

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2010-74
FEDDERS HEALTH MART)	
License No. 562,)	STATEMENT OF CHARGES
Respondent.)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2009).
3. On November 25, 2009, the Board renewed general pharmacy license number 562 for Fedders Health Mart (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy, subject to the laws of the State of Iowa and the rules of the Board.
4. At all times material to this statement of charges, Respondent was operating a general pharmacy at 52 Main Avenue North, Britt, Iowa 50423 with Sandra Hartwig as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009) and 657 Iowa Administrative Code § 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in Iowa, as evidenced by Respondent's employment of an unlicensed pharmacist.

COUNT II – EMPLOYING UNLICENSED PHARMACIST

Respondent is charged under Iowa Code §§ 155A.15(2) and 155A.15(2)(e) (2009), and 657 Iowa Administrative Code § 36.1(4)(aa), with allowing an unlicensed employee to practice pharmacy.

B. CIRCUMSTANCES

An investigation was commenced on June 28, 2010 which revealed the following:

1. Respondent operates a general pharmacy located at 52 Main Avenue North, Britt, Iowa 50423, with Sandra Hartwig as the pharmacist in charge. At all times material to this statement of charges, Harvey Eernisse was employed by Respondent as a pharmacist.
2. On April 23, 2010 the Iowa Department of Revenue notified the Board that Harvey Eernisse was potentially subject to license sanctions pursuant to Iowa Code chapter 272D ("Debts Owed To State or Local Government – Licensing Sanctions"). The Board served Eernisse notice regarding the potential suspension of his pharmacist license on April 28, 2010. The notice provided that Eernisse's license would be suspended 60 days following receipt of the notice unless the Department of Revenue certificate of non-compliance was withdrawn.
3. The Department of Revenue did not withdraw its certificate of non-compliance. Hence, Eernisse's license was suspended on June 27, 2010.
4. After verifying that the Department of Revenue had not withdrawn its certificate of non-compliance, a Board compliance officer contacted Respondent's pharmacist in charge, Sandra Hartwig, on July 6, 2010 and suggested that she be certain Eernisse's registration was current before allowing him to work. The compliance officer was informed that Eernisse was next scheduled to work on July 9th.
5. Eernisse worked at Respondent on July 9, 2010. Eernisse previously had worked at Respondent on July 1, 2 and 3, 2010, with a suspended license.

Wherefore, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

[Redacted Signature]

LLOYD K. JESSEN
Executive Director

On this 28 day of Sept. 2010, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

[Redacted Signature]

VERNON H. BENJAMIN, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

Fedders Healthmart-SOC 8-10.doc

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2010-74
Pharmacy License of)	
FEDDERS HEALTHMART,)	STIPULATION
License No. 562)	AND
Respondent)	CONSENT ORDER

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the "Board") and Fedders Healthmart (hereinafter, "Respondent") have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on September 28, 2010 shall be resolved without a hearing, as the Board and Respondent stipulate to the following:

1. Respondent's license to operate a general pharmacy in Iowa is evidenced by Pharmacy License Number 562, which is recorded in the permanent records of the Board.
2. Pharmacy License Number 562 is current and active until December 31, 2011.
3. The Board has jurisdiction over the parties and the subject matter herein.
4. A Statement of Charges was filed against Respondent on September 28, 2010.
5. Respondent has chosen not to contest the allegations set forth in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

6. On the date of the Board's approval of this Stipulation and Consent Order, Respondent's license shall be placed on probation for two (2) years, upon the following conditions:

- (a) Within three (3) months after the date of the Board's approval of this Stipulation and Consent Order, Respondent will submit to the Board *typewritten*¹ pharmacy policies and procedures for verification that all pharmacy employees are properly licensed or registered. Following review and approval by the Board, Respondent agrees to adopt, implement, and adhere to these policies and procedures
- (b) Respondent shall file sworn quarterly reports with the Board attesting to Respondent's compliance with the terms and conditions of this Stipulation and Consent Order. The reports shall be filed not later than March 5th, June 5th, September 5th and December 5th of each calendar year and *shall include a description of Respondent's most recent efforts to comply with this Stipulation and Consent Order.* Respondent's quarterly reports shall identify the current person responsible for compliance with Iowa law, and provide any other information deemed to be necessary, from time to time, by the Board.
- (c) Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of an Iowa pharmacy.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of \$500. The civil

¹ For the purposes of this order, "typewritten" policies may be generated on computer word-processing equipment.

penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate further action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

9. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

10. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

11. The State's counsel may present this Stipulation and Consent Order to the Board.

12. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary proceeding.

