

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-------------------------|---|-----------------------------|
| Re: |) | |
| Pharmacy License of |) | Case No. 2009-111 |
| WALGREENS #03876 |) | |
| License No. 1033, |) | 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 June 10, 2010, the Board renewed general pharmacy license number 1033 for Walgreens #03876 (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 1225 Seventh Avenue, Marion, Iowa 52302 with Lisa Kriegel 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 the state of Iowa, as evidenced by Respondent’s willful and repeated violations of standards related to patient counseling.

COUNT II -- FAILURE TO PROVIDE COUNSELING

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009), and 657 Iowa Administrative Code §§ 6.14(1) and 36.1(4)(w), with failing to provide counseling to patients and engaging in business practices intended to circumvent requirements for patient counseling.

B. CIRCUMSTANCES

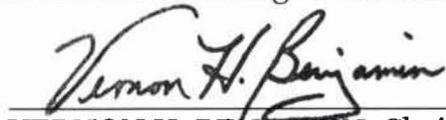
An investigation was commenced September 8, 2009, which revealed the following:

1. Respondent operates a general pharmacy at 1225 Seventh Avenue, Marion, Iowa 52302 with Lisa Kriegel as the pharmacist in charge.
2. When a patient picked up a new prescription (Simvastatin) at Respondent's drive-through window, no mention of counseling was made; the patient simply paid for the prescription and drove on.
3. Earlier in the day, the same patient picked up a prescription for Flonase. At that time he was asked, "Have you had this before?" When the patient answered in the affirmative, Respondent's employee made no offer to answer questions or otherwise counsel the patient.

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 20 day of July 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

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BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-------------------------|---|-----------------------------|
| Re: |) | Case No. 2009-111 |
| Pharmacy License of |) | |
| WALGREENS #03876 |) | SETTLEMENT AGREEMENT |
| License No. 1033, |) | AND |
| Respondent. |) | FINAL ORDER |

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy and Walgreens Pharmacy #03876, Respondent, enter into the following Settlement Agreement and Final Order to settle a licensee disciplinary proceeding currently pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued Pharmacy License No. 1033. That license is active and current until December 31, 2013.
2. A Statement of Charges was filed against Respondent on July 20, 2010.
3. Respondent at all times relevant to the Statement of Charges operated a general pharmacy at 1225 Seventh Ave., Marion, Iowa, with Lisa Kriegel as the pharmacist in charge.
4. The Board has jurisdiction over the parties and the subject matter of these proceedings.
5. Respondent has chosen not to contest the allegations in the Statement of Charges

and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

6. Respondent is hereby CITED for the failure to provide counseling to a patient on a new prescription, as described in the Statement of Charges, and is hereby WARNED that future violations of the law governing the practice of pharmacy in Iowa could result in further disciplinary action.
7. Respondent agrees to pay a civil penalty in the amount of \$1000. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within twenty (20) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.
8. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final 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 Final Order.
9. The State's legal counsel may present this Settlement Agreement and Final Order to the Board.
10. This Settlement Agreement and Final Order 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 the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.

11. The Board's approval of this Settlement Agreement and Final Order shall constitute a FINAL ORDER of the Board.

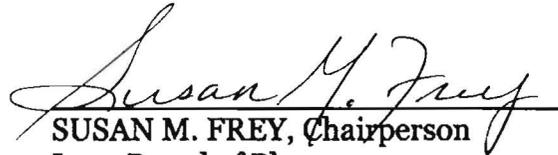
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 4th day of February 2013.



Walgreen
For Respondent

By his signature Mike Kulle acknowledges he is the Pharmacy Supervisor for Walgreens Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Walgreens Pharmacy #03876.

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the 13th day of March 2012.


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
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Kevin M. Reynolds
WHITFIELD & EDDY, P.L.C.
317 6th Ave., Suite 1200
Des Moines, IA 50309

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
Pharmacy License of)
WALGREENS PHARMACY #03876)
License No. 1033,)
Respondent.)

Case No. 2011-85

STATEMENT OF CHARGES

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 (2011).
3. On December 23, 2011, the Board renewed general pharmacy license number 1033 for Walgreens Pharmacy #03876 (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 1225 7th Avenue, Marion, Iowa 52302 with Jeanne Frommelt 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 a 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 departure 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 provide patient counseling.

