IN THE MATTER OF	*	BEFORE THE
JOHN F. VAN WIE, PD	*	STATE BOARD OF
Respondent	*	PHARMACY
License No. 10319	*	CASE NO. 18-006

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

FINAL CONSENT ORDER

The State Board of Pharmacy ("the Board") charged John F. Van Wie, PD ("the Respondent"), license number: 10319 under the Maryland Pharmacy Act (the "Act"), MD. Health Occ. 11 Code Ann ("H.O.") §§ 12-101 et. seq. (2014 Repl. Vol.) and certain provisions of the Board regulations found at Md Code Regs. tit. 10.34 et seq. Specifically, the Board charges the Respondent with violating the following:

H.O. § 12-313. Denials, reprimands, suspensions, and revocations – Grounds.

> (b) Subject to the hearing provisions of §12-315 of this subtitle, the Board, on the affirmative vote of 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:
>
> (25) Violates any rule or regulation adopted by the Board [.]

The Board also charges the Respondent with violating:

> **Code of Md. Regs tit. 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.

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

B. A pharmacist may not:

(3) Engage in unprofessional conduct.

Code of Md. Regs tit. 10, § 34.19[1]

.04 Pharmacy Environment.

The compounding, preparation, and dispensing of compounded sterile preparations shall be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards.

.09 Minimum Facility Requirements.

A. Controlled Environment.

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

(2) A pharmacist shall ensure that the controlled environment is:

(a) Accessible only to designated personnel; and

(b) Used only for the preparation of compounded sterile preparations, or such other task that require a controlled environment.

(3) The permit holder shall ensure that the controlled environment is:

(a) Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and

[1] The Board's Regulations incorporate by reference, the standards set forth in publication United States Pharmacopeia publication 797 ("USP 797").

(b) Air conditioned to maintain a temperature of the controlled environment according to 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;

(2) Contains no sinks or floor drains;

(3) Contains work surfaces constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized;

(4) If cytotoxic agents are routinely used in compounding preparations, contains room or rooms equipped with special pressurization requirements consistent with USP 797 Standards and the national institute for Occupational Safety and Health (NIOSH) Standards;

(5) Has in place appropriate environmental engineering control devices capable of maintaining USP 797 air-quality standards during normal compounding activity; and

(6) Contains the following equipment:

(a) A laminar airflow workstation or other suitable International Standards Organization (ISO) Class 5 compounding equipment;

(b) Waste containers that are approved by Occupational Safety and Health Administration (OSHA) for used needles and syringes, and for chemotherapy waste; and

(c) Ancillary supplies required for proper compounding.

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; and

(2) Contains the following equipment:

(a) A sink with hot and cold running water;

(b) Waste containers for personal protective equipment;

(c) An eyewash station or sink design suitable for flushing an eye injury; and

(d) A hazardous waste spill kit, if applicable.

.10 Minimum Requirements for Equipment.

A. The permit holder shall provide at least the following equipment that is maintained in working order:

(1) Adequate refrigerator and freezer space (if applicable);

(2) A sink and wash area in the anteroom;

(3) Appropriate waste containers for:

(a) used needles and syringes; and

(b) Cytotoxic waste including disposable apparel used in its preparation, if applicable;

(4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;

(5) If applicable to types of preparations compounded, biological safety cabinet, or compounding aseptic isolator that meets USP 797 Standards, dedicated for use with antineoplastics or other hazardous sterile preparations;

(6) Appropriate filters and filtration equipment; and

(7) A device for light/dark field examination.

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

(1) Autoclave;

(2) Automated compounding devices (for example, total parenteral nutrition compounding pumps);

(3) Electric balance;

(4) Convection oven;

(5) Thermometers or other temperature device; and

(6) Incubator.

.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.

B. The permit holder shall insure that the policy and procedure manual that sets forth the standard operating procedures with regard to compounding sterile preparations is implemented and adhered to.

C. The policy and procedure manual shall include policies and procedures governing the following:

(1) A risk-management program which includes documentation of outcomes including, but not limited to:

(a) An incident reporting system;

(b) An adverse drug reaction reporting system; and

(c) A preparation contamination reporting system;

(2) Security measures ensuring that the premises where sterile compounded preparations are stored and prepared are secured, to prevent access by unauthorized personnel;

(3) Equipment including, but not limited to:

(a) Procedures for use;

(b) Documentation of appropriate certifications; and

(c) Documentation of appropriate calibration and preventive maintenance if applicable;

(4) Sanitation standards and procedures including monitoring for bacterial microorganisms to demonstration effectiveness of cleaning activities;

(5) Reference materials as set forth in Regulation .16 of this chapter;

(6) Information concerning drug:

(a) Preparation;

(b) Storage and handling;

(c) Dispensing:

(d) Labeling;

(e) Beyond-use/expiration dating;

(f) Delivery;

(g) Destruction;

(h) Recalls; and

(i) Returns;

(7) Patient record keeping as set forth in Regulation .07 of this Chapter;