This Stipulation and Consent Order is voluntarily submitted by Fedders Healthmart to

the Iowa Board of Pharmacy for its consideration on this 10 day of May 2011.

[Redacted Signature]

FEDDERS HEALTHMART
Respondent
By Charlotte Fedders, Owner

Subscribed and sworn to before me by Charlotte Fedders, who has stated to me that she is the owner of Fedders Healthmart and is authorized to sign this Stipulation and Consent Order on behalf of Fedders Healthmart on this 10th day of May 2011.



[Redacted Signature]

NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 29 day of June 2011.

[Redacted Signature]

SUSAN FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Fedders Healthmart
52 Main Avenue North
Britt, Iowa 50423

Fedders Healthmart settle 1-11.doc

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2012-37, 2012-46,
Pharmacy License of)	2012-47, 2012-54, 2012-63,
FEDDERS HEALTH MART,)	2012- 134, 2012-180, 2013-1,
License No. 562,)	and 2013-14
Respondent.)	
)	STATEMENT OF CHARGES,
)	SETTLEMENT AGREEMENT
)	AND ORDER (COMBINED)

COMES NOW the Iowa Board of Pharmacy (Board) and Fedders Pharmacy (Respondent), on March 13, 2013, pursuant to Iowa Code sections 17A.12(2) 17A.10(2), and 272C.3(4) (2013), and enter into this Combined Statement of Charges, Settlement Agreement and Order to resolve a pending disciplinary matter.

A. STATEMENT OF CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2013) and 657 Iowa Administrative Code § 36.1(4)(b) with lack of professional competency as demonstrated by Respondent's (a) substantial deviation from the standards of learning and skill ordinarily possessed and applied by other Iowa pharmacies, (b) failure to exercise in a substantial respect that degree of care which is ordinarily exercised by an Iowa pharmacy and (c) willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by Respondent's failure to maintain adequate controls over controlled substances.

COUNT II – VIOLATION OF CONTROLLED SUBSTANCES LAWS

Respondent is charged with a failure to comply with controlled substances laws, in violation of Iowa Code §§ 124.306, 124.308, 124.402 and 155A.15(2)(c) (2013) and 657 Iowa Administrative Code § 36.1(4)(j).

COUNT III – FAILURE TO MAINTAIN AND PROVIDE RECORDS

Respondent is charged with failure to maintain and provide to the Board pharmacy records, including records relating to controlled substances, in violation of Iowa Code §§ 155A.15(2) and 155A.15(5)(h) (2013) and 657 Iowa Administrative Code 10.34, 10.35, 21.5, 36.1(4)(ac), and 36.1(4)(ag).

COUNT IV – FAILURE TO MAINTAIN AND PROVIDE RECORDS

Respondent is charged with failure to maintain and provide to the Board pharmacy records, including records of controlled substances, in violation of Iowa Code §§ 124.306, 155A.12(1) and 155A.12(4) (2013) and 657 Iowa Administrative Code 10.34, 10.35, 21.5, 36.1(4)(ac), and 36.1(4)(ag).

COUNT V – VIOLATING RULES OF THE BOARD

Respondent is charged with violating the rules of the Board, in violation of Iowa Code § 155A.15(2)(c) (2013), including 657 IAC 8.3(3) (pharmacist-documented verification); 8.26 (continuous quality improvement program); 10.33 (perpetual inventory of Schedule II controlled substances); 10.34(7) (ordering or distributing Schedule I or II controlled substances); and 10.35 (complete and accurate controlled substances inventory).

B. FACTUAL CIRCUMSTANCES

1. Respondent is a licensed general pharmacy in the State of Iowa. Respondent's license is currently active until December 31, 2013.
 2. At all times material to this Statement of Charges, Respondent was operating a general pharmacy in Britt, Iowa, with Lon Rosenthal as the pharmacist in charge from August 2011-April 2012, and with Gaylord Victora as the pharmacist in charge from May 2012 to the present.
 3. The Board filed a Statement of Charges against Respondent on September 28, 2010, alleging Respondent employed an unlicensed pharmacist for a period of time.
 4. Respondent entered into a Stipulation and Consent Order with the Board on June 29, 2011, in which it agreed to a two-year probation subject to a number of terms, including payment of a \$500 civil penalty and a requirement that policies and procedures for verifying pharmacy employees are properly licensed be submitted for Board approval. Respondent's pharmacy license is currently on probation under this Order through June 29, 2013.
- Case No. 2012-37*
5. The Board received a complaint regarding dispensing errors by Respondent in March 2012. In that case, the patient had a prescription for nortriptyline 25mg, which Respondent erroneously filled with nortriptyline 50mg capsules.

