

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Pharmacy License and Controlled Substances Act Registration of</p> <p>CVS PHARMACY #8443 License No. 1395 Registration No. 1107899 Respondent</p>	<p>CASE NOS. 2020-0049 & 2020-0153</p> <p>COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER</p>
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COME NOW the Iowa Board of Pharmacy (“Board”) and CVS Pharmacy #8443 (“Respondent”), 3419 16th Ave SW, Cedar Rapids IA 52404, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order (“Order”) pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of these cases pursuant to Iowa Code chapters 17A, 155A, and 272C, and 657 IAC 36.

A. STATEMENT OF CHARGES

**COUNT I
DISPENSING ERROR**

1. Respondent is charged with dispensing an incorrect prescription and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(41).

**COUNT II
FAILING TO BE ORDERLY AND CLEAN**

2. Respondent is charged with failing to be orderly and clean in violation of 657 IAC 8.5(5), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

**COUNT III
NON-COMPLIANT CQI PROGRAM**

3. Respondent is charged with failing to have a continuous quality improvement program that complies with the requirements of 657 IAC 8.26, and may be disciplined pursuant to Iowa Code sections 155A.15(2)(c) and 155A.15(2)(h), and 657 IAC 36.6(21) and 36.6(28).

**COUNT IV
FAILING TO COMPLY WITH PIC CHANGE RULES**

4. Respondent is charged with failing to comply with 657 IAC 8.35(6)“d” and 10.19(4) pertaining to a change of pharmacist in charge, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT V

FAILING TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION

5. Respondent is charged with failing to establish and maintain effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs in violation of 657 IAC 8.3(5)"b", and may be disciplined pursuant to Iowa Code section 155A.15(2)(i) and 657 IAC 36.6(21).

COUNT VI

FAILING TO ENSURE LEGAL OPERATION

6. Respondent is charged with failing to ensure legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy in violation of 657 IAC 8.3(2), including specifically violating the provisions cited in Counts I-V above and additionally 657 IAC 8.4(3), 8.7(2), 8.7(5), 8.14, and 8.19(3), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

B. FACTUAL CIRCUMSTANCES

7. Respondent's pharmacy license number 1395 is currently active through December 31, 2021 and Respondent's CSA registration number 1107899 is currently active through August 31, 2021.

8. In April 2020, Respondent misfiled a prescription for Janumet 50-1000 mg immediate release tablets with extended release tablets.

9. The pharmacy was unable to provide a written CQI report for the event and the next CQI quarterly meeting did not address the error.

10. The pharmacy was inspected in July of 2020 with several deficiencies noted, including the following:

- a. The pharmacy was disorganized, dirty, and not a conducive environment to providing quality care.
- b. Expired medications were found on the shelves and multiple stock bottles were shelved incorrectly.
- c. Events requiring CQI reports were not documented or reviewed as required.
- d. The pharmacy lacked documented training for technicians and support persons and lacked a permanent log.
- e. The electronic prescribing platform did not have the capability to identify the transmitting agent.

- f. There were discrepancies in documentation for two previous PIC changes and the required inventories were not completed in the appropriate timeframe.

11. In November 2020, Respondent submitted a report of significant losses of controlled substances due to employee pilferage.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

12. The Board has jurisdiction over the parties and the subject matter of these proceedings.

13. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

14. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

15. Respondent acknowledges that it has the right to be represented by counsel on this matter.

16. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

17. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

18. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

19. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

20. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

21. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

22. Respondent's pharmacy license and CSA registration are hereby placed on **PROBATION** for a period of three (3) years, subject to the following terms:

- a. Respondent shall pay a **CIVIL PENALTY** in the amount of six thousand-five-hundred dollars (\$6,500) within thirty (30) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.
- b. Respondent shall perform quarterly self-inspections and shall submit the self-inspection reports to the Board after each inspection. Each quarterly self-inspection must include all of the following: CQI review, controlled substances inventory and reconciliation for all Schedule II controlled substances and fifteen (15) Schedule III-V controlled substances that are high risk for diversion, inspection of inventory for expired products and organization, review of staff credentials and training, and any other areas identified by the Board for a particular inspection. The quarterly inspections shall be submitted on or before March 5th, June 5th, September 5th, and December 5th each year during the probationary period.
- c. Respondent shall appear before the Board upon request for purposes of evaluating performance of the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- d. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- e. Any documentation required to be submitted to the Board pursuant to this Order should be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.
- f. Respondent may request early release from probation after two (2) years. The Board, in its discretion, may grant such a request if Respondent has demonstrated compliance with this Order and the laws and regulations governing the practice of pharmacy.

23. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

By the signature below, signatory acknowledges they are authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

5/10/2021

Date



CVS PHARMACY #8443
Respondent Leo Lariviere, Director

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on _____ May 12, 2021 _____.



Chairperson
Iowa Board of Pharmacy