IN THE MATTER OF	*	**BEFORE THE**
OLADEJI YUSUF	*	**MARYLAND BOARD OF**
Respondent	*	**PHARMACY**
LICENSE NO: 20215	*	**CASE NO: 25-421**

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

CONSENT ORDER

On September 17, 2025, the Maryland Board of Pharmacy ("the Board") charged Oladeji Yusuf, License No. 20215 ("Respondent"), under the Maryland Pharmacy Act, ("the Act") Md. Code Ann., Health Occ., §§ 12-101 *et seq.*, and certain provisions of the Board's sterile compounding regulations found at Md. Code Regs. ("COMAR") 10.34.19 *et seq.*[1] ("the Regulations").

The Board charged the Respondent with violating the following provisions of the Act.

> **§ 12-313. Denials, reprimands, suspensions, and revocations — Grounds**
>
> . . . .
>
> (b) *In general* — Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may . . . reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:
>
> . . . .
>
> (25) Violates any rule or regulation adopted by the Board[.]

[1] Further, Board Regulation 10.34.19.02 incorporates by reference the standards set forth in United States Pharmacopeia publication 797 ("USP 797").

The pertinent provisions of the Regulations 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:

(a) United States Code, Title 21,

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

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

(d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

(e) COMAR 10.19.03;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error[.]

. . . .

B. A pharmacist may not:

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

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

COMAR 10.34.19. Sterile Pharmaceutical Compounding.

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.

05. General Requirements.

A licensed pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy shall control and supervise the section of the pharmacy that prepares compounded sterile preparations and is responsible for, at a minimum, the following:

A. Preparation of compounded sterile preparations within the pharmacy or decentralized pharmacy;

B. Storage of materials pertinent to the preparation of compounded sterile preparations, including drugs, chemicals, and biologicals, and the establishment of specifications for procurement of the materials;

C. Labeling of containers of compounded sterile preparations compounded within the pharmacy;

D. Recording of transactions of the pharmacy as may be applicable to State and federal laws and regulations, as may be necessary to maintain accurate control over, and accountability for, pharmaceutical materials; and

E. Ensuring that licensed pharmacists meeting the requirements of §A of this regulation, or registered pharmacy technicians under direct supervision of a licensed pharmacist meeting the requirements of §A of this regulation, prepare, compound, and dispense compounded sterile preparations.

06. Special Handling, Packaging, Labeling, and Beyond Use Dating.

A. The pharmacy shall make available special handling and packaging materials to maintain container integrity and drug stability of the prepared prescription orders, including antineoplastic or other hazardous sterile preparations, during handling and administration to the patient including:

(1) A reasonable effort to provide tamper-evident packaging if appropriate to setting;
(2) Proper in-transit storage consistent with preparation labeling; and
(3) Delivery to the patient within a reasonable time.

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:

(1) The date of preparation unless otherwise readily retrievable from prescription records;
(2) Time prepared, if applicable;
(3) The pertinent requirements for proper storage;
(4) The name of the prescriber, unless in an inpatient hospital setting;
(5) The name of the patient;
(6) Directions for use;
(7) The name of the base solution for infusion preparations;
(8) The name and concentration or amount of active drugs contained in the final sterile preparation;
(9) The name or identifying initials of the pharmacist who checked or prepared the compounded sterile preparation unless otherwise readily retrievable from prescription records;
(10) The name, address, and telephone number of the pharmacy unless in an inpatient hospital facility;
(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;
(12) Any ancillary and cautionary instructions as needed; and
(13) A pertinent warning consistent with applicable federal and State law that cytotoxic preparations are biohazardous, when applicable.

C. A pharmacy compounding sterile infusion preparations shall provide a 24-hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

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.

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;
(e) Records documenting inspection for expired or recalled pharmaceutical preparations or raw ingredients;
(f) Preparation records including compounding work sheets, and records of the registered pharmacy technicians' checking/sign-off process; and
(g) Preparation records including compounding work sheets and records of the pharmacists' checking/sign-off process.