6. In that case, Respondent also delivered another prescription to this patient. However, the prescription delivered was a prescription for another patient who lived ten miles away.
7. In that case, this patient also had a prescription for fentanyl 100 mcg/hr, which Respondent erroneously filled with fentanyl 50mcg/hr. The Board's investigation determined that Respondent's inventory for fentanyl patches was off for both strengths.
8. Respondent did not perform CQI for these errors.

Case No. 2012-46

9. The Board received a complaint regarding a dispensing error in March 2012. In that case, the patient had a prescription for metoprolol ER 25mg which Respondent erroneously filled with the immediate release formulation instead. The patient also stated that in January of 2011 he picked up prescriptions from Respondent that were not the prescriptions that had been called in by his provider, but duplicates of prescriptions that had been previously filled.

Case No. 2012-47

10. The Board received a complaint regarding a delay in filling of several prescriptions. Respondent's PIC agreed prescriptions are not always ready in a timely manner and that some patients do experience long waits.

Case No. 2012-54

11. The Board received a complaint regarding a dispensing error in November 2011. In that case, the patient had a prescription for doxazosin 1mg labeled with the Mylan brand, but Respondent dispensed a bottle labeled with the Teva brand. The patient identified this error. After being notified of the error by the patient, Respondent made a second dispensing error by dispensing Mylan doxazosin 2mg tablets. Again, the patient identified the error before using the medication.

Case No. 2012-63

12. The Board received a complaint regarding a dispensing error in March 2012. In that case, the patient had a prescription for Lipitor 20mg, which Respondent erroneously filled with Lipitor 40mg. The patient used the wrong dose of this medication for a period of time. During the investigation of this complaint, a health care provider stated to the Board that on numerous occasions over the prior months, Respondent states it has not received prescriptions faxed to it by this provider, and that Respondent has placed other provider's names on prescriptions written by this provider.

13. During an investigation of the complaints above, the Board found Respondent did not have in place a formal method of verifying prescriptions, such as a formal NDC prescription verification process; and did not have an accurate inventory of C-II medications.

14. On September 21, 2012, the Board entered into a Combined Statement of Charges, Settlement Agreement, and Order with Respondent's PIC, Lon Rosenthal. In that agreement Mr. Rosenthal agreed to the indefinite suspension of his pharmacist license due to his inability to practice pharmacy with reasonable skill and safety because he was abusing alcohol and experiencing cognitive deficits.

Case No. 2012-134

15. The Board received a complaint regarding a dispensing error in April 2012. In that case, the patient had a prescription for Coumadin 2mg, which Respondent erroneously filled with Coumadin 4mg. The patient took the wrong medication for eight days.

Case No. 2012-180

16. The Board received a complaint regarding a dispensing error in October 2012. In that case, Patient #1 had prescriptions for hydrochlorothiazide (HCTZ) 25mg and lisinopril 20mg. When Patient #1 picked up these prescriptions, Respondent gave him two prescriptions for Patient #2 instead, which were for HCTZ 25mg and benazepril 40mg. Patient #1 took the wrong medication for several weeks.

Case No. 2013-1

17. The Board received a complaint regarding a dispensing error in November 2012. In that case, the patient, who had recently undergone major surgery, had a prescription for long acting 12-hour Oxycontin 10mg#60 twice daily. Respondent erroneously filled the prescription with short acting oxycodone 10mg instead. The patient took the wrong medication for one month and experienced a significant deterioration of her condition during this time. No CQI was recorded for this complaint.

18. During investigation of this case, the Board determined Respondent's PQC electronic reporting database has never been used, as it contains no information.

19. During its investigation of this case, the Board performed a mini-audit of Respondent's controlled substance inventory and found the following:

- The C-II perpetual inventory is incomplete.
- There is no accountability for C-II drugs since Respondent's current PIC was employed. No initial controlled substance inventory was conducted

when Respondent's PIC changed in May of 2012. Prior inventory records were also not up to date.

- Respondent's controlled drug invoices are not properly maintained.
- Respondent's controlled drug prescriptions are not properly maintained.
- While present in Respondent's pharmacy, a Board Compliance Officer was told by a patient that she was never counseled on her medications.
- While present in Respondent's pharmacy, a Board Compliance Officer overheard a conversation regarding a mistake on a prescription for azithromycin. The mistake involved an unlicensed clerk improperly taking two separate prescriptions over the phone from an office nurse. The PIC informed the clerk this could not occur again. However, the PIC did not then call the provider back to verify these orders. One prescription for azithromycin 500mg once daily for five days was transcribed as a ZPak 250mg two tablets on day one, then one tablet daily for four days. The accuracy of the second prescription for cefprozil 250mg/5ml suspension was never confirmed.

