800 SW Jackson St., Suite 1414 Topeka, KS 66612

Alexandra Blasi, Executive Secretary

Phone: (785) 296-4056 Fax: (785) 296-8420 pharmacy@ks.gov www.pharmacy.ks.gov

Laura Kelly, Governor

April 5, 2024

Walmart Pharmacy #5219 702 SW 8th St, Mail Stop 0500 Bentonville AR 72716

RE: Case No. 24-005

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling \$1,500. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at <u>Pharmacy.Compliance@ks.gov</u>.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc: Sarah Browning Pharmacist-in-Charge Walmart Pharmacy #5219 550 Congressional Drive Lawrence KS 66049



BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of)
Walmart Pharmacy #5219
Pharmacy Registration Number 2-10241
)

Case No. 24-005

SUMMARY ORDER

NOW, on this 5th day of April, 2024 comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Walmart Pharmacy #5219 ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

 The Board has previously issued Respondent Registration No. 2-10241 which entitles Respondent to function as a pharmacy in the State of Kansas ("Respondent's Registration") at 550 Congressional Drive in Lawrence Kansas (the "Pharmacy").

2. On October 19, 2023, the Board received a complaint which alleged that pharmacy personnel at the Pharmacy dispensed two prescriptions to a patient "CM" that had been discontinued by the prescriber.

3. On December 6, 2023, the Board's inspector conducted an onsite investigation of the Pharmacy.

4. Entresto and Lisinopril Prescriptions:

- a. On September 1, 2023, a new prescription for Entresto was received by the Pharmacy electronically for patient CM. There were no notes from the prescriber to indicate the patient was to discontinue their existing prescription for lisinopril/hydrochlorothiazide (hctz).
- b. During prescription verification at the Pharmacy, pharmacist Seth Ruder performed an override to a conflict description which indicated coadministration of Entresto and ACE inhibitors (lisinopril/hctz) is contraindicated. Mr. Ruder entered a reason for override as "Dr. Approved." There was no documentation on the prescription indicating the prescriber was called or the name of the pharmacist approving the override. The prescription for lisinopril/hctz was not deactivated in the Pharmacy system.
- c. On September 22, 2023, the Entresto prescription was dispensed from the Pharmacy and counseling was provided to CM.
- d. On October 16, 2023, the lisinopril/hctz prescription was refilled and dispensed to CM, at the request of CM. While reviewing the refill request, pharmacist-incharge Sarah Browning performed an override to a conflict description which indicated coadministration of Entresto and ACE inhibitors (lisinopril) is contraindicated due to risk of severe angioedema. Ms. Browning entered a reason for override as "Dr. Approved." There was no documentation on the prescription indicating the prescriber was called or the name of the pharmacist approving the override. No counseling was provided to CM.
- e. On October 18, 2023, pharmacist Holly Wieligman created an electronic "medication event" with the following description: "Patient was given Entresto

and told to stop the lisinopril, the lisinopril was never deactivated and the Patient refilled even after counsel from Pharmacist and Dr, lisinopril was not caught on refill." This electronic event did not contain the requirements of an incident report.

f. As of December 6, 2023, an incident report had not been created for the "medication event" at the Pharmacy.

5. During the investigation, Ms. Browning indicated that incident reports are generated right before the Pharmacy's continuous quality improvement meeting.

- 6. Bumetanide Prescription:
 - a. On October 3, 2023, a new prescription for CM bumetanide 1mg was received by the Pharmacy electronically. "Dose increase to 1mg BID" was included in the electronic prescription. The prescription label included the note "***DOSE INCREASE TO 1mg" in the directions.
 - b. Ms. Browning performed the prescription final verification. The bumetanide 1mg prescription was dispensed from the Pharmacy and counseling was provided to CM by Ms. Browning. The patient's previous prescription for 0.5mg was not deactivated in the Pharmacy system.
 - c. On October 12, 2023, the 0.5mg bumetanide prescription was refilled and dispensed by the Pharmacy to CM, at the request of CM. While reviewing the refill request, Ms. Wieligman performed the drug utilization review and an override of duplicate therapy for the patient. No counseling was provided to CM and the Pharmacy system noted counseling was not required.
 - d. On October 18, 2023, the prescriber's office phoned the Pharmacy to

discontinue the 0.5mg bumetanide and the prescription was deactivated in the Pharmacy system.

7. During the investigation, Ms. Browning indicated that Pharmacy personnel do not deactivate prescription orders in the Pharmacy system without specific instruction from the prescriber because there is a chance the patient may revert to the previous drug strength.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed \$5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against a pharmacy upon a finding that the pharmacy has been operated in such a manner that violates the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.A.R. 68-7-12b(a)(6), "reportable incident" and "incident" shall mean a preventable medication error involving a prescription drug and resulting in the dispensing of a drug to a patient in a situation that results in or has the potential to result in serious harm to the patient.

4. Pursuant to K.A.R. 68-7-12b(c), as soon as possible after discovery of the incident, the pharmacist shall prepare a report containing the following information:

- a. he name, address, age, and phone number of any complainant, if available;
- b. the name of each pharmacy employee and the license number of each licensee involved;
- c. the date of the incident and the date of the report;
- d. a pharmacist's description of the incident;
- e. the prescriber's name and whether or not the prescriber was contacted; and

f. the signatures of all pharmacy employees involved in the incident.

5. The Pharmacy's dispensation of contraindicated medications to CM for Entresto and lisinopril/hctz without any documentation of prescriber outreach or approval had the potential to harm the patient (severe angioedema), which qualifies as a reportable incident under K.A.R. 68-7-12b(a).

6. The Pharmacy's dispensation of both 1mg and 0.5mg prescriptions for bumetanide to CM within 2 weeks without any documentation outreach to or confirmation from the prescriber had the potential to harm the patient (duplicate therapy), which qualifies as a reportable incident under K.A.R. 68-7-12b(a).

7. In completing the electronic "medication event" in the Pharmacy system for the Entresto and lisinopril/hctz prescriptions, Pharmacy personnel failed to include all required elements of an incident report required by K.A.R. 68-7-12b.

8. By the date of the investigation (December 6, 2023), Respondent had failed to complete a sufficient incident report, which was almost two months after the prescription overrides and dispensations occurred. Pharmacy personnel indicated incident reports are generated before quarterly meetings, which cannot be considered "as soon as possible after the incident," and is, therefore, a violation of K.A.R. 68-7-12b.

9. Based on the above, Respondent operated the pharmacy in violation of the regulations of the pharmacy act of the state of Kansas which is a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1).

<u>ORDER</u>

Based upon the foregoing findings of fact and conclusions of law, Respondent is ordered to pay a fine to the Board in the amount of \$1,500. Respondent has 30 days from the date of this order to pay the fine by check or money order.

Furthermore, Respondent shall retrain all Pharmacy personnel on prescription overrides and relevant documentation which complies with the Pharmacy Act.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi Executive Secretary Kansas Board of Pharmacy 800 SW Jackson, Suite 1414 Topeka, KS 66612

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IT IS SO ORDERED.

<u>4/5/2024</u> Date

<u>Alexandra Blasi</u>, JD, MBA

Alexandra Blasi, JD, MBA Executive Secretary Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 5th day of April, 2024, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Walmart Pharmacy #5219 702 SW 8th St, Mail Stop 0500 Bentonville AR 72716

And a copy sent to:

Sarah Browning Pharmacist-in-Charge Walmart Pharmacy #5219 550 Congressional Drive Lawrence KS 66049

<u>Cilley Blass</u> Kansas Board of Pharmacy Staff