

BEFORE THE IOWA BOARD OF PHARMACY

RE: Pharmacy License of MANLY DRUG STORE License No. 834 Respondent	CASE NO. 2020-0133 COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER
--------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------

COME NOW the Iowa Board of Pharmacy ("Board") and Manly Drug Store ("Respondent"), 621 G Ave, Grundy Center IA 50638, 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 this case pursuant to Iowa Code chapters 17A, 155A, and 272C, and 657 IAC 36.

A. STATEMENT OF CHARGES

COUNT I

IMPROPER DRUG PRODUCT SELECTION

1. Respondent is charged with engaging in improper drug product selection in violation of Iowa Code section 155A.32 and 657 IAC 8.3(2), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 155A.15(2)(f), and 657 IAC 36.6(21) and 36.6(41).

COUNT II

INACCURATE PRESCRIPTION PROCESSING DOCUMENTATION

2. Respondent is charged with failing to include the National Drug Code (NDC) of the actual drug product dispensed on the dispensing documentation in violation of 657 IAC 6.8 and 8.3(2), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT III

INCOMPLETE PRESCRIPTION LABELING

3. Respondent is charged with failing to include a unique identification number of the prescription on prescription labels in violation of 657 IAC 6.10(1)"a" and 8.3(2), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT IV

FAILURE TO ESTABLISH CQI PROGRAM

4. Respondent is charged with failing to establish a continuous quality improvement program in violation of 657 IAC 8.26 and 8.3(5)"c", 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 V
INADEQUATE POLICIES AND PROCEDURES

5. Respondent is charged with failing to establish and periodically review policies and procedures for all operations of the pharmacy in violation of 657 IAC 8.3(5)"a" and 23.7, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c), and 657 IAC 36.6(21).

B. FACTUAL CIRCUMSTANCES

6. Respondent's pharmacy license number 834 is currently active through December 31, 2021.

7. Respondent dispensed GaviLyte-C with a label for Nulytely when presented with a prescription for Nulytely.

8. Respondent dispensed a Novolog vial with a label for Novolog Flexpens.

9. The NDC number recorded in the prescription processing documentation did not match the NDC number of the actual product dispensed.

10. Several prescription labels included "Rx:0" instead of a unique prescription number.

11. Respondent had not established a functional CQI program and reportable events were not recorded for over three years.

12. Respondent's long term care policy and procedure manual had not been updated and failed to address proper notification to the facility when a drug or device is not readily available and proper labeling requirements.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

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

14. 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.

15. 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.

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

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

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

IT IS THEREFORE ORDERED:

23. Respondent's license is 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 five thousand dollars (\$5,000) 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. Within sixty (60) days of this Order, Respondent shall submit copies of updated policies and procedures addressing all violations set forth in this Order. Respondent shall implement and adhere to such policies and procedures.
- c. Respondent shall perform quarterly self-inspections and shall submit the self-inspection reports to the Board after each inspection. Each quarterly self-inspection must address all violations set forth in this Order and any other areas identified by the Board for a particular inspection. The quarterly inspection reports are due by March 5th (reporting on December-February), June 5th (reporting on March-May), September 5th (reporting on June-August), and December 5th (reporting on September-November).
- d. 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.

- 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.
- f. Any documentation required to be submitted shall be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.

24. 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.

6/13/21
Date

Davis Hoff P.C.
MANLY DRUG STORE
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on July 14, 2021

Brenda A. B.
Chairperson
Iowa Board of Pharmacy

RECEIVED

JUN 17 2021

IOWA JUSTICE DEPARTMENT

ADMINISTRATIVE LAW