

IN THE MATTER OF
CITY ACCESS PHARMACY

Permit No. P08345

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BEFORE THE
MARYLAND STATE
BOARD OF PHARMACY

Case No. 23-340

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PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) conducted annual community and sterile compounding inspections of City Access Pharmacy (the “Pharmacy”) on March 2 and 7, 2023. The Board’s inspectors observed several deficiencies relating to the Pharmacy’s sterile and non-sterile compounding practices as well as general pharmacy security.

In lieu of instituting formal proceedings against the Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board held a Pre-Charge Case Resolution Conference (“CRC”) with the Pharmacy on March 29, 2023. As a result, the Board and the Pharmacy have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. At all times relevant hereto, the Pharmacy possessed a Maryland pharmacy permit, Permit No. P08345, and operated in Beltsville, Maryland. The Pharmacy’s permit expires on May 31, 2024.

2. The Pharmacy provides community pharmacy services, to include compounding of sterile and non-sterile products. The Pharmacy is owned and staffed with one full-time pharmacist (“Pharmacist A”).
3. On March 2 and 7, 2023, the Board conducted annual and sterile compounding inspections of the Pharmacy which revealed several concerning observations regarding the Pharmacy’s sterile and non-sterile compounding practices, as well as general security concerns.
4. The Board’s inspection reports included observations of various deficiencies, to include the following:
 - a. The Pharmacy’s software system produces incorrect beyond-use dates for labeling of compounded products.
 - b. The Pharmacy fails to maintain complete compounding logs for compounded preparations.
 - c. The Pharmacy has not conducted appropriate USP 797 quality assurance testing on its personnel (i.e., training is witnessed and validated).
 - d. The Pharmacy does not use appropriate cleaning agents for clean rooms.
 - e. The Pharmacy compounded commercially available products without documented justification.
 - f. Master formulations were missing required information.
 - g. The Pharmacy’s hazardous compounding area was utilized for storage of non-hazardous materials.
 - h. Compounding recipes were altered without justification.
 - i. The Pharmacy’s hazardous compounding area door was kept open.

- j. The Pharmacy's clean room was shut down without adherence to protocols to recommence sterile compounding operations.
 - k. The Pharmacy lacked security restricting access to compounding areas.
 - l. The Pharmacy's medication refrigerator is located in patient waiting area.
 - m. The Pharmacy's sink cabinet in the anteroom had water damage.
 - n. The Pharmacy staff used improper garbing for access to the hazardous compounding room.
 - o. Several expired medications were found in inventory during a spot check.
5. The Pharmacy indicates that it compounds a maximum of two (2) compounded preparations per day.
 6. Since the inspection, the Pharmacy has modified its software to enable it to produce appropriate BUD's for labeling. In addition, the Pharmacy has installed a new sink and has amended its procedures to utilize separate cleaning equipment for hazardous, sterile and non-sterile areas.
 7. The Pharmacy indicates that its sterile equipment is certified every six (6) months.
 8. The Pharmacy has been cooperative with the Board throughout its inspections and follow-up.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Pharmacy is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§12-403(c)(1) and (13), and COMAR 10.34.10.01A(1) and B, 10.34.12 and 10.34.19.

ORDER

Based on an affirmative vote of the Board, it is this 15th day of May, 2023, hereby:

ORDERED that the Pharmacy shall immediately CEASE any and all compounding of sterile products unless and until:

a. Pharmacist A satisfactorily completes USP 797 training by a Board-approved training organization and submits written proof of completion to the Board; and

b. The Pharmacy submits to a Board inspection to ensure compliance with USP 797 requirements prior to commencing sterile compounding operations; and be it further,

ORDERED that the Pharmacy may continue to engage in non-sterile compounding, provided that the Pharmacy complies with USP 795 standards, to include:

a. Maintaining appropriate recordkeeping for each non-sterile compounded preparation, such as fully completed compounding worksheets;

b. Labeling each compounded preparation with all required information, such as appropriate beyond-use date and instructions for use, storage, and any applicable cautionary statements;


c. Prohibiting the compounding of commercially available products without documented justification of a permissible exception; and be it further,

ORDERED that, within thirty (30) days of the date of this Order, the Pharmacy shall institute security measures to segregate the restricted pharmacy personnel areas from the public areas, and relocate all pharmacy equipment (e.g., medication refrigerator) to restricted pharmacy areas; and be it further,

ORDERED that the Board reserves the right to initiate disciplinary or emergency action against the Pharmacy should further inspections or any environmental test results indicate material deficiencies which, in the Board's sole opinion, may pose a risk to public health and safety; and be it further,

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to the Public Information Act, Annotated Code of Maryland, General Provisions Article, Section 4-101 *et seq.*

5-15-23
Date


Deena Speights-Napata, M.A., Executive Director
for
Neil Leikach, R.Ph.
President, Maryland Board of Pharmacy

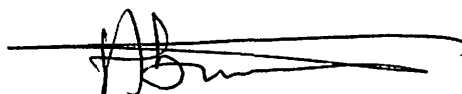
CONSENT

1. By signing this Consent, the Pharmacy submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Pharmacy the right to a full evidentiary hearing. The Pharmacy consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Pharmacy would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on the Pharmacy's behalf and to all other substantive and procedural protections provided by law.

2. By signing this Consent, the Pharmacy waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Pharmacy acknowledges that this is a formal order of the Board and as such is a public document.
4. The Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.
5. The Pharmacy signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Pharmacy fully understands the language, meaning, and effect of this Consent Order.

CITY ACCESS PHARMACY
Permit No. P08345

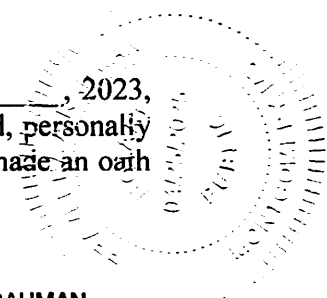
5/8/2023
Date



Oladeji Yusuf, R.Ph.
Owner

STATE OF MARYLAND
COUNTY/CITY OF Montgomery :
Silver Spring

I hereby certify that on this 8th day of May, 2023, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared OLADEJI YUSUF, on behalf of CITY ACCESS PHARMACY, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

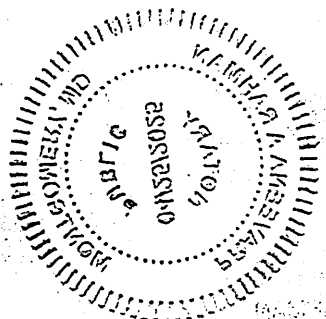


Draveena A. Rahman
Notary Public
My Commission Expires April 25, 2025
My commission expires: _____

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