



MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Maryland Board of Pharmacy
Shiela West, Compliance Investigator
4201 Patterson Avenue
Baltimore, MD 21215

August 27, 2019

VIA REGULAR & CERTIFIED MAIL
RETURN RECEIPT REQUESTED
ARTICLE #7017 3040 0000 9785 3660

Walgreen's Pharmacy # 10977
301 East Pulaski Highway
Elkton, Maryland 21921
Attn: Monique Catalan, R.Ph., Pharmacy Manager

Re: Permit No. P06735
Case No. 19-232
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Pharmacy Manager:

On January 15, 2019, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Walgreen's Pharmacy #10977 (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 labeling of prescription drugs. Specifically, the Board inspector noted a prepared prescription for Levemir FlexTouch Pen Inj. 3ml in the medication refrigerator with a label stating "use before mfg. labeled date" instead of an expiration date 1 year from the date of dispensing.

I. FINDINGS AND CONCLUSION

The Board finds that the Pharmacy prepared for dispensing a medication labeled with an incorrect expiration date, referring to the manufacturer's expiration date rather than 1 year from the date of dispensing.

Based upon deficiencies at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(16) and 12-505.

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 in the Notice above.

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 follow-up inspection indicate further or continued 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 Donna Goldberg, R.Ph., J.D., Investigations Supervisor, 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 guilty of the violations cited in the Report, the Board may suspend or revoke the pharmacy permit, or 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 AND
SUBMIT CORRECTIVE ACTION PLAN**

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
7175 Columbia Gateway Drive
Columbia, MD 21046

NOTE: Please include the case number, 19-232, on your check or money order to ensure proper assignment to your case.

The Pharmacy shall also submit to the Board a corrective action plan **within thirty (30) days** of the date of this Notice detailing, at minimum, actions to be taken to remedy the above labeling deficiency and an anticipated date of correction.

Upon the Pharmacy's payment of the civil monetary penalty and submission of a corrective action plan, this Notice will constitute the Board's final action with respect to the inspection dated January 15, 2019, and shall be a public document and order in accordance with the Maryland Public Information Act, Md. Code Ann., General Provisions Art. § 4-101, *et seq.*

If you have any questions concerning the instructions contained in this letter, please contact Donna Goldberg, RPh., J.D., Investigations Supervisor, at 410-764-3768.

Sincerely,



Deena Speights-Napata
Executive Director

cc: Andrew Militello, Walgreens, Director of Pharmacy & Retail Operations
Linda Bethman, AAG, Board Counsel