COUNT II I – FAILURE TO PROVIDE COUNSELING

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011), and 657 Iowa Administrative Code §§ 6.14(1) and 36.1(4)(w), with failing to provide counseling to

patients and engaging in business practices intended to circumvent requirements for patient counseling.

B. CIRCUMSTANCES

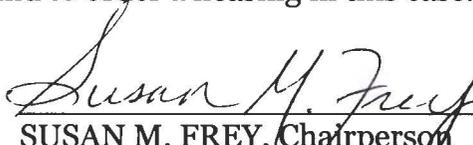
An investigation was commenced on June 12, 2011, which revealed the following:

1. At all times material to this Statement of Charges, Respondent operated a general pharmacy at 1225 7th Avenue, Marion, Iowa 52302.
2. During a "shopper survey" conducted by the Board, the pharmacy was presented with prescriptions for two drugs. The "shopper" also presented for purchase an over-the-counter medication which has a potential interaction with one of the prescribed medications.
3. At the time of purchase, the shopper received no counseling. Her prescriptions were rung up as prescriptions to an "established" patient rather than as new prescriptions.
4. The pharmacy technician who assisted the shopper did not wear a name tag.
5. While waiting for her prescriptions to be filled, the shopper observed a technician counseling other patients, and an absence of pharmacist counseling to the same patients.

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 R. JESSEN
Executive Director

On this 7th 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

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|----------------------------------|---|----------------------------|
| IN THE MATTER OF: |) | CASE NO: 2011-85 |
| |) | DIA NOS. 12PHB015 |
| Pharmacy License of |) | |
| WALGREENS PHARMACY #03876 |) | |
| License No. 1033 |) | |
| |) | FINDINGS OF FACT, |
| Pharmacist License of |) | CONCLUSIONS OF LAW, |
| JEANNE FROMMELT, |) | DECISION AND ORDER |
| License No. 20936 |) | |
| |) | |
| RESPONDENTS |) | |

On March 7, 2012, the Iowa Board of Pharmacy (Board) found probable cause to file Statements of Charges against Respondent Walgreens Pharmacy #03876 and Respondent Jeanne Frommelt. Both Statements of Charges alleged Lack of Professional Competency [Count I] and Failure to Provide Counseling [Count II].

The consolidated hearing was held on August 28, 2012 at 9:30 a.m. in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa.¹ The following members of the Board served as presiding officers for the hearing: Susan Frey, Chairperson; Edward Maier; James Miller; Edward McKenna; DeeAnn Wedemeyer Oleson; LaDonna Gratias; and Margaret Whitworth. Assistant Attorney General Theresa Weeg represented the state. Respondents appeared and were represented by attorney Kevin Reynolds. The hearing was open to the public at Respondents' request, in accordance with Iowa Code section 272C.6(1) and 657 IAC 35.19(10). Administrative Law Judge Margaret 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.

¹ At the request of the parties, the Board combined the hearing on this case with a case involving a different Walgreens pharmacy and pharmacist (Case No. 2011-86). The two cases presented the same legal issues. The parties agreed that separate decisions would be issued for the two cases.

THE RECORD

The record includes the testimony of Cheryl Anderson, R.Ph.; Jeanne Frommelt, R.Ph.; Michael Fuller, R.Ph.; State Exhibits 1-6 (See Exhibit Index for description) and Respondents' Exhibit A.

FINDINGS OF FACT

1. On January 9, 2009, the Board issued license number 20936 to Jeanne Frommelt, which authorized her 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, Jeanne Frommelt was employed as the pharmacist-in-charge for Walgreens Pharmacy #03876 in Marion, Iowa. Walgreens Pharmacy #03876 holds pharmacy license number 1033. (State Exhibits 1, 3)

2. The National Association of Boards of Pharmacy (NABP) operates a "Shopper Survey Program," which is used by the Iowa Board to assist its enforcement efforts. The NABP Shopper Survey Program contracts with experienced licensed pharmacists who will visit pharmacies as "shoppers" when requested to do so by a state Board of Pharmacy. The state Board provides a list of the pharmacies to be visited and also provides prescriptions made out in the shopper's own name by a cooperating health care provider. Immediately following the visit, the shopper fills out a "Shopper Survey Reporting Form." The form provides detailed information about the shopper's transaction and focuses on whether or not the shopper was properly counseled concerning the prescriptions and any over the counter products that were purchased. (Testimony of Cheryl Anderson, R.Ph.; State Exhibit 6)

3. This disciplinary hearing concerned a "shopper survey" conducted at Walgreens #03876 on June 12, 2011 at 1:25 p.m. by Cheryl Anderson, R.Ph. Ms. Anderson has been a registered pharmacist since 1981. She served as the Executive Director of the South Carolina Board of Pharmacy from 1996-2001 and has served as a Senior Consultant surveyor with the NABP since 1996. Ms. Anderson was accompanied to each pharmacy by a Compliance Officer with the Iowa Board. (Testimony of Cheryl Anderson, R.Ph.)

