



DEPARTMENT OF HEALTH

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

Maryland Board of Pharmacy

Neil Leikach, R.Ph., M.Sc., Board President

Deena Speights-Napata, M.A., Executive Director

4201 Patterson Avenue

Baltimore, MD 21215-2299

August 4, 2023

**VIA REGULAR & CERTIFIED MAIL
RETURN RECEIPT REQUESTED
ARTICLE #7019 2280 0000 6567 7082**

Mercy Medical Center Pharmacy

301 St. Paul Place

Baltimore, Maryland 21202

Attn: Gregory Smith, R.Ph., Pharmacy Manager

RE: Permit No. P00452
Case No. 23-337
Notice of Deficiencies, Recommended Civil Monetary Penalty,
and Opportunity for Hearing

Dear Pharmacy Manager:

On December 16, 2022, the Maryland Board of Pharmacy (the “Board”) conducted a sterile compounding inspection of Mercy Medical Center Pharmacy (the “Pharmacy”), followed by an annual pharmacy inspection on March 29, 2023, for compliance with statutes and regulations governing the operation of a pharmacy. The Board’s inspections indicated that the Pharmacy was not compliant with laws relating to storage of prescription drugs as well as certain quality assurance requirements for sterile compounding. Specifically, the Board’s inspectors noted approximately four (4) expired medications, consisting of 96 units, in the Pharmacy’s inventory. In addition, the Pharmacy failed to identify colony forming units (“CFU’s”) in its semiannual viable sampling as required under current USP 797 standards. The Board’s prior inspection reports from 2019 and 2021 indicate that spot checks found expired medications in the Pharmacy’s inventory.

I. FINDINGS AND CONCLUSION

The Board finds that the Pharmacy had approximately four (4) expired prescription medications, consisting of 96 units, in its inventory. The Board also finds that the Pharmacy failed to identify CFU’s in its semiannual viable sampling in accordance with current USP 797 standards.

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 Occ. Art. §§ 12-403(c)(1) and (12); COMAR 10.34.12 and 10.34.19.15C.

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 \$500.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and in the inspection reports, dated December 16, 2022, and March 29, 2023.

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 INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to ensure that the deficiencies noted herein have been addressed and corrected. Should the 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 recommended 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 Donna Goldberg, R.Ph., J.D., Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, **no later than thirty (30) days from 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, 23-337, 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 the December 16, 2022, and March 23, 2023, inspections, 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 Donna Goldberg, R.Ph., J.D., at 410/764-3768.

Sincerely,



Deena Speights-Napata, M.A.
Executive Director

cc: Linda Bethman, AAG, Board Counsel