(8) Handling, dispensing, and documentation of investigational drugs;

(9) A quality assurance program;

(10) Verification of training and competency guidelines;

(11) Compounding process medical fill verification procedures;

(12) Description of appropriate garb;

(13) Conduct guidelines for personnel in the controlled areas;

(14) Personnel responsibilities;

(15) Patient education, if appropriate;

(16) Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow workstations;

(17) Written procedures as applicable for handling antineoplastic agents and other hazardous substances including:

(a) Utilizing the proper equipment and supplies;

(b) A statement that compounding shall be conducted within a property certified biological safety cabinet or negative pressure compounding aseptic isolator;

(c) Proper use of protective attire; and

(d) Proper techniques to prevent both contamination of the preparation and chemical exposure of the individual preparing the prescription;

(18) Written procedures as applicable for the disposal of infectious materials or materials containing cytotoxic residues, or hazardous waste;

(19) Written documentation of policy and procedure changes based on data gathered from quality assurance evaluations; and

(20) Written documentation of policies and procedures assuring the sterility and stability of compounded sterile preparations.

.13 Attire.

A. When compounding sterile preparations, individuals shall comply with the following standards:

(1) Sequencing or garbing that complies with USP 797 Standards;

(2) Thorough hand-washing before gowning;

(3) Wearing clean room garb inside the designated area at all times which consists of:

(a) A non-shedding coverall or gown;

(b) Head and facial hair covers;

(c) A face mask; and

(d) Shore covers;

(4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area;

(5) All jewelry shall be removed;

(6) Sterile gloves are required; and

(7) Make-up may not be worn in the clean room.

.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.

C. The permit holder shall maintain records of training and demonstrated competence for individual employees for 5 years.

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 pracices.

(3) Evaluations shall include:

(a) Writing 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.

.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 dispenses;

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 fill verification results;

D. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators certified by a trained and qualified operator;

E. Clean room and anteroom certification by a trained and qualified operator according to USP 797 Standards;

F. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including antineoplastic agents and hazardous materials.

G. A formal written review process to report and evaluate compliance with this chapter; and

H. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

FINDINGS OF FACT

The Board finds that:

1. At all times relevant hereto, the Respondent was licenses to practice pharmacy in the State of Maryland.

2. The Respondent was originally licensed on or about August 2, 1984.

3. The Respondent's license expires on June 30, 2019.

4. At all times relevant hereto, the Respondent was a co-owner and permit holder of a pharmacy ("Pharmacy A") located in Rosedale, Maryland.[2] Pharmacy A operated under Maryland permit number: P04404.[3]

5. On or about March 1, 2016, Board inspectors conducted an annual sterile compounding inspection of Pharmacy A.

6. The Respondent was present during the inspection.

7. During the March 1, 2016 inspection, Board inspectors found deficiencies at the Pharmacy A. Board inspectors found that the Respondent did not: (1) perform

[2] The name of Pharmacy A referred to in this document have been omitted to protect confidentiality.

[3] Pharmacy A changed ownership in or around November, 2016.

environmental monitoring for the Compounding Aseptic Isolator ("CAI")[4]; (2) have a written program for training and conducting competency evaluations of sterile compounding personnel; (3) comply with policies and procedures for sterile compounding personnel; (4) perform media-fill and fingertip touch testing for sterile compounding personnel; and (5) comply attire requirements for sterile compounding.

8. During the March 1, 2016 inspection, Board inspectors noticed that Pharmacy A did not have an anteroom or a clean room.

9. The Board inspectors also noticed that Pharmacy A had a CAI that was not in a segregated compounding area.

10. The CAI was in an office area adjacent to the retail pharmacy store. The office area was carpeted. The office was also used for storage.

11. During the March 1, 2016 inspection, the Respondent told the Board inspectors that the sterile compounding at Pharmacy A was low to medium risk, non-hazardous, and patient specific.

12. Board inspectors have determined that Pharmacy A prepared batches of sterile injectables utilizing non-sterile starting ingredients and then sterilizing them using an autoclave.

13. In a letter to the Board dated March 8, 2016, the Respondent stated, "As of your visit and for some time prior we have not engaged in sterile preparations…"

[4] Compounding Aseptic Isolator means an enclosed positive or negative pressure environment especially designed for sterile preparation compounding that maintains a physical barrier between the workspace and the operator.

tit. 10, §34.10.19.04; Code of Md. Regs. tit.10, §34.19.12; Code of Md. Regs. tit.10, §34.19.13; Code of Md Regs. tit.10, §34.19.14; and Code of Md. Regs. tit.10, §34.19.15.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated H.O. §12-313(7) and (25); Code of Md. Regs. tit. 10, §34.10.01 A(1)(c) and (3) and B(3); Code of Md. Regs. tit. 10, §34.10.19.04; Code of Md. Regs. tit.10, §34.19.12; Code of Md. Regs. tit.10, §34.19.13; Code of Md Regs. tit.10, §34.19.14; and Code of Md. Regs. tit.10, §34.19.15.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 21st day of February, 2017 by a majority of the quorum of the Board, hereby

