

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	
Pharmacy License of	)	Case No. 2007-120
<b>HY-VEE PHARMACY #1382</b>	)	Case No. 2008-65
	)	Case No. 2008-96
License No. 1238,	)	Case No. 2008-110
Respondent.	)	Case No 2008-129

**STATEMENT OF CHARGES**

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

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 147, 155A and 272C (2009).
3. Effective December 7, 2009 the Board renewed the general pharmacy license of Hy-Vee Pharmacy #1238 (hereinafter, "Respondent") with Misty Frentress as the pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa the rules of the Board.
4. General pharmacy license 1238 is current and active until December 31, 2010.
5. Respondent is currently operating a general pharmacy at 1201 12<sup>th</sup> Avenue SW, LeMars, Iowa. At all times material to this Statement of Charges, Jeffrey Faber was the pharmacist in charge.

**A. CHARGES**

**COUNT I – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged under Iowa Code § 155A.15(2) (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 the state of Iowa.

## COUNT II – FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged under Iowa Code § 155A.15(2)(h) (2009), and 657 Iowa Administrative Code §§ 36.1(4)(ac) and 36.1(4)(u), with failing to maintain complete and adequate records of purchases, sales and disposal of drugs listed in the controlled substances act.

## COUNT III – FAILURE TO MAINTAIN CONTROL OVER DRUGS

Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1)(a) and 155A.15(2)(i) (2009), and 657 Iowa Administrative Code §§ 6.7 and 36.1(4)(u), with failing to maintain control over and accountability for drugs, including controlled substances.

## COUNT IV – EMPLOYING UNREGISTERED PERSONS TO WORK AS TECHNICIANS

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009) and 657 Iowa Administrative Code § 36.1(4)(aa) with knowingly aiding, assisting and procuring and employing non-technicians to perform the functions of a pharmacy technician.

## COUNT V – CIRCUMVENTING COUNSELING REQUIREMENTS

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009) and 657 Iowa Administrative Code § 36.1(4)(w) with attempting to circumvent patient counseling requirements.

### **B. CIRCUMSTANCES**

On November 14, 2007 an investigation (#2007-120) was commenced, revealing the following:

1. Respondent operated two pharmacies in LeMars. A single Hy-Vee pharmacy was created by consolidating the two separate Hy-Vee locations. The pharmacies were merged on September 23, 2007, with Jeff Faber as pharmacist in charge.
2. At the time of the physical consolidation, Respondent attempted to consolidate the records of the two stores, which were maintained on different software. Record consolidation was not successfully performed. Jeff Faber acknowledged that, after the pharmacy consolidation, inventory records were incorrect and, specifically, records relating to schedule II controlled substances were incorrect.
3. Shortly after consolidation, dispensing errors occurred (e.g., a Z-Pak dispensed instead of cholestyramine powder). Nevertheless, errors were not logged into Respondent's quality assurance program, as the program had not been

implemented. Respondent's customers had to wait extended periods to receive prescription fills.

4. An inspection of Respondent pharmacy on March 25, 2008 revealed 21 deficiencies, including the following:
  - a. Pharmacy cashiers were packaging prescriptions and were permitted, pursuant to the pharmacy policies and procedures, to perform prospective drug utilization review.
  - b. The Pharmacy's policy and procedure manual was outdated, incomplete and legally incorrect (e.g., permitting technicians to perform prospective drug utilization review; provisions for counseling were incorrect). Parts of the manual refer to K-Mart policies and procedures.
  - c. Expired drugs were in pharmacy stock.
  - d. Documentation of employee training was missing.
  - e. Continuous Quality Improvement (CQI) records were incomplete, and failed to include any record of errors involving long term care facilities.
  - f. Pharmacist licenses were not displayed.
  - g. Refrigeration practices were incorrect.
  - h. Bulk compounding records were incomplete, and labels on products did not list each ingredient or strength of ingredient.
  - i. The annual controlled substance inventory was not timely completed.
  - j. DEA 222 forms were not being correctly maintained.
  - k. Perpetual inventory records for controlled substances were being revised without preparation of an incident report.
  - l. The pharmacy's permanent log did not list unique codes or initials for 9 of the 12 technicians.
5. Counseling was not being provided to pharmacy patients who obtained fills of new prescriptions.

On July 9, 2008 a second investigation (#2008-65) was commenced, revealing the following:

6. At all times material to this investigation, and all other investigations described below, Jeff Faber was employed as the pharmacist in charge of Respondent pharmacy.
7. On March 26, 2008, a patient was prescribed Toprol XL 200mg. On the same day, the patient was dispensed Topamax 200mg by Respondent. The medication was dispensed in a container labeled as Toprol XL 200mg.
8. The verifying pharmacist not only failed to notice the error, he failed to counsel the patient regarding Toprol, which was a new medication for the patient.

