

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

Re:)	Case No. 2005-22
Pharmacy License of)	
WALGREENS # 05721,)	STATEMENT OF CHARGES
License No. 355,)	
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 (2005).
3. On December 21, 2004, the Board renewed Respondent general pharmacy license number 355 with Lori Uhlman 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 355 is current until December 31, 2006.
5. Respondent is currently operating a general pharmacy at 3140 Southeast 14th Street, Des Moines, Iowa 50320.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2) (2005) 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 with failing to maintain complete and adequate records of purchases and disposal of drugs, including controlled substances, in violation of Iowa Code §§ 155A.15.2(c) and 155A.15.2(h) (2005), and 657 Iowa Administrative Code §§ 36.1(4)(u) and 36.1(4)(cc).

COUNT III -- FAILURE TO MAINTAIN CONTROL OVER DRUGS

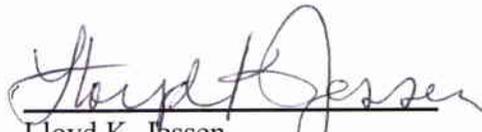
Respondent is charged with failing to maintain accurate control over and accountability for drugs, including controlled substances, in violation of Iowa Code §§ 124.308(3), 124.402(1)(a), 155A.15(2)(c) and 155A.15(2)(c) and (i) (2005), and 657 Iowa Administrative Code §§ 6.2, 6.7 and 36.1(4)(u).

B. CIRCUMSTANCES

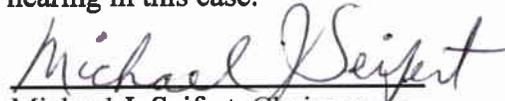
On or about March 14, 2005, an investigation was commenced, revealing the following:

1. Respondent's records are maintained in two places. Some records are maintained at Respondent's retail place of business, while others are maintained by at the corporate offices. The records have substantial inconsistencies.
2. Audits of Respondent's controlled substances records were difficult and inconclusive. Due to differences between the records maintained at Respondent's retail place of business and the records maintained by Walgreens' corporate offices, audit results varied depending on the source of the records.
3. Respondent was unable to provide controlled substance records in a timely manner. Some records were not provided for more than three weeks after requested by the Board's compliance officers.
4. Audits of Respondent's records reveal substantial overages and substantial shortages of controlled substances.
5. Although under the above described circumstances, many controlled substance records appear unreliable, Respondent's records support a conclusion that significant quantities of controlled substances – particularly hydrocodone – are missing and have been diverted from stock.
6. Due to the disarray of Respondent's controlled substance records, internal measures to detect and prove drug diversion would be largely ineffective.
7. Copies of DEA form 222 filed by Respondent were not appropriately maintained in Respondent's records.
8. Records relating to schedule II controlled substances were not maintained separately from records relating to other controlled substances.
9. Respondent's records were incomplete in instances where, due to variations between prescriptions as written and prescriptions as filled, Respondent's prescription records should have reflected contact with a prescriber.
10. Respondent's records also revealed dispensing errors and a failure to maintain hard copies of prescriptions.

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 7th day of June, 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.


Michael J. Seifert, Chairperson
Iowa Board of Pharmacy Examiners
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 50319

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

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IOWA PHARMACY EXAMINERS

Re:)	Case No. 2005-22
Pharmacy License of)	
WALGREENS #05721)	STIPULATION
License No. 355)	AND
Respondent)	CONSENT ORDER

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2005), The Iowa Board of Pharmacy Examiners (hereinafter, the "Board") and Walgreens #04973 (hereinafter, "Respondent") have agreed to settle a contested case currently on file with the Iowa Board of Pharmacy Examiners. The Statement of Charges filed against Respondent on June 7, 2005, and the licensee disciplinary proceeding shall be resolved without a hearing, as the Board and Respondent have agreed to the following Stipulation and Consent Order:

1. Respondent's license to operate a pharmacy was renewed December 27, 2005 as evidenced by Pharmacy License Number 355, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. General Pharmacy License Number 355 issued to and held by Respondent is current and in force until December 31, 2006.
3. The Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.
4. A Statement of Charges was filed against Respondent June 7, 2005.
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 set forth in the Statement of Charges, if proven in a

contested case proceeding, would constitute grounds for the discipline described herein.