Case No. 2013-14

20. The Board received a complaint regarding a dispensing error in January 2013. In that case, the patient had a prescription for generic Lexapro. When he picked up his refill for this prescription, Respondent erroneously also included in his bag a prescription for levothyroxine 0.05mg. The patient does not have a prescription for levothyroxine. No CQI was performed for this error. The pharmacy records regarding this incident were inadequate.

C. SETTLEMENT AGREEMENT

21. Respondent has filed an Answer concurrent with this Statement of Charges denying the charges. However, Respondent wishes to enter into this combined Statement of Charges and Settlement Agreement to resolve this matter and avoid a contested case hearing. Respondent does acknowledge that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

22. On the date of the Board's approval of this Settlement Agreement and Final Order, Respondent's license shall be placed on probation for a period of three (3) years, subject to the following terms:

- a. Respondent shall submit a \$2500.00 civil penalty to the Board. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within sixty (60) days of the date this Settlement Agreement is approved by the Board. All civil penalty payments shall be deposited into the State of Iowa's general fund.

- b. Respondent shall within thirty (30) days of the date this Settlement Agreement is approved by the Board complete a current, accurate and complete controlled substance inventory and submit it to the Board for review and approval.
- c. Respondent shall within sixty (60) days of the date this Settlement Agreement is approved by the Board, submit to the Board for its approval policies and procedures for the following areas of practice. Respondent agrees to comply with these policies and procedures while operating its pharmacy.
- i. drug recalls
 - ii. readily retrievable invoices for controlled/non-controlled medications
 - iii. CQI – Continuing Quality Improvement
 - iv. C-II drug storage
 - v. Long term care operations
 - vi. pharmacy technician duties
 - vii. pharmacy support person duties
 - viii. drug utilization review
 - ix. documentation of final verification of dispensed medications
 - x. perpetual inventory requirements
 - xi. disposal of expired medications
 - xii. proper recordkeeping for the dispensing of prescription drugs and controlled substances
 - xiii. proper recordkeeping for receipt of controlled substances
 - xiv. proper recordkeeping for annual controlled substance inventory.
- d. Respondent shall comply with all applicable Iowa pharmacy law and rules and all related federal requirements for controlled substances.
- e. Respondent shall submit quarterly reports to the Board. The reports shall be filed not later than December 5, March 5, June 5 and September 5 of each calendar year. These reports shall include Respondent's place of employment; current address; a narrative discussing Respondent's current compliance with the terms of this Settlement Agreement and Final Order; and any further information requested by the Board.
- f. Upon the Board's request, Respondent shall appear informally before the Board for the purpose of reviewing its compliance with the terms of this probation. Respondent shall be given reasonable notice of the date, time, and place for the appearances.

- g. Only the periods of time during which Respondent is actively operating as a pharmacy under its current Iowa license shall apply to the duration of the probation, unless otherwise approved by the Board.
- h. Respondent may request termination of its probation after at least one (1) year from the date of this Order, if Respondent can demonstrate full compliance with the terms and conditions of this Order. Early termination of the probation is at the discretion of the Board.

23. If Respondent violates or fail to comply with any of the terms or conditions of this Order, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacy license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 IAC § 36.

24. This Order is the resolution of a contested case. By entering into this Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Order.

25. The State's legal counsel may present this Combined Statement of Charges, Settlement Agreement and Order to the Board.

26. This proposed settlement is subject to the approval of the Board. If the Board fails to approve this Order, it shall be of no force or effect to either party. If the Board approves this Order, it shall be the full and final resolution of this matter.

27. The Board's approval of this Combined Statement of Charges, Settlement Agreement and Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

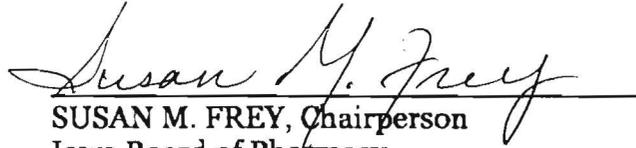
Signed by Respondent on this 8 day of March, 2013.

Charlotte Fedders

CHARLOTTE FEDDERS

By her signature Charlotte Fedders acknowledges she is the owner of Fedders Health Mart and is authorized to sign this Settlement Agreement and Final Order on its behalf.

On this 13th day of March, 2013, the Iowa Board of Pharmacy approved this Combined Statement of Charges, Settlement Agreement and Order.



SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa O'Connell Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Sally Reavely
WHITFIELD & EDDY, P.L.C.
317 Sixth Ave., Suite 1200
Des Moines, IA 50309-4195