ORDERED that the Respondent license shall be **REPRIMANDED**; and it is further

ORDERED that the Respondent shall perform no sterile compounding until he completes a Board approved course covering the requirements of USP 797; and it is further

ORDERED that Respondent shall pay a fine in the amount of five thousand dollars ($5,000.00) payable to the Maryland Board of Pharmacy, no later than one hundred eighty (180) days from the date that this Order is signed by the Board; and it is further

ORDERED that the Respondent shall practice pharmacy in accordance with the Maryland Pharmacy Act and all applicable laws and regulations; and it if further

14. In a letter to the Board dated April 4, 2016, the Respondent stated that "since our inspection the beginning of March, we have not prepared any sterile compounds and do not intend to compound sterile preparations going forward."

15. On August 24, 2016, Board investigators conducted a follow-up inspection at Pharmacy A.

16. During the August 24, 2016 inspection, Board inspectors found that Pharmacy A had filled five (5) sterile compound prescriptions since the March 1, 2016 inspection. The five (5) of the sterile compound prescriptions filled were for Leuprolide Microdose 50mcg/.02ml.

17. The Respondent did not believe that Leuprolide Microdose 50mcg/.02ml. qualified as a sterile compound because Leuprolide one of the ingredients for compounding was provided to Pharmacy A in prefilled vials and/or syringes.

18. The Board has determined that there has been no attempt by the Respondent to deceive the Board for any type of gain.

19. The Pharmacist A signed the dispensing logs acknowledging that Pharmacy A had dispensed five (5) sterile compounded prescriptions that Board inspectors found during the August 24, 2016 inspection.

20. The Respondent's conduct, as set forth above is a violation of H.O. §12-313(7) and (25); Code of Md. Regs. tit. 10, §34.10.01 A(1)(c) and (3) and B(3); Code of Md. Regs.

ORDERED that if the Respondent violates any of the terms of this Order, the Board, after notice and a show cause hearing, and a determination of violation, may impose any other disciplinary sanctions it deems appropriate, said violation being proved by a preponderance of evidence; and it is further

ORDERED that Respondent shall be responsible for all costs, incurred under this Order; and it is further

ORDERED that for purposes of public disclosure and as permitted by Md. General Provisions §§4-101 et seq. (2014), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law, and Order, and is reportable to any entity to whom the Board is obligated to report; and it is further

ORDERED that the effective date of this Order is the date that it is signed by the Board, and it is further

ORDERED that this Order is final and a public document pursuant to Md. General Provisions §§4-104 et seq. (2014).

2/21/2018
Date

Mitra Gavgani, Pharm. D.
President
State Board of Pharmacy

CONSENT OFJOHN F. VAN WIE, PD

I, John F. Van Wie, PD by affixing my signature hereto, acknowledge that:

1. I am represented by Paul J. Weber, Esquire.

2. I am aware that I am entitled to a formal evidentiary hearing before the Board, pursuant to Md. Code Ann., Health Occ. II §12-315 (2014 Repl. Vol. & 2017 Supp.) and Md. Code Ann., State Govt. II §§ 10-201 *et seq.* (2014 Repl. Vol. & 2017 Supp.).

3. I acknowledge the validity and enforceability of this Consent Order as if entered after 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 provided by law. I am waiving those procedural and substantive protections.

4. I voluntarily enter into and consent to the foregoing findings of fact, conclusions of law, and order and agree to abide by the terms and conditions set forth in this Consent Order, as a resolution of the Board's case, based on the findings set forth herein.

5. I waive my right to contest the findings of fact and conclusions of law, and I waive my right to a full evidentiary hearing, and any right to appeal this Consent Order as set forth in Md. Code Ann, Health Occ. II. § 12-316 (Rep. Vol. 2014 & 2017Supp.) and Md. Code Ann., State Govt. II §§ 10-201 *et seq.* (2014 Rep. Vol. & 2017 Supp.).

6. I acknowledge that by failing to abide by the terms and conditions set forth in this Consent Order, and, following proper procedures, I may be subject to disciplinary action.

7. I sign this consent order, without reservation, as my voluntary act and deed. I acknowledge that I fully understand and comprehend the language, meaning, and terms of this Consent Order.

1/25/2018
Date

John F. Van Wie, PD

NOTARY

STATE OF Maryland
CITY/COUNTY OF Anne Arundel

I hereby certify that on this 25th day of January, 2018, before me, a Notary Public for the State of Maryland and the City/County aforesaid, personally appeared John F. Van Wie and made oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS my hand and Notarial Seal.

Notary Public

My Commission Expires: 11/23/2020

ALFREDO REYES
NOTARY PUBLIC
ANNE ARUNDEL COUNTY, MD
MY COMMISSION EXPIRES
NOVEMBER 23, 2020