Ms. Anderson presented the following two prescriptions to the Walgreens #03876 pharmacy department:

- Ibuprofen 800mg #30 Sig: 1 tab tid NR; and
- Benazapril 40 mg #30 Sig: 1 tab daily NR

Both prescriptions had been issued by an Advanced Registered Nurse Practitioner on June 9, 2011.

Registered pharmacist Linda McCue was working in the pharmacy department along with two technicians. One customer was waiting in the pharmacy and the drive-through had a steady flow of customers while Ms. Anderson was present. Ms. McCue received the prescriptions from Ms. Anderson. Ms. McCue asked Anderson for her date of birth and address and also asked if she had any medical conditions or allergies. Although she was an out-of-state customer, Ms. Anderson was not asked for a phone number. Ms. Anderson asked McCue about any available discount plans and for a price comparison for a 7 day supply vs. a 30 day supply of her medication. Ms. McCue informed Anderson that it would take at least 20 minutes to fill her prescription. Ms. Anderson replied that she would be shopping in the store.

Cheryl Anderson had been directed to select an over-the-counter medication for purchase that could cause an adverse interaction with the prescriptions that she presented. Ms. Anderson selected Bayer Advanced ASA 500 mg #20. In Ms. Anderson's opinion, the pharmacist should have been prompted to counsel her about taking the aspirin and the ibuprofen together and should have asked her about any gastrointestinal concerns.

Ms. Anderson's two prescriptions were ready at 2:07 p.m. Ms. Anderson's name was called for prescription pick up by a pharmacy employee who was not the pharmacist on duty and who Ms. Anderson presumed was a pharmacy technician. This technician was not wearing an identification badge. Ms. Anderson presented her over-the-counter medication for purchase. The technician rang up Ms. Anderson's new prescriptions as an "established" patient to Walgreens even though Ms. Anderson had purchased fewer than five prescriptions from other Walgreens pharmacies in the past. Although the pharmacy had posted a sign stating that counseling occurs according to state law, no one provided Ms. Anderson any patient counseling on her new prescriptions. Ms. Anderson had no interaction with the pharmacist at all when she picked up her new prescriptions and made the over-the-counter purchase. (Testimony of Cheryl Anderson, R.Ph.; State Exhibit 6)

Ms. Anderson took notes during her shopping experience, which she used to complete the Shopper Survey Reporting Form. She also verbally reported her findings to the Board's Compliance Officer immediately following the visit. (Testimony of Cheryl Anderson, R.Ph.; State Exhibit 6)

4. Jeanne Frommelt has been a licensed pharmacist since 1996 and has been licensed in Iowa since 2009. She has served as a pharmacist-in-charge for the past fifteen years, and her pharmacist license has never been disciplined. Ms. Frommelt was the pharmacist-in-charge of Walgreens Pharmacy #03876 on June 12, 2011 but was not working at the time of Ms. Anderson's visit. Ms. Frommelt testified that she fully understands the Board's rules on counseling. Ms. Frommelt agreed that Ms. Anderson should have been counseled by the pharmacist on duty concerning her two new prescriptions. (Testimony of Jeanne Frommelt, R.Ph.; Respondents' Exhibit A)

Jeanne Frommelt testified that she has always followed the law concerning counseling and has fully trained her employees to follow the law. All pharmacy employees are required to review the state rules and the written store policies on patient counseling and to acknowledge their review in writing. For any prescription that is not a refill, the technician is required to ring up the purchase and then inform the customer that the pharmacist will speak to them. If the customer refuses counseling, the refusal must be made directly to the pharmacist and must be documented. The refusal is documented directly on the cash register and in the patient profile. This procedure was not followed when Ms. Anderson filled her new prescriptions on June 12, 2011. (Testimony of Jeanne Frommelt, R.Ph.; Cheryl Anderson, R.Ph.; State Exhibit 6)