6. Respondent's license shall be placed on probation for one (1) year. As a condition of probation, Respondent shall -- within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order -- propose to the Board *typewritten* pharmacy practices and procedures which shall include, but not be limited to the following;

- a. Accuracy of Records. A proposal for pharmacy record keeping which will assure the accuracy of records maintained at the pharmacy.
- b. Access to Records. A proposal to assure that complete, accurate and accessible records relating to controlled substances and other pharmaceuticals are maintained at the pharmacy or are accessible from another location within two business days of the request.
- c. Perpetual Inventory of Schedule-II Controlled Substances. A proposal for establishment of a perpetual inventory at the pharmacy for all schedule 2 controlled substances.

Once Respondent's proposals are approved by the Board, Respondent agrees to abide by the specific terms of its proposals.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of \$1000. This civil penalty payment shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board. All civil penalty payments shall be deposited into the State of Iowa general fund.

8. Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the operation of pharmacy.

9. Should 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 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.

10. 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.

11. 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.

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

This Stipulation and Consent Order is voluntarily submitted by Walgreens #05721 to the Iowa Board of Pharmacy Examiners for its consideration on this ____ day of _____ 2006.

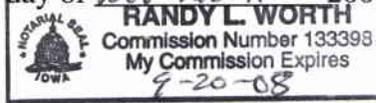
Lori Uhlman

Walgreens #05721

Respondent

By Lori Uhlman, R.Ph.
Pharmacist In Charge

Subscribed and sworn to before me by Lori Uhlman, who has stated to me that he/she is the pharmacist in charge of Walgreens #05721 and is authorized to sign this Stipulation and Consent Order on behalf of Walgreens #05721 on this 8th day of November 2006.



NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

Lorinda Tiszell

Lorinda Tiszell

Walgreens #05721

Respondent

By LORINDA TISZELL

Subscribed and sworn to before me by LORINDA TISZELL, who has stated to me that he/she is a/an DIVISIONAL DIRECTOR, PHARMACY OPERATIONS with Walgreen Co. and is authorized to sign this Stipulation and Consent Order on behalf of Walgreen Co. on this 31st day of OCTOBER 2006.



Karen A. Kessler

NOTARY PUBLIC IN AND FOR THE
STATE OF ILLINOIS

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on this 15 day of Nov. 2006.



MICHAEL J. SEIFERT
Board Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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

Dwayne A. Piñon, R.Ph.
Senior Attorney
Corporate & Regulatory Law
Walgreen Company
104 Wilmot Road, MS #1447
Deerfield, IL 60015

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BEFORE THE BOARD OF PHARMACY STATE OF IOWA

**IN THE MATTER OF THE STIPULATION AND CONSENT ORDER AGAINST
WALGREENS #05721, RESPONDENT**

2005-22

TERMINATION ORDER

DATE: November 19, 2007

1. On November 16, 2006, a Stipulation and Consent Order was accepted by the Iowa Board of Pharmacy placing the license to practice pharmacy, number 826 issued to Walgreens #05721, on probation for a period of one year 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 PHARAMCY


Paul Abramowitz, Board Chairperson
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2007-138
WALGREENS PHARMACY 05721)	
License No. 355,)	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. Effective December 8, 2008, the Board renewed the general pharmacy license of Walgreen Pharmacy 05721 (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 355 is current and active until December 31, 2009.
5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 3140 Southeast 14th Street, Des Moines, Iowa 50320, with Scott Rospond as pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (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 – CIRCUMVENTING COUNSELING REQUIREMENTS

Respondent is charged pursuant to Iowa Code § 155A.15(2)(c) (2007) and 657 Iowa Administrative Code § 36.1(4)(w) with attempting to circumvent patient counseling requirements.

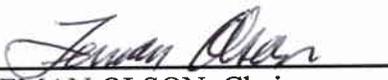
B. CIRCUMSTANCES

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 R. JESSEN
Executive Director

On this 17 day of February 2009, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.


