

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Pharmacy License and Controlled Substances Act Registration of</p> <p>EVANSDALE PHARMACY, License No. 513 Registration No. 1101791 Respondent.</p>	<p>CASE NO. 2017-143</p> <p>COMBINED STATEMENT OF CHARGES, ORDER TO SHOW CAUSE, SETTLEMENT AGREEMENT, AND FINAL ORDER</p>
--	--

COME NOW the Iowa Board of Pharmacy ("Board") and Evansdale Pharmacy ("Respondent"), 3506 Lafayette Rd, Evansdale Iowa 50707, and enter into this Combined Statement of Charges, Order to Show Cause, 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 this case pursuant to Iowa Code chapters 17A, 124, 155A, and 272C (2017), and 657 IAC chapters 10 and 36.

A. STATEMENT OF CHARGES

1. 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).
2. Respondent is charged with failing to implement or participate in a continuous quality improvement (CQI) program in violation of 657 IAC 8.26, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).
3. Respondent is charged with failing to dispose of any materials containing patient-specific or confidential information in a manner to preserve patient confidentiality in violation of 657 IAC 8.16(5), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).
4. Respondent is charged with failing to comply with the current revision of USP Chapter 795 standards, specifically by failing to keep adequate compounding records, in violation of 657 IAC 20.3, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).
5. Respondent is charged with failing to remove outdated drugs or devices from dispensing stock in violation of 657 IAC 8.8, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).
6. Respondent is charged with failing to take a complete and accurate inventory of all stocks of controlled substances as required by 657 IAC 10.19, and may be disciplined pursuant

to Iowa Code section 124.304(1)(d), 155A.15(2)(c), and 155A.15(2)(h), and 657 IAC 10.12(1)"d" and 36.6(21) and (29).

7. Respondent is charged with failing to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of 657 IAC 10.13, and may be disciplined pursuant to Iowa Code section 124.304(1)(d), 155A.15(2)(c), and 155A.15(2)(i), and 657 IAC 10.12(1)"d" and 36.6(21).

8. Respondent is charged with failing to establish and periodically review policies and procedures covering all operations of the pharmacy in violation of 8.3(5)(a), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

9. Respondent is charged with failing to document changes to the perpetual inventory record in a manner consistent with 657 IAC 10.18(3), and may be disciplined pursuant to Iowa Code section 124.304(1)(d), 155A.15(2)(c), and 155A.15(2)(h), and 657 IAC 10.12(1)"d" and 36.6(21) and (29).

10. Respondent is charged with disposing of controlled substances in violation of 657 IAC 10.22 and 10.23, may be disciplined pursuant to Iowa Code section 124.304(1)(d), 155A.15(2)(c), and 657 IAC 10.12(1)"d" and 36.6(21) and (29).

11. Respondent is charged with failing to develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy in violation of 657 IAC 3.17, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

B. FACTUAL CIRCUMSTANCES

12. Respondent's Iowa pharmacy license number 513 is currently active through December 31, 2017. Respondent's Iowa Controlled Substances Act registration number 1101791 is currently active through August 31, 2019.

13. In August 2017, Respondent underwent a routine inspection. After the initial visit, Respondent was visited three subsequent times by a Board compliance officer. The following deficiencies were discovered during the inspection and subsequent visits:

- a. The pharmacy was disorderly and dirty.
- b. The pharmacy did not have a continuous quality improvement (CQI) program in place.
- c. Materials containing patient information were not being shredded in a timely fashion.
- d. The pharmacy was not keeping a production log for non-sterile compounded prescriptions.

