

**BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA**

Re:)	Case No. 2000-679
Pharmacy License of)	
FAMILY PHARMACY (STRATFORD))	STATEMENT OF CHARGES
License No. 679)	
Respondent)	

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners 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 (2001).
3. Effective January 1, 2001, the Board renewed Respondent general pharmacy license number 679 with Fred C. Marcalus as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 679 is current until December 31, 2001.
5. Respondent is currently operating a general pharmacy at 803 Shakespeare Street, Stratford, Iowa 50240 with Fred C. Marcalus as the pharmacist in charge.

COUNT I

The Respondent is charged under Iowa Code § 155A.15(2)(c) (2001) and 657 Iowa Administrative Code §§ 6.2(1)(a) & (b), 8.20, and 36.1(4)(u) & (w) with failure to ensure that its pharmacists provide adequate patient counseling.

COUNT II

The Respondent is charged under Iowa Code § 155A.15(2) (2001) and 657 Iowa Administrative Code §§ 6.6(1) and 36.1(4)(u) with inadequate security of the prescription department and permitting access to the prescription department when a pharmacist is not on site.

COUNT III

The Respondent is charged under Iowa Code § 155A.15(2) (2001) and 657 Iowa Administrative Code §§ 6.6(3) and 36.1(4)(u) with dispensing or distributing prescription medications to patients or others during the temporary absence of the pharmacist.

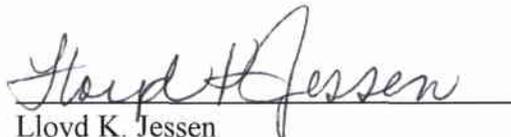
COUNT IV

The Respondent is charged under Iowa Code §§ 155A.15(2) and 155A.6(6) (2001), and 657 Iowa Administrative Code §§ 6.2(1)(f), 6.2(1)(k), 6.2(2), 22.4, 22.19 and 36.1(4)(u) with employing a pharmacy technician without a current, active Iowa technician registration.

THE CIRCUMSTANCES

1. During an investigation of the Respondent's pharmacy operations, a Board investigator discovered the following information:
 - (a) The non-pharmacist employees at the Respondent's pharmacy regularly sell prescriptions to patients or others when the pharmacist is not present in the pharmacy.
 - (b) Patients do not receive counseling from a pharmacist on new prescriptions as required by the Board's rules when they pick up prescriptions in the pharmacist's absence.
 - (c) The prescription department is not secured in a way that prevents access to the prescription department when the pharmacist is absent.
 - (d) An employee of the Respondent's pharmacy who is not registered as a technician regularly performs technician duties in the Respondent's pharmacy.

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 Secretary/Director

On this 10 day of October, 2001, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.



Matthew C. Osterhaus, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Shauna Russell Shields
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

**BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA**

Re:)	Case No. 2000-675
Pharmacy License of)	
FAMILY PHARMACY (STRATFORD))	STIPULATION
License No. 675)	AND
Respondent)	CONSENT ORDER

COME NOW the Iowa Board of Pharmacy Examiners (“the Board”) and Family Pharmacy (Stratford) (“Respondent”) and, pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2001), enter into the following Stipulation and Consent Order settling the contested case currently on file.

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Statement of Charges filed against the Respondent on October 10, 2001, shall be resolved without proceeding to hearing, as the parties have agreed to the following Stipulation and Consent Order:

1. That the Respondent’s license to operate a pharmacy was renewed effective January 1, 2001, as evidenced by Pharmacist License Number 675, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That General Pharmacy License Number 675 issued to and currently held by the Respondent is current and in force until December 31, 2002.
3. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against the Respondent on October 10, 2001.
5. This Stipulation and Consent Order is entered into in order to resolve disputed claims and constitutes no admission on the part of the Respondent.
6. The Respondent shall pay a civil penalty of \$200.00 within 30 days of the date of approval of this Stipulation and Consent Order by the Board. The Respondent shall deliver a check made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The check shall be deposited into the general fund of the State of Iowa.
7. Respondent's license shall be placed on probation for two (2) years, with the following conditions, beginning on the date this Stipulation and Consent Order is accepted by the Board:
 - a. Within sixty (60) days of the date of approval of this Stipulation and Consent Order by the Board, the Respondent will *provide its typewritten* policies and procedures for operating the Respondent's pharmacy in a legal manner. Such policy and procedure shall include how the Respondent's pharmacy will ensure: (a) proper pharmacy security, (b) proper handling of the temporary absence of the pharmacist, (c) the proper utilization of registered pharmacy technicians, (d) that patient counseling is provided by a licensed pharmacist, and (e) that prospective drug use review is performed by a licensed pharmacist. Following review and approval by the Board, the Respondent agrees to adopt, implement, and adhere to these policies and procedures whenever operating a pharmacy in the State of

Iowa.

- b. During probation, Respondent shall file sworn quarterly reports with the Board attesting to its compliance with all the terms and conditions of this Stipulation and Consent Order. The reports shall be filed not later than March 5, 2003, June 5, 2003, September 5, 2003; December 5, 2003, March 5, 2004, June 5, 2004, September 5, 2004, and December 5, 2004. The quarterly reports shall identify the current pharmacist in charge and all staff pharmacists and any further information deemed necessary by the Board from time to time.

8. The Respondent may apply to the Board for modification of the provisions of Respondent's probation, including termination of the probation, after Respondent has successfully completed one year of probation. Respondent understands that the determination of whether to modify or terminate its probation will remain in the Board's discretion.
9. The Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of a pharmacy.
10. Should the Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend the Respondent's Iowa license to operate a pharmacy or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code § 36.1.
11. This Stipulation and Consent Order is the resolution of a contested case. By

- entering into this Stipulation and Consent Order, the 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.
12. 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.
13. The Board's approval of this Stipulation and Consent Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

14. This Stipulation and Consent Order is voluntarily submitted by the Respondent to the Board for its consideration on the 29 day of November 2002.



Family Pharmacy (Stratford)
Fred C. Marcalus, R.Ph.
Pharmacist in charge,
Respondent

Subscribed and sworn to before me by Fred C. Marcalus, who has stated to me that he/she is the pharmacist in charge of Family Pharmacy (Stratford) and that he/she is authorized to sign this Stipulation and Consent Order on behalf of said Family Pharmacy (Stratford) on this 29th day of November, 2002.



NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

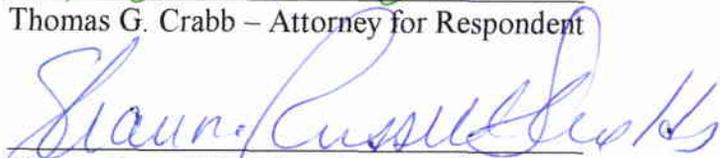


15. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 4 day of December, 2002.


KATHERINE A. LINDER, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

APPROVED AS TO FORM:


Thomas G. Crabb – Attorney for Respondent


Shauna Russell Shields – Attorney for State

cc: Thomas G. Crabb
505 5th Avenue
Suite 630
Des Moines, Iowa 50309
ATTORNEY FOR RESPONDENT

Shauna Russell Shields
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319
ATTORNEY FOR STATE

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2006-7
FAMILY PHARMACY (Stratford))	
License No. 679,)	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 (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 (2007).
3. The general pharmacy license number 679 of Family Pharmacy (hereinafter, "Respondent") was renewed, effective December 3, 2007, with Fred Marcalus as 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 679 is current and active until December 31, 2008.
5. Respondent is currently operating a general pharmacy at 803 Shakespeare Street, Stratford, Iowa 50130, with Fred Marcalus as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged pursuant to Iowa Code § 155A.15(2) (2007) 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 pursuant to Iowa Code §§ 124.306, 155A.15.2(c) and 155A.15.2(h), and 657 Iowa Administrative Code §§ 36.1(4)(u) and 36.1(4)(ac), with failing to maintain complete, adequate and accurate records of purchases and disposal of drugs, including controlled substances.