On September 24, 2008 a third investigation (#2008-96) was commenced, revealing the following:

9. On September 18, 2008 a patient who had been prescribed Vibramycin (Doxycycline) 100mg took the prescription to the Respondent pharmacy, where she was told the pharmacist was having difficulty reading the script. Despite this difficulty, the prescriber was not contacted to verify the prescription or the prescriber's name.
10. Ultimately, the patient was dispensed Nitrofurantoin 100mg, instead of Vibramycin. The prescriber name was incorrect on the label of the medication dispensed. Jeff Faber checked the prescription fill before it was dispensed.
11. Faber claimed to have been unaware of the dispensing error; however the patient reported the error to the pharmacy when she filled a subsequent prescription (a Z-pak) for treatment of the same illness.

On October 21, 2008 a fourth investigation (#2008-110) was commenced, revealing the following:

12. On October 15, 2008, a patient phoned Respondent pharmacy seeking an early refill of her prescription for hydrocodone APAP 500. The patient's prescriber had provided the pharmacy specific instructions with the prescription: "must last one month. Do not fill early."
13. Despite the prescriber instructions, 90 tablets were dispensed to the patient on October 15, 2008 – 13 days before the authorized refill date.

On December 17, 2008 a fifth investigation (#2008-129) was commenced, revealing the following:

14. A patient, who had received a prescription for 15 tablets of Tylenol 3, was dispensed 15 tablets of Furosemide 40 mg instead.

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.

  
LLOYD K. JESSEN  
Executive Director

On this 1<sup>st</sup> day of June 2010, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

  
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

Edwin McIntosh  
Dorsey & Whitney  
801 Grand Avenue, Suite 3900  
Des Moines, Iowa 50309-2790

Hy-Vee LeMars#2 5-10

**BEFORE THE IOWA BOARD OF PHARMACY**

Re: )  
Pharmacy License of )  
**HY-VEE PHARMACY 1382** )  
License No. 1238, )  
Respondent. )

Case No. 2010-79

**STATEMENT OF CHARGES**

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

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") 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 (2011).
3. Effective November 14, 2011, the Board renewed Respondent's general pharmacy license number 1238 for Hy-Vee Pharmacy 1382 (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. General pharmacy license number 1238 is current until December 31, 2012.
5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 1201 12<sup>th</sup> Avenue, Southwest, LeMars, Iowa 51031 with Misty Frentress as the pharmacist in charge.

**A. CHARGES**

**COUNT I – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011) 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.

## COUNT II – VIOLATION OF CONTROLLED SUBSTANCES LAWS

Respondent is charged under Iowa Code §§ 124.212A, 124.212B, 124.306, 124.402(c), 155A.15(2)(c) (2011), and 657 Iowa Administrative Code §§ 10.32, 36.1(4)(i) and 36.1(4)(j), with violating controlled substances laws.

## COUNT III – FAILURE TO MAINTAIN AND PROVIDE RECORDS

Respondent is charged under Iowa Code §§ 155A.15(2) and 155A.15(5)(h) (2011) and 657 Iowa Administrative Code §§ 8.4(3), 10.34, 10.35, 21.5, 36.1(4)(ac), 36.1(4)(ag) and 36.1(4)(i), with failure to maintain and provide to the Board pharmacy records, including records relating to controlled substances.

## COUNT IV – FAILURE TO MAINTAIN ADEQUATE CONTROLS

Respondent is charged under Iowa Code §§ 124.306, 124.402(1), 155A.15(2)(c) and 155A.15(2)(i) (2011), and 657 Iowa Administrative Code § 6.7 and 36.1(4)(i), with failing to maintain adequate control over and accountability for controlled substances.

## COUNT V – PROCURING PERSONS TO PERFORM AS TECHNICIAN

Respondent is charged under Iowa Code § 155A.15(2)(c) and 155A.15(2)(e) (2011), and 657 Iowa Administrative Code §§ 36.1(4)(i) and 36.1(4)(l), with knowingly aiding, assisting and procuring non-technicians to perform the functions of a pharmacy technician.

## COUNT VI – ATTEMPTING TO SUBVERT AN INVESTIGATION

Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2011), and 657 Iowa Administrative Code §§ 36.1(4)(i) and 36.1(4)(z), with attempting to subvert a Board investigation.

## COUNT VII – CIRCUMVENTING COUNSELING REQUIREMENT

Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2011), and 657 Iowa Administrative Code §§ 36.1(4)(i) and 36.1(4)(w), with attempting to circumvent patient counseling requirements.

## COUNT VIII – UNETHICAL CONDUCT

Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2011), and 657 Iowa Administrative Code §§ 8.11(1) and 36.1(4)(i), with unethical conduct; specifically, falsification of information provided in response to an insurance company audit.

