holder shall ensure that pharmacy personnel engaging in compounding sterile preparations are trained and demonstrate competence in the safe handling and compounding of compounded sterile preparations and parenteral solutions, including cytotoxic

agents if applicable.

. . . .

D. The permit holder shall ensure the continuing competence of pharmacy personnel engaged in compounding sterile preparations.

E. A pharmacy that compounds sterile preparations shall comply with the following training requirements:

(1) The pharmacy shall establish and follow a written program of training and performance evaluation designed to ensure that individuals working in the designated area have the knowledge and skills necessary to perform the assigned tasks properly and include at least the following:

(a) Aseptic technique with media fill verification at a frequency defined by risk level as described in USP 797 Standards:

(i) 12 months for low and medium risk; and

(ii) 6 months for high risk;

(b) Pharmaceutical calculations and terminology;

(c) Compounding sterile preparation documentation process;

(d) Quality assurance procedures;

(e) Aseptic preparation procedures;

(f) Proper cleansing, gowning, and gloving techniques;

(g) General conduct in the controlled area;

(h) Cleaning, sanitizing, and maintaining equipment used in the controlled area;

(i) Sterilization techniques for high risk preparations; and

(j) Container, equipment, and closure system selection.

(2) Individuals assigned to the controlled area shall successfully complete practical skills training in aseptic technique and aseptic area practices.

(3) Evaluations shall include:

(a) Written testing;

(b) Observation for adherence to aseptic technique and aseptic area policies and procedures; and

(c) Media fill verification as set forth in §E(1)(a) of this regulation.

**COMAR 10.34.19.15. Quality Assurance.**

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned "beyond use" dating period through a written quality assurance program that includes:

A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;

B. The phases of compounded sterile preparation, distribution, storage, administration, and directions for use for each type of preparation dispensed;

C. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards and if microbial contamination is suspected, for example, in the event of positive media fill verification results;

. . . .

E. Clean room and anteroom certification by a trained and qualified

operator according to USP 797 Standards[.]

**COMAR 10.34.21.03. Duties of the Permit Holder.**

. . . .

B. Ensure that unlicensed personnel:

(1) Receive appropriate training for the tasks that the pharmacist assigns unlicensed personnel to perform in the prescription area;

(2) Receive training that will enable unlicensed personnel to understand how the provisions of Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland, apply to:

(a) Prescription records, and

(b) The requirements for confidentiality of patient specific information; and

(3) When performing tasks in the prescription area, maintain proper:

(a) Sanitation;

(b) Hygiene;

(c) Biohazard precautions; and

(d) Infection control[.]

**COMAR 10.34.26.03. Pharmacy Staff Education.**

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

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

B. Maintain records for a minimum of 2 years:

(1) Verifying completion of education referred to in §A of

this regulation; and

(2) Demonstrating the content of the education.

On January 7, 2020, the Respondent-Pharmacy, along with their attorney, Howard Schulman, Esquire, and the 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.

## I. 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 September 29, 2008. The Respondent-Pharmacy's permit expires on May 31, 2020.

2. At all times relevant, the Respondent-Pharmacy has engaged in low-risk and high-risk sterile compounding.

3. On July 16, 2019, the Board's Surveyor and Board Inspector conducted an annual sterile and community pharmacy inspection of the Respondent-Pharmacy.

4. The inspection revealed the following:

a. The Respondent-Pharmacy was cluttered with boxes of paperwork throughout the pharmacy area.

b. The Respondent-Pharmacy used a dorm-style "mini-fridge" with integrated freezer for storage of sterile medications. The freezer section did not have a thermometer to monitor temperature.

c. Temperatures of the sterile compounding refrigerator were not recorded[1].

d. A bottle of orange juice was found in the sterile compounding refrigerator.

e. Prepared medication that was found in the mini-fridge freezer section was indicated to be refrigerated and the medication did not have a beyond-use-date ("BUD") on the label.