COUNT III – FAILURE TO MAINTAIN CONTROL OVER DRUGS

Respondent is charged pursuant to Iowa Code §§ 124.308(3), 124.402(1)(a), 155A.15(2)(c) and 155A.15(2)(i) (2007), and 657 Iowa Administrative Code §§ 6.7 and 36.1(4)(u), with failing to maintain accurate control over and accountability for drugs, including controlled substances.

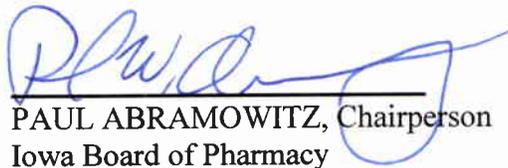
B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

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 4th day of March 2006, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.


PAUL ABRAMOWITZ, 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

FamilyPh(Stratford)-SOC

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:)	CASE NO: 2006-07
)	DIA NOS. 08PHB006-008
Pharmacist License of)	
FREDERICK MARCALUS)	
License No. 13175)	
)	FINDINGS OF FACT,
Pharmacy License of)	CONCLUSIONS OF LAW,
FAMILY PHARMACY (Dayton))	DECISION AND ORDER
License No. 706)	
)	
Pharmacy License of)	
FAMILY PHARMACY (Stratford))	
License No. 679)	
)	
)	
RESPONDENTS)	

On March 4, 2008¹, the Iowa Board of Pharmacy (Board) found probable cause to file Statements of Charges against Respondents Frederick Marcalus, Family Pharmacy (Dayton), and Family Pharmacy (Stratford). All three Statements of Charges alleged Lack of Professional Competency [Count I], Failure To Maintain Adequate Records [Count II], and Failure to Maintain Control Over Drugs [Count III]. The Statements of Charges against Frederick Marcalus and Family Pharmacy (Dayton) further alleged Improper Delegation of Pharmacist Functions [Count IV].

The consolidated hearing was held on June 28, 2011 at 2:15 p.m. in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members of the Board served as presiding officers for the hearing: Susan Frey, Chairperson; Edward Maier; DeeAnn Wedemeyer Oleson; Mark Anliker; James Miller; and LaDonna Gratias. Assistant Attorney General Scott Galenbeck represented the state. Respondents were represented by attorney Thomas Crabb. The hearing was closed to the public at Respondents' election, in accordance with Iowa Code §272C.6(1). Administrative Law Judge Margaret

¹ The parties stipulated at hearing that the pharmacies' Statements of Charges are incorrectly dated. The Statements of Charges were filed in 2008, not 2006.

LaMarche assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order for their review, in conformance with their deliberations.

THE RECORD

The record includes the testimony of Compliance Officer Jean Rhodes and Frederick Marcalus, State Exhibits 1-9 (See Exhibit Index for description of 1-7; Exhibits 8 and 9 are the November 2005 Inspection Reports for both pharmacies), Family Pharmacy Stratford Exhibits A-0 (photographs); and Dayton Exhibits A-K (also photographs).

FINDINGS OF FACT

1. On February 1, 1966, the Board issued license number 13175 to Frederick Marcalus, thereby authorizing him to engage in the practice of pharmacy in the state of Iowa, subject to the laws of the state and the rules of the Board. At all times material to the Statements of Charges, Frederick Marcalus was the owner and pharmacist-in-charge at Family Pharmacy in Dayton, Iowa (License No. 706) and the Family Pharmacy in Stratford, Iowa (License No. 679). (State Exhibits 1-3; Testimony of Frederick Marcalus)
2. In December 2002, the Board fined Respondents Frederick Marcalus, Family Pharmacy Stratford, and Family Pharmacy Dayton and placed them on probation for a period of two years. The probationary conditions included the establishment of policies and procedures for operating the pharmacy in a legal manner, including: ensuring proper pharmacy security, proper handling of the temporary absence of the pharmacist, and proper utilization of registered pharmacy technicians. (State Exhibit 4, p. 2)
3. On November 9, 2005, Pharmacy Compliance Officer Jean Rhodes conducted a routine inspection of the Family Pharmacy in Dayton. Family Pharmacy in Dayton sells general merchandise and over-the-counter medications, as well as providing pharmacy services. The store's hours were 9-5:30, Monday-Saturday. However, the pharmacy or prescription department was only open from 12-1:30 and 2:30-5:30, Monday-Friday.