(2) In addition to the records requirement in §B(1) of this regulation, for batch compounded sterile preparations, a pharmacy compounding sterile batch preparations for future use shall have records indicating the:

(a) Drug and ingredient names;
(b) Lot numbers;
(c) Expiration dates;
(d) Drug/diluent amounts; and
(e) Date on which the compounded sterile batch preparations were prepared.

(3) A pharmacy shall maintain records of media fill verification results for 5 years.

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 tasks 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
(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 environment;
(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.

D. 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.

E. The requirements specified in §§B(1) and C(1) of this regulation are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with the:

(1) Compounding aseptic isolator conditions set forth in USP 797 Standards; and
(2) Isolator vendor or manufacturer specifications.

13. Attire.

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

...

(1) Sequencing of 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) Shoe covers;
(4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area; ...
(6) Sterile gloves are required ....

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;

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:

1. At all relevant times, the Respondent was licensed to practice pharmacy in the State of Maryland. The Respondent was originally licensed to practice pharmacy in Maryland on or about July 15, 2011. The Respondent's license expires on November 30, 2026.

2. At all relevant times, the Respondent has owned and worked as the sole pharmacist for a pharmacy in Maryland (the "Respondent-Pharmacy"). At all relevant times, 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 November 12, 2020. The Respondent-Pharmacy's permit expires on May 31, 2026.

3. At all relevant times, the Respondent-Pharmacy provides community pharmacy services, to include compounding of sterile and non-sterile products.

4. On March 14, 2025, the Board's Surveyor conducted an annual sterile compounding inspection of the Respondent-Pharmacy that revealed several concerning observations regarding the Respondent-Pharmacy's sterile and non-sterile compounding practices.

5. The Board's inspection report documented observations of various deficiencies, including the following:

a. The Pharmacy was broken into on 2/19/2025, according to the Respondent, but nothing was stolen. As such, a DEA 106 was not submitted. The door into the pharmacy and into the back was damaged, and was a medication refrigerator.

b. The Pharmacy did not have hood certification reports or videos of smoke studies available for review.

c. The Respondent does not enter rooms with an environmental technician during certification. A certification cannot be considered dynamic as required by USP 797 without doing so.

d. The Pharmacy does a surface sampling in the hood weekly, and certifier performs room surface sampling semiannually. USP 797 requires monthly surface sampling of all ISO classified areas (rooms and hoods) including critical and high touch areas.

e. The Pharmacy is not trending viable growth as required by USP 797.

f. The Pharmacy stated it had updated to new USP 797 standards; however none of the policies appear to have been updated to new standards.

g. SOP 1.4 states that components such as syringes if opened into the hood do not need to be sanitized with IPA prior to entering ISO5.[2] USP 797

[2] ISO 5 refers to a standard from the International Organization for Standardization (ISO) that defines a cleanroom environment with a maximum of 3,520 particles of 0.5 microns or larger per cubic meter of

requires all items to be sanitized with IPA prior to entering a stricter ISO classification. A typical protocol would be to stage compounding within the hood and sanitize all items coming in, including syringes within their outer wrappers and then opening them in the hood prior to use.

h. Atropine needs to be processed further to ensure acceptable levels of endotoxins. The Pharmacy only filters CSPs[3] which does not eliminate endotoxins. Phentolamine Mesylate with mannitol is required for 1 formulation. The Respondent does not triturate it with mannitol to measure per formulation.

i. The compounding record for hydroxocobalamin 20mg/ml contains multiple typos including "TITTLE" and "PPCA". There are no dates for approval, and two temperatures are indicated for storage in fridge / freezer.

j. Compounding record had yellow stains. As such, Board surveyor unsure if stains spread contamination during compounding process.

k. The PCCA formulary reference and USP 797 require a particle filter when starting from powers. The Pharmacy is currently not utilizing one.

l. Cleaning logs do not indicate a cleaning agent and only mention sanitizing with IPA. Walls or other equipment cleaning is not listed on logs. Also, the same form is used for each room indicating the same equipment is in all rooms including scale, pH meter, hoods, and sink.