LEMAN OLSON, 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

WalgreensSE14-SOC 12-08

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF THE
STATEMENT OF CHARGES AGAINST:

CASE NO. 2007-138
DIA NO. 09PHB012

WALGREENS PHARMACY 05721
License No. 355

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
DECISION AND ORDER

RESPONDENT

On February 17, 2009, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges and Notice of Hearing against Walgreens Pharmacy 05721 (Respondent), alleging the following violations:

- Count I: Lack of Professional Competency
- Count II: Circumventing Counseling Requirements

The hearing was held on July 21, 2009 at 3:40 p.m. The following members of the Board presided at the hearing: Vernon Benjamin, Chairperson; Susan Frey, DeeAnn Wedemeyer Oleson; Edward L. Maier; Mark Anliker, Margaret Whitworth, and Ann Diehl. The state was represented by Assistant Attorney General Scott Galenbeck. Respondent was represented by attorney Kevin Reynolds. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1) and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with its deliberations.

THE RECORD

The record includes the testimony of the witnesses, State Exhibits 1-10, and Respondent Exhibits A-G (See Exhibit Indexes for description; Respondent Exhibit G is a DUR Detail Screen similar to Exhibit A but more legible).

FINDINGS OF FACT

1. Effective December 8, 2008, the Board renewed general pharmacy license #355 issued to Walgreens Pharmacy 05721 (hereinafter "Walgreens"). At all times material to the Statement of Charges, Walgreens was operating a general pharmacy at 3140

Southeast 14th Street in Des Moines, Iowa 50320, with Scott Rospond as the pharmacist in charge. (State Exhibits 1, 3)

2. On December 31, 2007, a Walgreens' patient filed a complaint with the Board. The patient, who was an active and healthy 47-year-old, reported that he had been prescribed simvastatin for slightly elevated cholesterol since at least November 2006. He refilled the prescription for simvastatin each month at Walgreens. In December 2007, the patient's physician prescribed the antibiotic clarithromycin for him for pneumonia. The prescription was for a course of ten days. The patient filled the clarithromycin prescription at Walgreens on December 4, 2007.

Within 5 or 6 days of starting the medication, the patient developed "very nasty pains" in his arms, shoulders, and upper back. The patient had experienced minor pains in both arms since starting the simvastatin, but had not connected these symptoms to the drug. The patient did some internet research after reading a Consumer Reports Newsletter that mentioned statin drugs and arm pains. He quickly found several warnings from the drug companies and from the National Institute of Health (NIH) warning not to take clarithromycin with a statin. The warnings stated that the combination can worsen the muscle breakdown and lead to kidney failure and death. By this time (December 18th) the patient had finished the clarithromycin prescription. His physician agreed that he should stop taking the statin and felt that the arm pains would disappear within a few days. However, the patient did not mention the clarithromycin/statin interaction to his physician, apparently because he did not want to offend the physician.

As of December 28, 2007 when he filed the complaint, the patient continued to experience considerable pain in his arms, shoulders and upper back, which caused him sleepless nights and interfered with his ability to function. He reported that while he was not happy with his family physician, he was very displeased with Walgreens. He felt that Walgreens should not have allowed him to take the clarithromycin or should have told him to stop taking the statin. (Testimony of Roger Zobel; State Exhibit 1-A)

3. The National Institute of Health has publicized the possibility of a secondary drug interaction between simvastatin and clarithromycin. (State Exhibit 1-B)

4. On January 4, 2008, the Board's investigator interviewed Scott Rospond, who was the pharmacist in charge at Walgreens 05721 when the clarithromycin prescription was filled for the patient/complainant. Mr. Rospond had no specific recollection of this prescription and had to rely on the pharmacy's records for the information he gave the

Board's investigator. (Testimony of Scott Rospond; State Exhibit 1) Mr. Rospond provided the investigator with a copy of the patient's medication history and the refill histories for the simvastatin and the clarithromycin. He explained that the "R" on the patient's simvastatin record for March 29, 2007, June 29, 2007, and December 1, 2007 was an "edit" that meant the patient refused counseling on that prescription refill. The patient's clarithromycin record did not contain a similar entry indicating that the patient refused counseling for that prescription. (Testimony of Roger Zobel; State Exhibits 1-D, 1-E and 1-F).

Scott Rospond also provided the following written statement to the Board's investigator:

When Rx is input & verified by pharmacist to check for interaction. The computer checks for interaction & reviewed by the pharmacist. The **offer to counsel** is done on all new Rxs. The pt refused counseling on simivastin.