Linda McCue was the only pharmacist on duty when Ms. Anderson filled her prescriptions on June 12, 2012. Ms. McCue had reviewed the state rules and the store specific policies on counseling and had signed off on them on March 8, 2010, March 23, 2010 and again on May 15, 2011, which was approximately a month prior to Ms. Anderson's visit. (Testimony of Jeanne Frommelt, R.Ph.; Respondents' Exhibit A)

The Statement of Charges was filed on March 7, 2012. Prior to that date, Jeanne Frommelt and Walgreens were not notified of the results of the shopper survey, and no one from the Board contacted them for any response or defense. Ms. Frommelt asked Pharmacist Linda McCue what happened on June 12, 2012,

but she was unable to recall very much about Anderson's transaction. Ms. McCue did recall that the transaction involved a lot of questions about quantities and prices but could not remember much else about it. Walgreens has store video of the pharmacy area, but the video was no longer available 9 months after the transaction. (Testimony of Jeanne Frommelt, R.Ph.)

Ms. Frommelt was unable to explain why Ms. Anderson was not counseled other than to speculate that Ms. McCue may have been distracted by a phone call or a problem in the pharmacy. Ms. Frommelt agreed that a distraction in the pharmacy did not excuse the failure to provide counseling to Ms. Anderson. Ms. Frommelt was upset that she was not immediately notified of the problem following the shopper survey so that she could address it with Ms. McCue in a timely manner. Linda McCue has now been counseled concerning this incident but has not been disciplined. Ms. McCue has had no other known performance issues in the pharmacy. (Testimony of Jeanne Frommelt, R.Ph.)

Ms. Frommelt knew of no other performance issues involving the pharmacy technician who waited on Cheryl Anderson and rang up her purchases. She could not explain why the technician was not wearing an identification badge. To her knowledge, the technician had always previously followed state law and store policy with respect to patient counseling. (Testimony of Jeanne Frommelt, R.Ph.)

5. Michael Fuller is the District Pharmacy Supervisor for Walgreens #03876 and is responsible for supervising Jeanne Frommelt. Mr. Fuller described Ms. Frommelt as a capable competent pharmacist and pharmacist-in-charge. In his opinion, Ms. Frommelt has fulfilled her responsibilities as the pharmacist-in-charge for Walgreens #03876 by posting proper signage at the pharmacy, having store specific policies and procedures, properly training and mentoring her employees, and enforcing state laws and store policies. (Testimony of Michael Fuller, R.Ph.)

CONCLUSIONS OF LAW

Motion to Dismiss For Failure To Comply With 657 IAC 36.2(5)

657 IAC 36.2(5) provides:

36.2(5) Investigation of allegations. In order to determine if probable cause exists for a disciplinary hearing, the board, the executive director, or someone designated by the executive director shall cause an investigation to be made into the allegations of the complaint. The licensee, registrant, or permittee who is the subject of the complaint shall be given the opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of the contested case.

Respondents assert that the Statements of Charges should be dismissed because Board staff did not comply with 657 IAC 36.2(5). Prior to filing the Statement of Charges, no one from the Board spoke to Respondents to request their position or defense with respect to the allegations. Respondents argue that the use of the word "shall" in the rule makes this a mandatory requirement and that failure to comply requires dismissal of the charges as a matter of law.

The state, relying on the cases of *Willet v. Cerro Gordo County Zoning Board of Adjustment*, 490 N.W.2d 556(Iowa 1992) and *Taylor v. Department of Transportation*, 260 N.W.2d 521 (Iowa 1977), argued that the use of the word "shall" in the rule does not necessarily make the rule "mandatory." The state argued that if the rule is "directory" rather than "mandatory" then dismissal is only required if Respondents were prejudiced by the failure to follow the rule.

In *Taylor*, the Iowa Supreme Court discussed the "mandatory-directory dichotomy" when it interpreted a statute that used the word "shall" to require the director of the department of transportation to grant a person accused of operating while intoxicated an opportunity to be heard within twenty days after receipt of the hearing request. The issue was whether the failure to grant the hearing within the twenty days required the department to dismiss its action to revoke the person's driver's license. The Court noted that the mandatory-directory dichotomy does not refer to whether a statutory duty is obligatory or permissive but rather relates to whether the failure to perform the admitted duty will have the effect of invalidating the governmental action which the requirement affects. *Id.* at 523.

