

**IN THE MATTER OF
SOUTHERN MARYLAND
COMPOUNDING CENTER**

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**BEFORE THE MARYLAND
BOARD OF PHARMACY**

Permit No. P05973

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Case No. 19-144

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PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) received a complaint on November 2, 2018, from a hospital pharmacist in Philadelphia, Pennsylvania, regarding improper labeling of compounded medications dispensed to her pediatric patient. The Board opened an investigation and conducted an inspection of Southern Maryland Compounding Center (the “Pharmacy”), Permit No. P05973. The Board’s inspection indicated that the Pharmacy’s software system failed to provide accurate beyond-use-dates and compounding worksheets for compounded medications. In addition, the Pharmacy lacked appropriate recordkeeping for refilled compounded preparations, quality assurance testing of pharmacy personnel, and received environmental test results indicating mold growth in the hood.

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 April 3, 2019. 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. P05973, and operated at 3460 Old Washington Road, Waldorf, Maryland. The Pharmacy's permit expires on May 31, 2020.
2. The Pharmacy provides community pharmacy services, to including compounding of sterile and non-sterile products.
3. On November 2, 2018, the Board received a complaint filed by a hospital pharmacist in Philadelphia, Pennsylvania, regarding compounded medications dispensed to her pediatric patient by the Pharmacy that were mislabeled with incorrect beyond-use-dates.
4. The Board immediately opened an investigation into the complaint and an inspection of the Pharmacy was conducted on February 29, 2019.
5. The Board's inspection noted the following:
 - a. The Pharmacy's software system produces incorrect beyond-use-dates for labeling of compounded products.
 - b. The Pharmacy's software system produces incorrect NDC's numbers and expiration dates for ingredients listed on compounding worksheets.
 - c. The Pharmacy fails to maintain accurate compounding logs for refills of compounded medications.
 - d. The Pharmacy has not conducted required USP 797 quality assurance testing on its personnel (e.g. media fill and fingertip testing).
 - e. The Pharmacy lacks nail cleaners for hand washing as required by USP 797.
 - f. Random sampling revealed seven (7) expired medications in inventory.

- g. The Pharmacy's environmental testing results evidenced mold growth on two surface areas in the aseptic isolator, which constitutes an actionable excursion.
6. The Pharmacy failed to file an adverse event report with the Board as required. The Pharmacy asserts that it did not believe an adverse event report was required since the laboratory report indicated that the Pharmacy "passed" the environmental testing.
7. The Pharmacy did not engage in any root cause analysis, corrective action measures, or retesting in follow-up to the findings of mold growth.
8. The Pharmacy has amended its procedures to specifically address the issues relating labeling with correct beyond-use-dating.
9. The Pharmacy has been cooperative with the Board throughout its investigation.

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), (13) and (15), and COMAR 10.34.10A(1) and B, 10.34.12 and 10.34.19.

ORDER

Based on an affirmative vote of the Board, it is this 29th day of May, 2019, hereby:

ORDERED that the Pharmacy shall immediate CEASE any and all compounding of sterile products; and be it further,

ORDERED that the Pharmacy may continue to engage in non-sterile compounding for refills of existing prescriptions only; and be it further,

ORDERED that, within thirty (30) days of the date of this Order, the Pharmacy shall engage a Board-approved mentor with specific expertise in sterile and non-sterile compounding; and be it further,


ORDERED that, within ninety (90) days of the date of this Order, the Pharmacy's owner and manager, shall successfully complete ten (10) continuing education credits in sterile and non-sterile compounding and submit proof of completion to the Board; and be it further,

ORDERED the Pharmacy may petition the Board to commence sterile compounding and compounding new prescriptions for non-sterile products provided that the Board-approved mentor submits to the Board a report detailing the Pharmacy's satisfactory compliance with USP 795 and 797; 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 actionable excursions 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.*

5-29-19
Date



Deena Speights-Napata, MA Executive Director
for
Kevin Morgan, Pharm.D.
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 into 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.

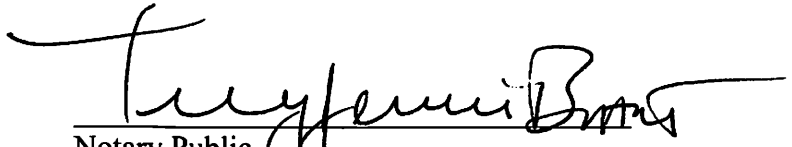
SOUTHERN MARYLAND COMPOUNDING
CENTER
Permit No. P05973

5/29/2019
Date


Peterpaul Ijezie, R.Ph.
Owner

STATE OF MARYLAND
COUNTY/CITY OF St Mary:

I hereby certify that on this 12th day of May, 2019, before me, a Notary Public of the State of Maryland and County/city aforesaid, personally appeared PETERPAUL IJEZIE, on behalf of SOUTHERN MARYLAND COMPOUNDING CENTER, and made an oath in due form that the foregoing Consent was his voluntary act and deed.


Notary Public
My commission expires: 12/19/2021

Torrey Jermain Bryant
NOTARY PUBLIC
St. Mary's County, Maryland
My Commission Expires December 19, 2021