Carolyn Marcalus, who was the staff pharmacist at the time and is now the pharmacist in charge, arrived at the pharmacy after Ms. Rhodes started her

inspection. The pharmacy also employed four pharmacy technicians. The prescription department consisted of a counter with a cash register, shelving behind the counter, and three prescription bays located behind the area of shelving. The prescription bays each had bi-fold wooden doors, which could be closed and locked. The counter area could not be secured. (Testimony of Jean Rhodes, Fred Marcalus; State Exhibit 8; Dayton Exhibits A-D)

On November 14, 2005, Ms. Rhodes issued an Inspection Report for the Family Pharmacy in Dayton listing eighteen areas of non-compliance with Board rules that required correction. The areas of non-compliance included, but were not limited to:

- a) Technician Marian Strandberg's registration expired on November 30, 2004 and needed to be current. **657-3.3.**
- b) The pharmacy operation did not have pharmacy operation policies and procedures as required by board rule. A handout was provided to use as a guideline. **657-6.2.**
- c) Each pharmacist on duty was responsible for the security of the pharmacy department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records. The prescription department was required to be locked by key or combination so as to prevent access when a pharmacist was not on site. **657-6.7.**

However at the time of the inspection, Ms. Rhodes observed completed prescriptions and many stock bottles on the unsecured counter in the pharmacy area. The pharmacy had bays that could be locked to secure medications but this has not been the practice. On Saturdays, the store's pharmacy department was closed but its retail operation was open and the medications on the pharmacy's counter were left unsecured.

- d) In the temporary absence of the pharmacist (short duration, not to exceed two hours) the pharmacist in charge may designate persons to be present in the prescription department to perform technical and non-technical functions designated by the pharmacist in charge. In the absence of the pharmacist, the pharmacy shall notify the public that the

pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns. **657-6.7(2).**

Ms. Rhodes noted that the pharmacy technician routinely unlocks the nursing home medication bay and begins filling unit dose cassettes after the store's opening at 9:00 a.m. The pharmacist normally did not arrive until noon. On day of inspection, the pharmacist arrived at 11:45 a.m. This routine exceeded the two hour time limit for temporary pharmacist absences.

e) DEA form 222, #053087472, was found to be missing during the controlled substances audit. **657-10.34(6).**

f) The pseudoephedrine inventory needed to be signed and dated. Prescription pseudoephedrine products needed to be inventoried. **657-10.35.**

g) The pharmacist had not done the required daily verification of controlled substance refills for many months. **657-21.5.**

4. On November 9, 2005, Pharmacy Compliance Officer Jean Rhodes also conducted a routine inspection of the Family Pharmacy in Stratford, Iowa. Frederick Marcalus was present at the time of the inspection. Family Pharmacy in Stratford sells general merchandise and over-the-counter medications and also provides pharmacy services. The store's hours were 9-6, Monday-Saturday. However, the prescription department (pharmacy) was only open from 2:30-6:00, Monday-Friday. The prescription department had a pull-down shade that was secured by a cord attached to hooks. It could not be locked. (Testimony of Jean Rhodes, Fred Marcalus; State Exhibits 9, 5-2; Stratford Exhibit O)

On November 14, 2005, Ms. Rhodes issued an Inspection Report for Family Pharmacy in Stratford that listed nine areas of non-compliance with Board rules that required correction. The areas of non-compliance included, but were not limited to:

a) The pharmacy did not have pharmacy operation policies and procedures as required by board rule. A handout was provided to use as a guideline. **657-6.2.**

b) At the time of the inspection, the pharmacy had a pull down shade secured by a cord tied to hooks. The pharmacy could not be locked when only the retail section of the store is open. The medication refrigerator was located in the retail section of the store. This same deficiency had been cited on the previous inspection of the pharmacy. (See Stratford Exhibit O) **657-6.7**

c) The pharmacy did not have a permanent log with the signatures and initials for all pharmacists and technicians. **657-8.4(2)**.

d) The pharmacy did not retain information on the sender of faxed prescriptions. **657-21.3**.