(State Exhibit 1-C, emphasis added) At hearing, Mr. Rospond characterized his phrase "offer to counsel" as a misstatement. Mr. Rospond testified that Walgreens' pharmacists provide counseling to patients on all new prescriptions. (Testimony of Scott Rospond)

5. At a later date, Walgreens' corporate office gave the Board an "Audit/Board of Pharmacy Inspection Report", which contains additional details about the patient's clarithromycin prescription. (Respondent Exhibit B)¹ According to Walgreens District Supervisor Mike Fuller, this report form was not provided at the investigator's visit because it is a new tool that only became available in the past year. Only a pharmacy manager can print the report, and it is only provided to the Board's compliance officers.

a. Exhibit B shows that the patient's clarithromycin prescription was entered by a pharmacy technician on December 4, 2007 at 3:49:05 p.m. Scott Rospond reviewed the clarithromycin prescription at 3:55:23 p.m.

When a prescription is entered into Walgreens' database, the computer program automatically checks for and reports any possible drug interactions. A Drug Utilization Review (DUR) screen appears and must be reviewed by a pharmacist. Respondent

¹ Respondent Exhibit B and State Exhibit 8 are identical. Hereinafter all references will be to Respondent Exhibit B.

Exhibits A and G are examples of the DUR screen that likely appeared when the patient's clarithromycin prescription was entered into the database. The DUR screen warned the pharmacist that the likelihood of an adverse drug interaction for the combination of simvastatin 10 mg tablets with clarithromycin 500 mg tablets was "probable," and that the severity of the interaction was "major." The DUR screen also stated that the "pharmacologic and toxic effects of simvastatin 10 mg may be increased by clarithromycin 300 mg tablets" and that their coadministration may increase the risk of liver dysfunction and rhabdomyolysis. (Testimony of Scott Rospond; Respondent Exhibits A, B, G)

Scott Rospond was familiar with the potential drug interaction between the two drugs and concedes he would have recognized the potential drug interaction even if he had not read the information on the DUR screen. However, Mr. Rospond did not consider the potential interaction to be serious or potentially life threatening.

A pharmacist must review the DUR screen, resolve any DUR issues, and then override the DUR screen before the computer will allow the prescription to be filled. One way to resolve the DUR issue in this case would have been for the pharmacist to call the prescriber, point out the potential drug interaction, and ask if the prescriber wanted to change the prescription to another antibiotic or tell the patient to stop taking the simvastatin while he was taking the clarithromycin. Scott Rospond initially testified that he did not call the patient's physician and later testified that he did not recall calling the physician. The preponderance of the evidence supports the conclusion that Mr. Rospond did not call the physician.

Scott Rospond testified that in December 2007, his usual practice was to print the DUR screen, override the DUR system, and then staple the DUR screen to the patient's receipt. The printed DUR screen alerts the person at the register that counseling is required before the prescription is sold. In addition, the prescription receipt would have reflected that this was a new prescription, which also requires patient counseling. The DUR screen does not leave the pharmacy and must be removed before the prescription is delivered to the patient. According to Mr. Rospond, when the patient picked up the prescription, either he or another pharmacist would then advise the patient of the potential drug interaction, ask the patient what his physician told him to do about it, and potentially recommend that the patient discontinue the simvastatin until he finished taking the clarithromycin.

b. Exhibit B further shows that at 3:55:28 p.m., Scott Rospond overrode three DUR warnings for the patient's clarithromycin prescription. The three warnings are

listed on Exhibit B as DUR Type 03 with a DUR Severity of 3, DUR Type 08, and DUR Type 23 with a DUR Severity of 1. None of these numbers appear on the DUR screen at the pharmacy. Mr. Rospond testified that he was not familiar with the universal system for rating drug interactions, and he did not know what the numbers stood for. His district supervisor was also unfamiliar with the rating system. Mr. Rospond could not recall receiving any patient counseling training from Walgreens after his initial training in 2001. (Testimony of Scott Rospond; Mike Fuller; Respondent Exhibits A, B, G; State Exhibit 8)

c. Exhibit B further shows that a pharmacy technician filled the patient's prescription at 3:59 p.m. However, the patient did not pick up the clarithromycin prescription until 6:10:49 p.m. Scott Rospond's shift ended at 6:00 p.m. on December 4, 2007, and he does not recall if he was still present in the pharmacy when the patient picked up the prescription. Respondent Exhibit B shows that a pharmacy technician made entries into the computer system stating that consultation application documentation was required for the prescription but that "Patient refused consultation." This entry is inconsistent with the computer record that Mr. Rospond gave to the Board's investigator, which had no entry concerning patient counseling.² (Compare Respondent Exhibit B and State Exhibit 1-F). (Testimony of Scott Rospond)