f. There was no documentation of daily calibration of the scale or the incubator in the anteroom.[2]

g. Quality assurance was not documented including, but not limited to, refrigerator/freezer/incubator temperatures, room and hood pressures, cleaning of sterile areas, or annual review of policies and procedures.[3]

h. The anteroom and clean room[4] were not maintained in an aseptic manner. The gowning room was a non-controlled area with dirt/dust on the floor and the tracks for the sliding doors to the anteroom were not cleaned regularly as they appear to have a build-up of debris. The room pressure and hoods were turned off when not in use. Viable air or surface sampling of hoods and clean rooms was not conducted.

i. The Respondent-Pharmacy was not using nail-picks or alcohol-based surgical scrub with immediate and persistent antimicrobial activity.

j. The Respondent-Pharmacy was not using sterile bactericide or a sterile cleaning agent in the hood (The Respondent-Pharmacy was

[1] [1] The Pharmacist-Owner produced documents at the CRC that there was a brief time from July 1, 2019 to July 15, 2019 when temperature was not recorded due to a personnel change but that from July 17, 2019 through December 31, 2019, temperature was recorded.

[2] "Anteroom" means the area, room, or rooms where personnel perform hand hygiene and garbing immediately adjacent to the designated clean room where the compounding of sterile preparations is performed. COMAR 10.34.19.03(B)(3).

[3] The Pharmacist-Owner produced documents at the CRC that the lack of documentation only existed for the period of July 1, 2019 to July 15, 2019.

[4] "Clean room" means a room with an International Standards Organization (ISO) Class 5 environment or an ISO Class 7 environment that meets USP 797 Standards, inside which compounding occurs within an ISO Class 5 engineering control device such as a laminar airflow workstation or a biological safety cabinet. COMAR 10.34.19.03(B)(6).

using sterile alcohol wipes to clean the hood and non-sterile Sporicidin in the hood and clean rooms).

k. A 30-day expiration date was given to all sterile compounded products. Medication labels did not have a BUD. However, at the time of the inspection the pharmacist was working with the label program company to ensure the proper BUD was printed on the label.

l. Documentation of training and competency assessments (e.g., fingertip, media-fill, cleaning, hand hygiene, and garbing) for licensed and unlicensed personnel[5] were not conducted every six months as required for high-risk compounding.

5. During the inspection the following were requested of the Respondent-Pharmacy:

i. Provide the following by July 23, 2019:

i. Proof of purchase of nail-picks, alcohol based surgical scrub with persistent activity, sterile one-step bactericidal cleaner.

ii. Proof of documentation of refrigerator and freezer temperature logs, pressure logs, cleaning logs, and sterile, balance calibration.

ii. Provide the following by July 31, 2019:

i. Proof of sterile compounding training including cleaning, hand hygiene, and garbing competencies, media fill testing, and fingertip testing.

ii. Room and hood certification and environmental testing reports.

6. By email dated July 30, 2019, the Respondent-Pharmacy notified the Board's Surveyor that the Respondent-Pharmacy planned on continuing sterile compounding until

[5] At the time of the inspection the Respondent-Pharmacy employed three pharmacists, two registered technicians, and one unlicensed pharmacy extern. None of these person, however, worked with sterile compounding, except for one pharmacist who left the Respondent's employment on June 29, 2019, leaving only Pharmacist-Owner as the only person working with sterile compounding.

the end of the year 2019, and requested an extension to August 30, 2019, for completion of the testing reports. The Respondent-Pharmacy also attached the following documentation: airflow visualization test certification, balance enclosure certification, airflow tests, HEPA filter integrity tests, particle count tests, compounding aseptic isolator test, chamber pressure tests, airflow smoke pattern test, and the preparation ingress and egress test.

7. By email dated July 31, 2019, the Board's Surveyor granted the Respondent-Pharmacy an extension until August 30, 2019, to provide documentation of sterile training, and reminded the Respondent-Pharmacy that they never submitted the following items which were due July 23, 2019:

a. "Proof of purchase of nail-picks, alcohol based surgical scrub with persistent activity, sterile one-step bactericidal cleaner."

b. "Proof of documentation of refrigerator and freezer temperature logs, pressure logs, cleaning logs, and sterile balance calibration."