Whether a statute is mandatory or directory depends on legislative intent. When statutes do not resolve the issue expressly, statutory construction² is necessary. If

² The rules of statutory construction also apply when interpreting agency rules. *Iowa Federation of Labor v. Dept. of Job Services*, 427 N.W.2d 443 (Iowa 1988).

the prescribed duty is essential to the main objective of the statute, the statute is ordinarily mandatory and a violation will invalidate subsequent proceedings under it. If the duty is not essential to accomplishing the principal purpose of the statute but is designed to assure order and promptness in the proceeding, the statute is ordinarily directory and a violation will not invalidate subsequent proceedings unless prejudice is shown. *Id.* at 522-523.

The Board is satisfied that subrule 36.2(5) is directory, not mandatory. The main objective of 657 IAC chapter 36, which provides authority for the board to discipline licensees and registrants, is the protection of the public. It would undermine this legislative objective if disciplinary cases were dismissed, without the necessity of showing any prejudice, for a failure to comply with subrule 36.2(5).

Respondents have failed to establish that they were prejudiced by the failure to comply with subrule 36.2(5). The obvious purpose of the rule is to allow the Board to consider the licensee's response when deciding whether formal charges are warranted. The rule only requires that licensees be given the opportunity to present their position or defense "prior to" the filing of the charges. No other time requirements are imposed by the rule, and the opportunity to respond may be given months after the underlying incident. The Board does not believe that compliance with the rule in this case would have provided Respondents with the ability to dispute these charges, which are based on a thoroughly documented shopper survey. The Motion to Dismiss based on failure to comply with 657 IAC 36.2(5) is hereby DENIED.

Count I: Lack of Professional Competency

The Board is authorized to discipline both pharmacists and pharmacies for any violation of Iowa Code chapter 155A or any rule of the Board. Iowa Code §§155A.12(1); 155A.15(2)(c)(2011).

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, registrant, or permittee is guilty of professional incompetency. Professional incompetency, as defined by rule, includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

(4) 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.

657 IAC 36.1(4)"b"(1)-(4).

A. *Respondent Jeanne Frommelt.* The preponderance of the evidence failed to establish that Respondent Jeanne Frommelt is professionally incompetent, as that term is defined in 657 IAC 36.1(4)"b," based on the June 12, 2011 shopper survey at Walgreens Pharmacy #03876. Ms. Frommelt was neither present nor working at the pharmacy at the time of the shopper survey. Ms. Frommelt did not know the results of the shopper survey until the Board filed its Statement of Charges against her in March 2012. Ms. Frommelt was not specifically charged with failing to fulfill her duties as a pharmacist-in-charge. Even if she had been so charged, the preponderance of the evidence failed to establish that Ms. Frommelt failed to fulfill her legal obligations as a pharmacist or as the pharmacist-in-charge. The charges against Jeanne Frommelt for lack of professional competency must be dismissed.

B. *Respondent Walgreens Pharmacy #03876.* The preponderance of the evidence in the record established that Walgreens Pharmacy #03876 demonstrated a lack of professional competence on June 12, 2011 when its pharmacist completely failed to provide counseling to a patient who presented two new prescriptions. Board rule 657 IAC 6.14(1), is absolutely clear and requires counseling by the pharmacist for all new prescriptions. The testimony of Cheryl Anderson, coupled with her detailed contemporaneous report, clearly established that Pharmacist Linda McCue failed in her duty to counsel Ms. Anderson. Ms. McCue was well aware that Ms. Anderson had two new

prescriptions because Ms. Anderson handed her the prescriptions to fill and asked questions about pricing options. When questioned about the transaction more than six months later, Ms. McCue was apparently able to recall this conversation with Ms. McCue. She knew these prescriptions were being filled in the pharmacy and knew (or should have known) that counseling was required. The complete lack of pharmacist counseling is a substantial deviation from minimum standards. The pharmacy must be held responsible for the errors made by its staff, including the pharmacy technician who failed to follow proper procedures and the pharmacist on duty who failed to provide counseling.

Count II: Failure To Provide Counseling

657 IAC 6.14(1) provides, in relevant part:

6.14(1) Counseling required. Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to 657-8.21(155A), a pharmacist shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy.
- c. Intended use of the drug, if known, and expected action;
- d. Special directions and precautions for preparation, administration, and use by the patient;
- e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- f. Techniques for self-monitoring drug therapy;
- g. Proper storage;
- h. Prescription refill information;
- i. Action to be taken in the event of a missed dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

...