In December 2007, the Walgreens computer system would not allow a prescription to be sold unless the cashier entered either a "1" indicating that the patient accepted consultation or a "2" indicating that there was no consultation. Both Scott Rospond and District Supervisor Mike Fuller acknowledged that the entry on Exhibit B stating that this patient refused counseling is not necessarily accurate. Walgreens has determined that there was a "glitch" in their computer "linking" prior to 2008 which caused the system, in at least some circumstances, to enter the "patient refused consultation" language as a default when no specific entry was made with respect to counseling. This "glitch" has since been corrected. (Testimony of Scott Rospond; Mike Fuller)

6. The Board's investigator called the patient/complainant the day prior to the hearing. The patient reported that his muscle pain persisted approximately six weeks. The Board's investigator asked the patient if he was counseled when he picked up the clarithromycin prescription, and the patient responded that he honestly could not say one way or the other if he was counseled. The patient later called the investigator back

² Board rules provide that the absence of any record of 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 6/14(6).

and told him that he thought someone asked him if he had any questions for the pharmacist. (Testimony of Roger Zobel)

The Board concludes that the patient did not receive counseling from a Walgreens' pharmacist concerning the potential interaction between the simvastatin and clarithromycin, based both on the substance of his December 2007 complaint and on the records and testimony provided by Walgreens and Scott Rospond. It is highly unlikely that the patient would have refused counseling or that he would have taken both drugs at the same time if he had been warned and properly advised of the serious potential drug interaction.

7. In 2008, Walgreens upgraded its computer system to ensure that a patient can not complete the purchase of a prescription without receiving counseling on drug-drug interactions. Walgreens linked the CAP system so that only a pharmacist or a pharmacist-intern can remove the block put on a prescription by the pharmacist requiring counseling before the prescription is sold. The new system also permits the reviewing pharmacist to add comments to the system explaining the drug interaction. Walgreens also removed the "glitch" in its system that allowed a default entry to appear in an Audit Report indicating that patient counseling was refused when no such entry was made at the time of sale. (Testimony of Mike Fuller)

CONCLUSIONS OF LAW

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Iowa Code §155A.15(2)(c)(2007) authorizes the Board to impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation for any violation of Iowa Code chapter 155A or of the Board's rules.

657 IAC 36.1(4) provides, in relevant part:

36.1(4) *Grounds for discipline.* The board may impose any of the disciplinary sanctions set out in rule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts or offenses:

...

b. Professional incompetency. Professional incompetency includes but is not limited to:

...

(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.

(emphasis added). The legislature has authorized the Board to specify by rule minimum standards of professional responsibility in the conduct of a pharmacy. Iowa Code section 155A.13(9). The Board has adopted rules governing General Pharmacy Practice at 657 IAC chapter 6 and Universal Practice Standards at 657 IAC chapter 8.

657 IAC 8.21 requires pharmacists to conduct prospective drug use review for purposes of promoting therapeutic appropriateness and ensuring rational drug therapy. This includes reviewing the patient record, the information obtained from the patient, and each prescription drug or medication order to identify drug-drug interactions. Upon recognizing a drug-drug interaction, the pharmacist is required to take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

657 IAC 6.14 provides, in relevant part:

6.14(1) Counseling required. Upon receipt of a new prescription drug order 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:

...

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;

...

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.

The preponderance of the evidence established that Respondent Walgreens 05721 violated Iowa Code §155A.15(2)(c)(2007) and 657 IAC 36.1(4)(b) by demonstrating a repeated departure from or failure to conform to the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

On December 4, 2007, Walgreens 05721 dispensed a new prescription for clarithromycin to a patient without providing patient counseling as required by 657 IAC 6.14. Counseling was required for two reasons: this was a new prescription and the prospective drug use review revealed a serious potential drug interaction. A series of preventable errors occurred in the filling and dispensing of this prescription that led to the patient leaving the pharmacy with the prescription and without receiving any counseling concerning the serious potential drug interaction. These errors could have been prevented through proper interventions to resolve the drug-drug interaction at the time the prescription was reviewed and through improvements to pharmacy policies, procedures, and its computer system. Indeed as of the date of the hearing, Walgreens 05721 had implemented the improvements necessary to prevent such errors from reoccurring.