8. On August 2, 2019, a packing slip with a ship date of July 31, 2019, and pictures were provided showing the Respondent-Pharmacy purchased a surgical scrub brush with sponge and nail pick, as well as, LpH st sterile disinfectant (one-step bactericidal cleaner).

9. On August 2, 2019, the Respondent-Pharmacy also provided daily monitoring logs for July 16, 2019 through August 2, 2019 showing: refrigerator and freezer temperatures, balance calibration, work area and equipment cleaning, and hood cleaning.

10. On August 26, 2019, the Respondent-Pharmacy provided documentation of media-fill and fingertip testing.[6]

11. By email dated August 28, 2019, the Board's Surveyor reminded the Respondent-Pharmacy that they still needed to submit the following:

a. "Proof-of-purchase of an alcohol based surgical scrub with persistent activity- this is a[n] item like Purell hand sanitizer which has an extra ingredient with the Isopropyl alcohol which remains on your hands to keep the bioburden down. It is to be applied after hand cleansing and before donning gloves."

b. "Daily tracking of the CAI/room pressures."

c. "Training and competencies that cover section 10 in the inspection report. I did receive the media fill and fingertip testing."

d. "Results of the environmental testing. I saw you had it conducted but I need to review the growth report."

12. The Board's Surveyor also informed the Respondent-Pharmacy that the photographs of the media plates submitted by the Respondent-Pharmacy revealed that all four of the plates failed due to having more than two colonies grown.

13. The Respondent-Pharmacy was also notified that they incorrectly performed their fingertip testing. The Board's Surveyor instructed the Respondent-Pharmacy that "[f]ingertip testing should be conducted by gently rolling/pressing the tip of each finger and thumb onto an agar media, all 8 fingers and both thumbs are to be tested. It should be conducted like being fingerprinted."

[6] According to the fingertip testing validation submitted, the two agar plates were streaked using only one finger per hand in violation of standard fingertip testing protocol.

14. On August 29, 2019, Respondent-Pharmacy provided the results of the environmental sampling report, which indicated passing results.

15. A review of the provided materials found that the Respondent-Pharmacy did not purchase alcohol-based surgical scrub with persistent activity, the fingertip testing was performed incorrectly, and the pictures of the media plates revealed excessive microbiological growth. Additionally, documentation of the pressure of the CAI[7]/rooms and semi-annual training and remaining competencies had not been provided. As of the date of this charging document, the Respondent-Pharmacy has not responded to the request for the outstanding items or clarification of the fingertip testing.

16. At the Case Resolution Conference held on January 7, 2020, as well as afterwards, the Respondent-Pharmacy advised the Board that it has ceased filling sterile compound prescriptions. The Respondent-Pharmacy has also provided the Board with documentation showing the following:

a. A photograph of nailpicks and Purell

b. Photographs of fingertip testing plates for tests completed on September 22, 2019 and September 25, 2019, albeit without a description of how the tests were performed

c. documentation of the pressure of the CAI/rooms

d. documentation of completion of training on: 1) Sterile Compounding USP 797 Update on August 29, 2019; 2) Compounding Non-Sterile Topical Medications to Address Topical Infections on February 12, 2019; 3) Essential Elements of Hazardous Drug Compounding on

[7] CAI means "compounding aseptic isolator" which is an enclosed positive or negative pressure environment especially designed for sterile preparation compounding that maintains a physical barrier between the workspace and the operator. COMAR 10.34.19.03(B)(10).

May 12, 2018; 4) Biological Indicators on April 19, 2019; and 5) Sterilization and Depyrogenation on April 22, 2018.

e. clean room Certification Reports dated 7-9-18, 1-17-19 and 7-30-19; BIO Sampling Report dated 7-30-19; Drug Refrigerator and Freezer monitoring log from July 16, 2019 to December 31, 2019; Isolator Hood Pressure log from 7-16-19 to 12-31-19; and Isolator Photo.

f. Respondent's purchase documents demonstrating the Respondent purchased an upright freezer on August 2, 2019. Respondent asserts that the freezer did have an appropriate thermidor.

g. The pharmacy obtained alcohol-based surgical scrub from its own retail pharmacy and thereby did not have purchase receipts.