(Testimony of Jean Rhodes; State Exhibit 9)

5. Ms. Rhodes gave both pharmacies an opportunity to come into compliance with Board regulations. On January 11, 2006, Respondents filed a written response to the November 14, 2005 deficiency correction notices. The response to the Dayton Inspection Report stated that:

- all medication containers had been moved off the pharmacy counter and into lockable sections of the pharmacy; and
- the pharmacist now arrives at 10:30 a.m. In the event the pharmacist is absent longer than 2 hours staff was instructed to lock the prescription bays until the pharmacist arrives.

In response to the Stratford Inspection Report, Respondents stated that they had contacted a local cabinet maker and would discuss and proceed with making the prescription department more secure. (Testimony of Jean Rhodes; State Exhibit 4, pp. 2-3)

6. In February 2006, Compliance Officer Jim Wolfe re-visited the Family Pharmacy in Stratford. The pull down shade was still being used in the prescription department and had not yet been replaced. No sign was posted to indicate that the pharmacist was absent.

On May 15, 2006, Compliance Officer Jean Rhodes returned to the Family Pharmacy in Stratford for further follow-up. The pull down shade was still being used, but the medications refrigerator had been moved. On May 16, 2006,

Ms. Rhodes spoke to Frederick Marcalus by phone, and he reported that the carpenter had taken final measurements, and a screen barrier should be installed in the prescription department within the next two weeks. (Testimony of Jean Rhodes; State Exhibit 4)

7. On May 15, 2006, Compliance Officer Jean Rhodes also returned to the Family Pharmacy in Dayton for follow-up.

a) Jean Rhodes sat in her car outside the Family Pharmacy in Dayton from 10:00 to 11:00 a.m., but did not see anyone enter or exit the pharmacy. When she entered the pharmacy at 11:00 a.m., the pharmacist was not present and a pharmacy technician was working behind the pharmacy counter filling nursing home cassettes. The pharmacy technician told Ms. Rhodes that the pharmacist (Carolyn Marcalus) normally arrives at noon and that she normally closes the pharmacy bays at 11:00 a.m. if the pharmacist had not arrived.

b) Ms. Rhodes observed 10 prescriptions, 3 medication bottles, and a vial containing three tablets of Zithromax 500 mg on the unsecured pharmacy counter. One of the prescriptions was for Oxycontin, a Schedule II narcotic, and was dated 10-14-04. Several of the prescription bags were very dusty, indicating that they had been there for some time. When Carolyn Marcalus arrived at the pharmacy at noon, Ms. Rhodes asked her about the medications on the unsecured pharmacy counter. Ms. Marcalus stated that she had recently been pulling old prescriptions that had not been picked up and had left them on the counter.

(Testimony of Jean Rhodes; State Exhibit 4)

8. Jean Rhodes returned to the Family Pharmacy in Stratford on May 31, 2006 and observed a new plastic lattice barrier that had been installed in the prescription department in place of the pull down shades. The holes in the lattice were large enough for Ms. Rhodes to put her hand through. The sliding middle lattice panel was secured with a latch hook, which was accessible through the holes. (Testimony of Jean Rhodes; State Exhibit 5; Stratford Exhibit O)

9. On June 16, 2009, Jean Rhodes and Jim Wolfe returned to the Family Pharmacy in Stratford to conduct a follow-up inspection. At the time of this

visit, the sliding lattice panel was secured with a chain and a padlock. The wooden door to the prescription department had a deadbolt lock. There was an open area between the top of the lattice and the ceiling of the prescription department. There was no alarm system. (Testimony of Jean Rhodes; State Exhibit 6)