## COUNT IX – OBTAINING A FEE BY MISREPRESENTATION

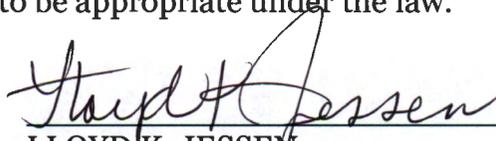
Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(t) with obtaining a fee by misrepresentation.

### B. CIRCUMSTANCES

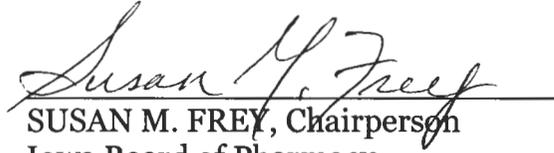
An investigation was commenced on July 27, 2010 which revealed the following:

1. At all times material to this Statement of Charges, Respondent was operating a general pharmacy at 1201 12<sup>th</sup> Avenue Southwest, LeMars, Iowa 51031, with Misty Fentress as the pharmacist in charge.
2. Respondent did not maintain complete and accurate records relating to sales of products containing pseudoephedrine.
3. Cashiers and pharmacy support personnel employed by Respondent bagged prescription medications, reconstituted liquid oral antibiotics, opened the pharmacy without a pharmacist present and performed other duties outside the scope of their authorized activities.
4. Respondent's pharmacist in charge directed a pharmacy support person to lie to the Board regarding, among other things, the scope of the support person's activities.
5. Respondent's pharmacist in charge directed an employee to falsify signatures in response to an insurance company audit.
6. The pharmacy alarm system was not used when the pharmacy was closed.
7. Some prescriptions were assigned a new number after a year had passed, as a basis for dispensing additional refills.
8. Respondent's annual controlled substance inventory was incomplete.
9. Counseling relating to all new prescriptions was not performed.
10. An inspection of the pharmacy, conducted August 4, 2010, revealed the following deficiencies:
  - a. Prescription labels did not contain identification of the checking pharmacist.
  - b. Pharmacy records were being stored outside the pharmacy.
  - c. Inventory records were incomplete; some lacked beginning and ending dates.
  - d. Records relating to temporary personnel were incomplete.

**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.

  
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LLOYD K. JESSEN  
Executive Director

On this 7<sup>th</sup> day of March 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

  
SUSAN M. FREY, 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

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**BEFORE THE IOWA BOARD OF PHARMACY**

Re: )  
Pharmacy License of )  
**HY-VEE PHARMACY #1382,** )  
License No. 1238 )  
Respondent )

Case Nos. 2007-120, 2008-65,  
2008-96, 2008-110, 2008-129  
and 2010-79

**STIPULATION  
AND  
CONSENT ORDER**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the "Board") and Hy-Vee Pharmacy #1382 (hereinafter, "Respondent") have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on June 1, 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 1238, which is recorded in the permanent records of the Board.
2. Pharmacy License Number 1238 is current and active until December 31, 2012.
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 denies the allegations contained in the Statement of Charges, but in the interest of settlement has chosen not to contest the allegations. Respondent 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 five (5) years, upon the following conditions:

(a) Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of an Iowa pharmacy.

(b) Consistent with subparagraph (a) above, all pharmacy technicians employed by Respondent shall be registered in compliance with Iowa law and the Board's administrative rules, and Respondent shall assure that all customers receive counseling in accordance with Board rules.

(c) Within 60 days of the Board's approval of this Stipulation and Consent Order, Respondent shall submit, for the Board's approval, a written plan by which Respondent intends to address each of the issues identified in the Statement of Charges, Counts I through IX, adopted by the Board on March 7, 2012.

(d) 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 December 5, March 5, June 5 and September 5 of each calendar year and shall include a description of Respondent's most recent efforts to comply with this Stipulation and Consent Order, including paragraphs (b) and (c) above. Respondent's quarterly reports shall list and verify the registration of all pharmacy technicians employed by Respondent, 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.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of \$12,000. The civil 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 Hy-Vee Pharmacy #1382 to the Iowa Board of Pharmacy for its consideration on this 27 day of JUNE 2012.

Hy-Vee Pharmacy 1382  
Misty Denton  
HY-VEE PHARMACY #1382  
Respondent  
By Misty Denton, R.Ph.  
Pharmacist In Charge

Subscribed and sworn to before me by Misty Denton, who has stated to me that he/she is the pharmacist in charge of Hy-Vee Pharmacy #1382 and is authorized to sign this Stipulation and Consent Order on behalf of Hy-Vee Pharmacy #1382 on this 27 day of June 2012.



Esther M. Shrader  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 10th day of July 2012.

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

cc: Theresa Weeg  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

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801 Grand Avenue,  
Des Moines, IA 50309**

Hy-Vee (LeMars) settle 5-12.doc  
revised