## II. CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated Health Occ. § 12-403(c)(1)-(2), § 12-403(c)(11)(ii)(1)-(2), § 12-403(c)(12), § 12-403(c)(13)(iii), § 12-403(c)(16), § 12-505(a), § 12-505(b)(2)(i)(1)-(4), COMAR 10.34.19.06(B)(11), COMAR 10.34.19.06(D), COMAR 10.34.19.07(B)(1)(a)-(d), COMAR 10.34.19.09(A)(1), COMAR 10.34.19.09(B)(1), COMAR 10.34.19.09(C)(1), COMAR 10.34.19.10(B)(3), COMAR 10.34.19.10(B)(5)-(6), COMAR 10.34.19.11(C), COMAR 10.34.19.11(E), COMAR 10.34.19.11(G), COMAR 10.34.19.12(A), COMAR 10.34.19.14(B), COMAR 10.34.19.14(D), COMAR 10.34.19.14(E)(1)-(3), COMAR 10.34.19.15(A)-(C), COMAR 10.34.19.15(E), COMAR 10.34.21.03(B)(1)-(3), and COMAR 10.34.26.03(A)-(B).

## III. ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 14th day of February, 2020, 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 shall pay a monetary **fine in the amount of TWO THOUSAND FIVE HUNDRED ($2,500) DOLLARS** within six months 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
7175 Columbia Gateway Drive
Columbia, MD 21046

Please reference Case Number 20-057 on your check or money order to ensure proper assignment to your case; and it is further

**ORDERED** that the Respondent-Pharmacy shall **CEASE AND DESIST** from sterile compounding in Maryland and shall not resume sterile compounding in Maryland unless and until the Respondent-Pharmacy receives an inspection by the Board, or its designee, that demonstrates that the Respondent-Pharmacy is in compliance with all Federal and State laws, as well as properly equipped for sterile compounding, including proof of purchase of alcohol-based surgical scrub with persistent activity, satisfactory fingertip testing, media plate testing with passing results, documentation of the pressure of the CAI/rooms, and documentation of required trainings and competencies; 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; and it is further

**ORDERED** that if the Respondent-Pharmacy resumes sterile compounding in Maryland, it shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to its operation as a pharmacy; and it is further

**ORDERED** that the Respondent-Pharmacy shall bear all cost(s) associated with complying with the Consent Order; and it is further

**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; and it is further

**ORDERED** that 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; and it is further

**ORDERED** that the Consent Order shall be a public document pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq*. (2014).

2-14-2020
Date

Deena Speights-Napata
Executive Director, for
Kevin Morgan, Pharm.D., President
State Board of Pharmacy

## CONSENT

I, Omotayo Awotunde, owner of East Pines Pharmacy and Medical Equipment, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of East Pines Pharmacy and Medical Equipment, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights East Pines Pharmacy and Medical Equipment 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 East Pines Pharmacy and Medical Equipment 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 East Pines Pharmacy and Medical Equipment'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 East Pines Pharmacy and Medical Equipment and understand its meaning and effect.

February 12, 2020
Date

Omotayo Awotunde, Owner
East Pines Pharmacy and Medical Equipment

**NOTARY**

**STATE OF** Maryland

**COUNTY/CITY OF:** Prince George's

**I hereby certify that on this** 12 **day of** February, **2020, before me, a Notary Public of the State of** Maryland **and** County/City aforesaid, **personally appeared Omotayo Awotunde, and made an oath in due form that the foregoing Consent Order was his voluntary act and deed.**

**AS WITNESSETH my hand and notarial seal.**

Notary Public

JERRY C. McCLOUD
MY COMMISSION EXPIRES
NOTARY
PUBLIC
SEPTEMBER 19, 2021
HOWARD COUNTY, MD

**My Commission Expires:** 9/19/2021