10. On June 16, 2009, Compliance Officers Jennifer Tiffany and Jennifer O'Toole conducted an inspection of the Family Pharmacy in Dayton and prepared a Summary of Non-Compliance that listed ten (10) Areas Needing Correction. Security of the prescription department was their primary concern. They observed that the main dispensing counter had an open window space that could not be locked or closed in any manner. Each of the prescription bays had bi-fold (accordion doors) that could be shut and locked but the shelving does not go to the ceiling. There was an approximately two foot open space above each prescription bay, which may allow unauthorized access to prescription medications. (Testimony of Jean Rhodes; State Exhibit 7)

11. There have been no documented drug losses at either pharmacy. One month prior to the hearing, Respondent Frederick Marcalus installed an alarm system at the Family Pharmacy in Dayton at the request of his daughter, Carolyn Marcalus, who is now the pharmacist in charge. Respondent's daughter told him that she felt more secure with an alarm system in place. Respondents have no plans to install an alarm system at the Family Pharmacy in Stratford. (Testimony of Frederick Marcalus; Jean Rhodes)

CONCLUSIONS OF LAW

Count I – Lack of Professional Competency

Iowa Code §155A.12(1)(2005, 2007) provides, in relevant part, that the Board may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a pharmacist license, or place a license on probation if the Board finds that a licensee has:

1. Violated any provision of this chapter or any rules of the Board adopted under this chapter.

Iowa Code §155A.15(2)(c)(2005, 2007) provides, in relevant part, that the Board may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a

license, or place a pharmacy license on probation if the Board finds that a licensee has:

...

- c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee has violated any provision of this chapter or any rule adopted under this chapter.

657 IAC 36.1(4)(b) provides that the Board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when it determines that a licensee is guilty of professional incompetency. Professional incompetency includes but is not limited to a willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

As the pharmacist in charge of Family Pharmacy in Dayton and Stratford at all times relevant to the Statements of Charges, Respondent Frederick Marcalus has violated Iowa Code section 155A.12(1)(2005, 2007) and 657 IAC 36.1(4)(b). Respondents Family Pharmacy-Dayton and Family Pharmacy-Stratford have also violated Iowa Code section 155A.15(2)(c)(2005, 2007) and 657 IAC 36.1(4)(b). As further described in connection with Count III, both pharmacies have repeatedly failed to conform to the minimal standard or acceptable and prevailing practice of pharmacy with respect to pharmacy security. In addition, Family Pharmacy Dayton repeatedly failed to comply with the Board rule concerning temporary absence of pharmacists.

Count II: Failure To Maintain Adequate Records

The Board is authorized to discipline pharmacists and pharmacies for failure to keep and maintain complete, adequate, and accurate records required by Iowa Code chapter 155A or rules of the Board. Iowa Code sections 124.306; 155A.15(2)(c); 155A.15(2)(h)(2005, 2007); 657 IAC 36.1(4)(u) and (ac). Although a number of deficiencies were noted during the November 2005 and May 2006 inspections that involved record keeping, the Board was satisfied that these issues were corrected in a relatively timely manner. Based on this record, the Board has decided not to find violations or impose sanctions based on any of the deficiencies involving records.

Count III: Failure To Maintain Control Over Drugs

The Board is authorized to discipline pharmacists and pharmacies for failure to maintain adequate control over and accountability for drugs, including controlled substances. Iowa Code sections 124.308(3), 124.402(1)(a), 155A.12(1)(2005,2007) and 657 IAC 6.7 and 36.1(4)"u." At all times relevant to the Statements of Charges, 657 IAC 6.7 provided, in relevant part:

657-6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescriptions drugs, records for such drugs, and patient records as provided in 657-Chapter 21.