m. For sporicidal, the Pharmacy mixes hydrogen peroxide for first aid with Nutra-max disinfectant cleaner. This is HIGHLY DANGEROUS and must be stopped immediately. Mixing cleaning agents can make hazardous and deadly gasses.

n. The Pharmacy does not utilize a proper sporicide for monthly cleaning. A specific sporicidal product must be purchased (EPA registered one step sporicidal cleaner).

o. The Pharmacy ships medications, but has not shipped sterile products. Tamper evident packaging is not available to ensure CSPs reach patient safely and unadulterated.

p. Patients are only verbally instructed on signs of contamination of

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air.

[3] Compounded sterile preparations.

CSPs. Medication guides are not provided for compounded products.

q. The Respondent stated he is using a dry heat oven to depyrogenated glassware but it is not documented. Endotoxin challenge vials have not been utilized to validate the oven cycle (required at least annually).

r. The Pharmacy compounds (non-sterile) HDs[4] primarily hormones; however, they have prepared Hydroxyurea, in the past, which is a group-1antineoplastic. Proper HD handling and disposal information was not provided to patients.

s. The Pharmacy utilizes formularies from PCCA. Formularies all state you must use the exact products listed in formulary to be able to get full BUDs[5] without further validation. The Pharmacy does not order strictly from PCCA and has changed the final container (vial) from what PCCA lists (syringe).

t. The Pharmacy dispenses in multidose containers. For example, hydroxocobalamin is dispensed as a #30 day supply in #15 2 mL vials. Patients are instructed to pull a 1 mL dose and use the vial for 2 days. Multidose containers have not been tested or verified for efficacy. Two formulations for Hydroxocobalamin (PF and paraben water) were provided. One specifically states "DO NOT DISPENSE IN MULTIDOSE VIALS". Bottles are not labeled as multidose and do not have the language to discard after certain number of days such as "Discard after 28 days".

u. The Pharmacy is currently utilizing clear glass vials. Hydroxocobalamin formulary requires protection from light, and other formularies require amber vials.

v. Eye drops and injectables are all dispensed in multidose containers with 30-day BUDs which the patients are instructed to freeze the containers and then pull one out, use it for a certain number of days (2 or 3), discard the vial and then thaw the next. These directions are not clearly indicated on the labels nor in the information provided. It is not clear if the patients understand if the 30 BUD of the last vile is a hard line regardless on when vial was thawed for use.

w. Fingertip and surface sampling require 48hrs 35° by USP 797. Times were not documented to ensure proper amount of time, and times and dates not indicated on forms.

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[4] Hazardous drugs.

[5] Beyond Use Date.

x. The Pharmacy does not possess all the required reference materials for its practice. The Pharmacy does not have an account with USP and as such does not have access to the Pharmacopeia including chapters 795, 797, and 800.

y. The Respondent stated Gentamicin Bladder Irrigation Solution receives a 10-day BUD, however the label states 30 days. Sterility testing is not performed to extend BUD.

z. Hood cleaning observational checklist only mentions one disinfectant. There is no follow-up of IPA.

aa. The individual who performed competency observations was not trained in sterile compounding.

bb. Competency training does not include cleaning of the rooms.

cc. The Respondent did not limit access or enforce line of demarcation into the cleanroom.[6] The Board Surveyor was not required to garb up prior to entering the cleanroom.

dd. The HD non-sterile compounding area is entered through the anteroom.[7] The Respondent does not gown up to enter the room if not compounding. Shoe covers were put on to enter, but were not removed prior to leaving HD room, and were worn throughout the entire Pharmacy;

ee. Some components utilized for sterile compounding, and paperwork were stored in non-sterile HD room. Per USP 800, these items must be considered contaminated with HD and need to be labeled for HD for safety precautions.

ff. Shoe covers were not put on over the line of demarcation.

gg. Line of demarcation was outside of the cleanroom. As such a clean side cannot be established.

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[6] "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).