The potential drug interaction for simvastatin and clarithromycin was well known in December 2007, and Scott Rospond admitted that he would have been aware of the interaction between the two drugs even without reviewing the DUR screen. The DUR screen (Respondent Exhibits A, G) clearly stated that the combination of simvastatin and clarithromycin presented the potential of "major" and "probable" adverse consequences to the patient. It was not a minor drug interaction as suggested by Mr. Rospond in testimony. Mr. Rospond's failure to recognize the seriousness of the potential drug interaction was a judgment error.

Given the probability of a severe drug interaction, Scott Rospond should have contacted the prescriber to address and resolve the DUR issues prior to overriding the system and allowing the prescription to be filled. Mr. Rospond likely could have reached the prescriber if he called at 3:55 p.m. when he was performing the DUR review. If the prescriber had been timely contacted and alerted to the potential drug interaction, he likely would have either changed the antibiotic prescription or would have advised the patient to stop the simvastatin while he was taking the antibiotic. The pharmacist could have provided this information to the patient at the time of counseling.

Scott Rospond clearly did not call the physician. He could not recall that he did so, and the Audit Report shows that he overrode the DUR within seconds of reviewing the information. Even if Scott Rospond attached the DUR screen to the patient's receipt consistent with his usual practice, this was an insufficient procedure to ensure that the DUR was properly resolved and the patient received the required counseling. Exactly what happened is unknown. If the DUR sheet was attached to the receipt, either it fell off or was removed by an employee who did not recognize or understand its significance. The patient was allowed to purchase the prescription and leave the pharmacy without receiving the required counseling. It must be emphasized that an offer to counsel, even if this did occur, does not satisfy the counseling requirements. 657 IAC 6.14(1). In addition, asking the patient if there are questions for the pharmacist does not constitute counseling.

Multiple errors within the pharmacy led to the delivery of the clarithromycin prescription to the patient on December 4, 2007 without proper resolution of the potential drug interaction and without counseling. These errors constituted repeated departures from the minimal standard and from the acceptable and prevailing practice of pharmacy in the state of Iowa.

COUNT II – CIRCUMVENTING COUNSELING REQUIREMENTS

657 IAC 36.1(4) (w) provides that the board may sanction a licensee for attempting to circumvent the patient counseling requirements, or for discouraging patients from receiving patient counseling concerning their prescription drug orders.

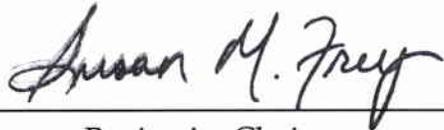
The Board had serious concerns, both about the system failures that prevented this patient from receiving required counseling and about Respondent's former computer system that allowed "patient refused consultation" to be recorded as a default. The Board's rules clearly provide that counseling is required for all new prescriptions, as well as following a prospective drug review under 657 IAC 8.21. 657 IAC 6.14(1). A patient's refusal of counseling must be documented and the absence of such a record shall be presumed to signify that the offer was accepted and counseling was provided. 657 IAC 6.14(6). It appears that Respondent has now upgraded its procedures to ensure that counseling occurs and has corrected the so-called "glitch" in the computer system that allowed "patient refused counseling" to be entered as a default. The Board was not persuaded that this was an intentional feature of Respondent's computer program. The preponderance of the evidence failed to establish that Walgreens 05721 attempted to circumvent patient counseling requirements or discourage patients from receiving counseling as alleged in Count II.

DECISION AND ORDER

The Board believes that the concerns raised by this case have largely been resolved by changes made by Walgreens 05721 to its procedures and its computer system since December 2007. For this reason, the Board has elected not to place the pharmacy on probation at this time. IT IS THEREFORE ORDERED that within sixty (60) days of the date of this Decision and Order, Respondent Walgreens Pharmacy 05721 shall provide documentation to the Board signed by each of its pharmacists, pharmacy technicians, pharmacist-interns, and clerks that they have personally reviewed the pharmacy's Drug Utilization Review Policy and its Patient Counseling Policy within the previous sixty (60) days and that they understand the provisions of those policies.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondent 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 17 day of August, 2009.



Vernon Benjamin, Chairperson
Iowa Board of Pharmacy

cc: Scott Galenbeck, Assistant Attorney General

This final decision of the Board can be appealed in accordance with the Iowa administrative procedures Act.