6.7(1) Department locked. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

Effective April 4, 2007, the Board enacted the following rule at 657 IAC 8.5(3):

8.5(3) Secure barrier. The pharmacy department shall be **surrounded** by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than solid material with a continuous surface **if the openings in the material are not large enough to permit the removal items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent.** The plans and specifications of the barrier shall be submitted to the board for approval prior to the start of construction. The board may also require on-site inspection of the facility or pharmacy department prior to the pharmacy's opening or relocation. The pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657-6.7(124, 155A) or 657-7.6(124, 155A).

(emphasis supplied).

It is essential for prescription departments to be adequately secured against theft, diversion, or unauthorized access, both while the prescription department is

open and when it is closed. The preponderance of the evidence established that Respondents have repeatedly failed to ensure adequate security for the prescription departments at the Family Pharmacies in Stratford and Dayton, in violation of Iowa Code sections 124.308(3), 124.402(1)(a), 155A.12(1), and 657 IAC 6.7 and 36.1(4)"u." The security in these pharmacies did not satisfy Board rules in effect at the time of the inspections in 2005 and 2006 and they do not satisfy the current Board rule at 657 IAC 8.5(3).

While some improvements were made at the Family Pharmacy in Stratford following the May 16, 2006 inspection, those changes were inadequate to secure the prescription department. The holes in the lattice were large enough to permit a hand to reach through and potentially retrieve items on the other side, and there is an open space of several feet above the lattice. At the time of the May 31, 2006 re-inspection, the sliding lattice door was only secured by a latch hook. Although Respondents have now secured the lattice with a chain and padlock, the holes in the lattice are still too large to provide an adequate barrier. Moreover, it does not appear that the lattice itself is sufficiently sturdy to withstand blunt force.

In addition, the bi-fold doors in place at the Family Pharmacy in Dayton are of inadequate strength to properly secure the prescription bays. Respondents must improve security at both pharmacies to satisfy 657 IAC 6.7 and 8.5(3). The barrier surrounding the prescription departments must be of adequate strength that it cannot be easily removed, penetrated or bent. Respondents must submit plans and specifications for the barriers to the Board office for approval prior to commencing any construction. Board staff is authorized to review and approve the plans and specifications.

Count IV- Improper Delegation of Pharmacist Functions

At all times relevant to the Statements of Charges, 657 IAC 6.7(2) provided, in relevant part:

6.7(2) Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during the temporary absence of the pharmacist.

A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

The preponderance of the evidence established that Respondents Frederick Marcalus (as the pharmacist in charge) and Respondent Family Pharmacy-Dayton violated Iowa Code section 155A.15(2)(2005, 2007) and 657 IAC 6.7(2), 36.1(4)(i) and 36.1(4)(u) in 2005 and 2006 by willfully and repeatedly maintaining an open pharmacy for more than two hours in the absence of a pharmacist.

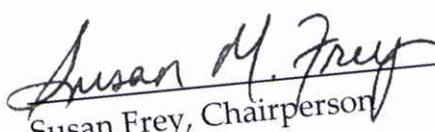
DECISION AND ORDER

IT IS THEREFORE ORDERED that Respondents Fred Marcalus, Family Pharmacy-Dayton, and Family Pharmacy-Stratford shall take Board-approved action to improve security and to fully comply with 657 IAC 6.7 and 8.5(3) in the prescription departments of both pharmacies, no later than November 15, 2011. Respondents must submit plans and specifications to the Board office prior to commencing construction of any barrier.

IT IS FURTHER ORDERED that Respondents Fred Marcalus and Family Pharmacy-Dayton shall pay a civil penalty of one thousand dollars (\$1,000) for the violations under Count IV of the Statements of Charges.

IT IS FURTHER ORDERED, pursuant to Iowa Code §272C.6 and 657 IAC 36.18(2), that Respondents Fred Marcalus, Family Pharmacy-Dayton, and Family Pharmacy-Stratford shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board shall bill Respondents for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondents shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 13th day of July, 2011.


Susan Frey, Chairperson
Iowa Board of Pharmacy

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cc: Scott Galenbeck, Assistant Attorney General
Thomas Crabb, Respondents' Attorney

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.