[7] "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).

hh. A light was falling in the anteroom.

ii. Caulking between wall panels was cracking. This was repaired after last visit. However, caulk was just put over the existing caulk which is not an effective repair.

jj. Wood was exposed under the sink and missing caulk around joint.

kk. A cardboard box was in the anteroom, and light and dark cardboard panels in prep room for visual inspection. Cardboard is prohibited from the cleanroom.

6. During the inspection, the Board Surveyor requested the Respondent and Respondent-Pharmacy to submit corrective actions addressing the reported observations by April 4, 2025.

7. The Respondent and Respondent-Pharmacy did not respond by April 4, 2025.

8. On April 11, 2025, the Board Surveyor contacted the Respondent and Respondent-Pharmacy for an update and requested additional documentation.

9. On April 21, 2025, the Respondent and Respondent-Pharmacy responded to the Board Surveyor.

10. Thereafter, the Board Surveyor sent additional questions and follow-up requests to the Respondent and Respondent-Pharmacy which they partially answered.

11. On May 19, 2025, the Board Surveyor requested additional documents and provided an additional opportunity for the Respondent and Respondent-Pharmacy to respond to the list of observations, including those that were not previously addressed.

12. On May 27, 2025, the Respondent and Respondent-Pharmacy responded to the Board Surveyor but did not fully or adequately address the March 14, 2025 inspection observations or provide all of the requested documents.

13. Based on the March 14, 2025 observations of the Board Surveyor and the subsequent responses of the Respondent and Respondent-Pharmacy, the Board's annual sterile compounding inspection also concluded in part that the Respondent continues to show a lack of understanding of the requirements of USP 797, and the Respondent was unaware of the requirements of the revisions of USP 797 despite stating they have updated their policies of the new requirements.

14. Additionally, the Board's annual sterile compounding inspection concluded in part that the Respondent deviates from PCCA's compounding formulary without regard to the stability of the components.

PRIOR DISCIPLINARY ACTION

15. On May 15, 2023, in Case No. 23-340, the Respondent-Pharmacy and the Board entered into a Pre-Charge Consent Order after an annual community and sterile compounding inspection observed several deficiencies relating to its sterile and non-sterile compounding practices as well as general pharmacy security. As part of the Consent Order, the Respondent-Pharmacy agreed to immediately cease all compounding of sterile products until the Respondent satisfactorily completed USP 797 training, and the Respondent-Pharmacy passed a Board inspection to ensure compliance with USP 797. On September 20, 2023, the Respondent-Pharmacy was approved to resume sterile compounding.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law the violated of the following provisions of the Act: Health Occ. § 12-313(b)(25) and COMAR 10.34.10 and 10.34.19.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is on this 2nd day of February, 2026, by the affirmative vote of the majority of the members of the Board then serving:

ORDERED that the Respondent's license to practice pharmacy in the State of Maryland is hereby **REPRIMANDED**; and it is further

ORDERED that the Respondent shall permanently **CEASE AND DESIST** from sterile compounding at City Access Pharmacy Maryland; and it is further

ORDERED if the Respondent wishes to practice sterile compounding at a Pharmacy other than City Access Pharmacy, the Respondent shall request prior Board approval to do so; and it is further

ORDERED that the Respondent shall practice in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and it is further

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

ORDERED that the Respondent 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 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.*

2-2-26
Date

Deena Speights-Napata, M.A.
Executive Director, for
Kristopher Rusinko, President
Maryland Board of Pharmacy

CONSENT

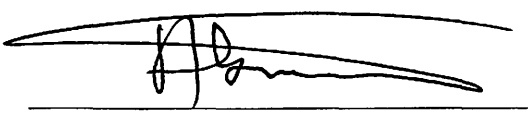
I, Oladeji Yusuf, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my 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 my 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 and understand its meaning and effect.

1/29/2026
Date



Oladeji Yusuf, License No. 20215

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Prince George's

I hereby certify that on this 29th day of January, 2026, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **Oladeji Yusuf**, 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

My Commission Expires: May 1st, 2029

MICHAEL PEREZ MEJIA
Notary Public
Prince George's County
Maryland
My Commission Expires May 1, 2029