6.14(6) Refusal of consultation. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657 IAC 36.1(4)"w" authorizes the Board to discipline licensees for attempting to circumvent the patient counseling requirements, or discouraging patients from receiving patient counseling concerning their prescription drug orders.

A. *Respondent Jeanne Frommelt.* For the same reasons provided in connection with Count I, the preponderance of the evidence failed to establish that Respondent Jeanne Frommelt failed to provide counseling to patients, in violation of 657 IAC 6.14(1), or that she engaged in business practices intended to circumvent requirements for patient counseling, in violation of 657 IAC 36.1(4)"w." The charges against Ms. Frommelt must be dismissed.

B. *Respondent Walgreens Pharmacy #03876.* For the same reasons provided in connection with Count I, the preponderance of the evidence established that Walgreens Pharmacy #03876 failed to provide counseling to a patient on June 12, 2011, in violation of 657 IAC 6.14(1). 657 IAC 6.14(1) is absolutely clear and requires counseling by the pharmacist for all patients who present new prescriptions. The complete lack of counseling for Ms. Anderson was a substantial and serious violation of this rule. The pharmacy must ultimately be held responsible for the errors and omissions of its pharmacy technicians and pharmacists.

The evidence in this record is insufficient to establish that Respondent Walgreens Pharmacy #03876 attempted to circumvent the patient counseling requirements or that it discouraged patients from receiving patient counseling concerning their prescription drug orders, in violation of 657 IAC 36.1(4)"w."

DECISION AND ORDER

IT IS THEREFORE ORDERED that the Statement of Charges filed against Pharmacist Jeanne Frommelt on March 7, 2012 is hereby DISMISSED.

IT IS FURTHER ORDERED that pharmacy license 1033, issued to Respondent Walgreens Pharmacy #03876, is hereby placed on probation for a period of two (2) years, subject to 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 paragraph (A) above, Respondent shall ensure that all customers receive counseling in accordance with Board rules.

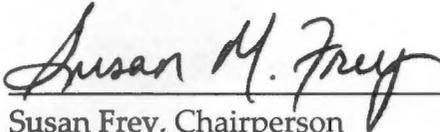
C. Respondent's District Manager and Pharmacist-in-charge shall file sworn quarterly reports with the Board attesting to Respondent's compliance with the terms and conditions of this Decision and Order. The reports shall be filed not later than December 5, March 5, June 5, and September 5 of each calendar year and shall include a description of Respondent's most recent efforts to comply with this Decision and Order, including paragraph (B) above. The reports shall include an account of what Respondent is doing, beyond basic training, to ensure that counseling is taking place in accordance with Board rules. Respondent's quarterly reports shall also provide any other information deemed to be necessary, from time to time, by the Board.

IT IS FURTHER ORDERED that Respondent shall pay a civil penalty in the amount of \$2500. 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 thirty (30) days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondent Walgreens Pharmacy \$03876 shall pay \$75.00 for fees

associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 21 day of Sept., 2012

A handwritten signature in cursive script that reads "Susan M. Frey". The signature is written in black ink and is positioned above a horizontal line.

Susan Frey, Chairperson
Iowa Board of Pharmacy

cc: Theresa O'Connell Weeg, Assistant Attorney General
Kevin Reynolds, 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.

BEFORE THE BOARD OF PHARMACY STATE OF IOWA

**IN THE MATTER OF THE FINDINGS OF FACT,
CONCLUSIONS OF LAW, DECISION AND ORDER AGAINST
WALGREENS PHARMACY #03876, RESPONDENT
2011-85**

TERMINATION ORDER

DATE: September 21, 2014

1. On September 21, 2012, a Findings of Fact, Conclusions of Law, Decision and Order was accepted by the Iowa Board of Pharmacy placing the license to practice pharmacy, number 1033 issued to Walgreens Pharmacy #03876, on probation for a period of two years under certain terms and conditions.
2. Respondent has successfully completed the probation as directed.
3. The Board directed that the probation placed upon the Respondent's license to practice pharmacy should be terminated.

IT IS HEREBY ORDERED:

That the probation placed upon the Respondent's license to practice pharmacy is terminated, and the license is returned to its full privileges free and clear of all restrictions.

IOWA BOARD OF PHARMACY



Edward L. Maier, Board Chairperson
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688