- e. Expired drugs were located throughout the pharmacy, including in the dispensing inventory and the refrigerator.
- f. The most recent annual inventory of controlled substances was missing several controlled substances, including diazepam, carisoprodol, and codeine cough syrup. The inventory did not include expired controlled substances that were found on the floor of the office, controlled substances that were in the will-call bin, expired controlled substances found throughout the pharmacy, and controlled substances that needed to be returned to stock.
- g. Controlled substances were scattered throughout the pharmacy and not secured.
- h. A policy and procedure manual could not be immediately located. When the manual was located, it had not been updated since 2008. The manual did not contain policies regarding delivery, mail-outs, or technician training.
- i. There were several entries for changes in the perpetual inventory for Schedule II controlled substances that did not have an explanation of the incident.
- j. Controlled substances were being destroyed by staff. No records were kept.
- k. There was no evidence of any technician training.

14. Respondent had previously been cited for several of the deficiencies identified above.

C. ORDER TO SHOW CAUSE

15. Pursuant to Iowa Code section 124.304(1)(d) and 657 IAC 10.10(1)"d", the Board may suspend, revoke, or restrict a controlled substances registration upon a finding that the registrant has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined under that section.

16. A registrant's compliance with applicable state and local laws is a factor to be considered when determining whether a registration is inconsistent with the public interest, pursuant to Iowa Code section 124.303(1)(b) and 657 IAC 10.10(4)"b".

17. The Statement of Charges and Factual Circumstances described in sections A and B above render Respondent's registration inconsistent with the public interest and serve as the basis for this Order to Show Cause.

18. Respondent is ordered to show cause why its controlled substances registration should not be suspended. In lieu of proceeding with a show cause hearing, Respondent agrees to resolve this matter by entering into the following Settlement Agreement and Final Order.

D. SETTLEMENT AGREEMENT AND FINAL ORDER

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

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

21. 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.

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

23. 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.

24. 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.

25. 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.

26. This Order shall not be binding as to any new complaints received by the Board.

27. 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.

28. 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.

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

IT IS THEREFORE ORDERED:

30. Respondent's license and registration are **SUSPENDED**, but the suspensions are **STAYED** for sixty (60) days. During the stayed suspension, Respondent shall correct all deficiencies identified in the Statement of Charges and Factual Circumstances above. If the deficiencies are not corrected within sixty (60) days, the stay will be lifted and Respondent's license will be **INDEFINITELY SUSPENDED** until such time as all deficiencies are corrected.

31. Following the period of suspension, Respondent's license and registration shall be placed on **PROBATION** for a period of three (3) years, subject to the following terms:

- a. Within sixty (60) days, Respondent shall pay a **CIVIL PENALTY** in the amount of two thousand five hundred dollars (\$2500). 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 Eighth Street, Suite E, Des Moines IA 50309.
- b. Respondent shall complete self-inspections on a monthly basis and submit documentation of each self-inspection at quarterly intervals to the Board. Board compliance officers may conduct on-site inspections at any time. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during a self-inspection or Board inspection are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion may be considered a violation of this Order.
- c. Respondent shall conduct a physical inventory of all controlled substances every three (3) months. The inventory must be reconciled with the Schedule II perpetual inventory record and with the electronic inventory. Each physical inventory and documentation of reconciliation shall be sent to the Board.
- d. Respondent shall submit documentation of the monthly self-inspections and the quarterly physical inventories of controlled substances on a quarterly basis, with such reports being due no later than March 5th, June 5th, September 5th, and December 5th of each year. Such documentation should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309, or emailed to Amanda.Woltz@iowa.gov.

e. 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.

32. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 124, 147, 155A, and 272C, and 657 IAC chapters 10 and 36.

This Combined Statement of Charges, Order to Show Cause, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the ___ day of _____, 20__.

Ric E Foreman

EVANSDALE PHARMACY
Respondent

By this signature, *Ric E Foreman* acknowledges s/he is the owner for Respondent and is authorized to sign this Combined Statement of Charges, Order to Show Cause, Settlement Agreement, and Final Order on behalf of Respondent.

This Combined Statement of Charges, Order to Show Cause, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 16 day of January, 2018.

Susan Henger

Chairperson
Iowa Board of Pharmacy