

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

#### **Maryland Board of Pharmacy**

Kristopher Rusinko, PharmD, Board President Deena Speights-Napata, M.A., Executive Director 4201 Patterson Avenue Baltimore, MD 21215-2299

November 6, 2024

VIA REGULAR & CERTIFIED MAIL RETURN RECEIPT REQUESTED ARTICLE #: 7019 2280 0000 6567 9017

Northwest Hospital Center Pharmacy Attn: Norbert Robinson, R.Ph., Director of Pharmacy 5401 Old Court Road Randallstown, MD 21133

Re:

Permit No. P01143 Case No. 25-016

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

# Dear Pharmacy Manager:

On April 26, 2024, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Northwest Hospital Center Pharmacy (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated that the Pharmacy was not compliant with laws relating to the compounding of sterile products. Specifically, the Board inspector noted that the Pharmacy failed to submit to the Board mandatory filings for two (2) adverse event reports ("AER's") documenting certain adverse events that occurred on October 30, 2023, and January 17, 2024. The Board's records reflect that the Pharmacy was previously advised and educated regarding the mandatory reporting requirements for AER's.

#### I. FINDINGS AND CONCLUSION

The Board finds that the Pharmacy failed to submit the required documentation for adverse event reports dated October 30, 2023, and January 17, 2024. Adverse event reports, including any corrective actions taken or proposed, must be filed with the Board within five (5) calendar days of the adverse event.

Based upon the deficiencies noted at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Gen. Art. § 12-403(c)(1) and COMAR 10.34.19.18.

## II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and the Inspection Report, dated April 26, 2024.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

# III. FOLLOW-UP ACTIONS REQUIRED; BOARD INSPECTION

Please be advised that the Pharmacy shall immediately submit to the Board its most recent surface and air samples conducted as part of its semi-annual testing.

Please also be advised that the Board of Pharmacy will perform a follow-up inspection of the Pharmacy to ensure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

### IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Trina Leak, Pharm.D., Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, no later than thirty (30) days of the date of this Notice.

Please be advised that at the hearing the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy in violation of the Maryland Pharmacy Act, the Board may suspend or revoke the pharmacy permit, impose civil penalties, or both. If the Pharmacy requests a hearing but fails to appear, the Board may nevertheless hear and determine the matter in its absence.

## V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Wells Fargo Bank Attn: State of MD - Board of Pharmacy Lockbox 2051 401 Market Street Philadelphia, PA 19106

NOTE: Please include the case number, <u>25-016</u>, on your check or money order to ensure proper assignment to your case.

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to this matter, and shall be a public document and order under the Maryland Public Information Act, Md. Code Ann., General Provisions Art. § 4-101, et seq., and posted and reported in accordance with State and federal laws.

If you have any questions concerning the instructions contained in this letter, please contact Trina Leak, Pharm.D., Compliance Director, at 443-635-8318.

Sincerely,

Deena Speights-Napata, M.A.

**Executive Director**