

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2010-138
LEEDS PHARMACY)	
License No. 227,)	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 155A and 272C (2011).
3. Effective December 12, 2011, the Board renewed Respondent's general pharmacy license number 227 for Leeds Pharmacy (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy, subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 227 is current until December 31, 2012.
5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 4029 Floyd Boulevard, Sioux City, Iowa 51108 with Thomas Dodds as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(b) with lack of professional competency as demonstrated by Respondent's (a) substantial deviation from the standards of learning and skill ordinarily possessed and applied by other Iowa pharmacies, (b) failure to exercise in a substantial respect that degree of care which is ordinarily exercised by an Iowa pharmacy and (c) willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by Respondent's failure to maintain adequate controls over controlled substances.

COUNT II – VIOLATION OF CONTROLLED SUBSTANCES LAWS

Respondent is charged with a failure to comply with controlled substances laws, in violation of Iowa Code §§ 124.306, 124.308, 124.402 and 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(j).

COUNT III – FAILURE TO MAINTAIN AND PROVIDE RECORDS

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

COUNT IV – FAILURE TO GIVE NOTICE OF CLOSURE TO BOARD

Respondent is charged under Iowa Code §§ 155A.15(2)(c) and 155A.19(1)(a) (2011), and 657 Iowa Administrative Code § 8.35(7), with failing to give two weeks prior notice to the Board of Respondent's intention to close a pharmacy.

B. CIRCUMSTANCES

An investigation was commenced on November 3, 2010 which revealed the following:

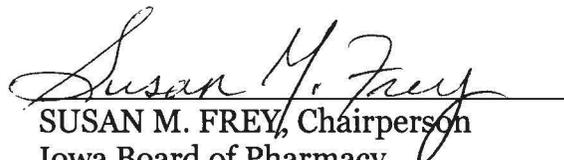
1. At all times material to this Statement of Charges, Respondent was operating a general pharmacy at 4029 Floyd Boulevard, Sioux City, Iowa 51108 with Thomas Dodds as the pharmacist in charge.
2. Respondent dispensed Actos 15mg to a patient, rather than the prescribed Celexa 30mg, resulting in the patient experiencing severe edema.
3. An inspection of Respondent on March 23, 2011 revealed the following:
 - a. Respondent did not assign prescription numbers to some prescription hard copies.
 - b. Respondent did not keep documentation of the pharmacist responsible for checking cassettes and bubble packs before they were dispensed.
 - c. The refrigerator temperature was below freezing.
 - d. Respondent had no policy or procedure regarding drug recalls; no policy or procedure for giving notice of a recall to patients in nursing facilities.
 - e. Receipts for controlled substances were not signed by a responsible person. Respondent was not creating an electronic record of receipt of Schedule II controlled substances.
 - f. Respondent had no policy covering how a proper temperature will be maintained during delivery of drugs and devices that are temperature sensitive.
 - g. Respondent did not have a formal Continuous Quality Improvement program.

- h. Respondent has not documented destruction of returned controlled substances.
 - i. Respondent did not maintain an inventory record of Schedule III, IV and V controlled substances.
 - j. Respondent did not have a policy or procedure relating to receipt and identification of returned drugs.
 - k. Respondent has been re-packaging medication originally dispensed to long term care patients by other pharmacies. The medications were stored by Respondent in bins designated for individual patients, then dispensed in unit dose packages.
4. Respondent failed to give the Board 30 days notice of the closing of the 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 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

Re:) Case Nos. 2010-138, 2011-169,
Pharmacist License of) and 2012-33
LEEDS PHARMACY)
License No. 227,) **MOTION TO AMEND**
Respondent.) **STATEMENT OF CHARGES**

COMES NOW the State of Iowa and moves to amend the Statement of Charges in this matter, as set forth below, and in support thereof states as follows:

1. The State seeks to amend the pending charges to assert new factual allegations.
2. The hearing in this matter is scheduled for August 28, 2012.
3. The Iowa Supreme Court allowed a similar amendment to the statement of charges in the case of Rosen v. Board of Medical Examiners, 539 N.W.2d 345 (Iowa 1996). In that case the Supreme Court allowed a request for amendment to enlarge the factual basis supporting the charges, even though it was made in the course of the hearing itself.
4. It is in the interest of justice to allow this amendment. The new factual allegations concern Respondent's ability to safely practice medicine, and therefore affect the public's health and welfare. There is sufficient time to prepare a defense to these new complaints. It would be unnecessary duplication of the time and resources of both parties and the Board to require the Board to initiate an entirely new proceeding in this matter.
5. A copy of the amended charges proposed by the State is attached as Exhibit A. The substantive changes are the additions of Count V and paragraphs 5-9.

RECEIVED

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IOWA BOARD OF PHARMACY

WHEREFORE, the State of Iowa requests the Board amend the charges as set forth above.

Respectfully submitted,

THOMAS J. MILLER
ATTORNEY GENERAL OF IOWA



THERESA O'CONNELL WEEG
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover Bldg.
Des Moines, IA 50319
515.281.5328
tweeg@ag.state.ia.us

cc: Connie Diekema
FINELY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut St., Suite 1900
Des Moines, IA 50309

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid, and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the 21st day

of August, 2012.

R. Sales

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case No. 2010-138, 2011-169,
Pharmacy License of) and 2012-33
LEEDS PHARMACY)
License No. 227,) **STATEMENT OF CHARGES**
Respondent.) (First Amended)

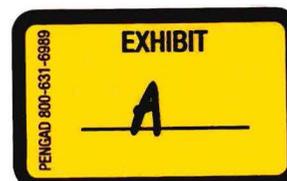
COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).
3. Effective December 12, 2011, the Board renewed Respondent's general pharmacy license number 227 for Leeds Pharmacy (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy, subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 227 is current until December 31, 2012.
5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 4029 Floyd Boulevard, Sioux City, Iowa 51108 with Thomas Dodds as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(b) with lack of professional competency as demonstrated by Respondent's (a) substantial deviation from the standards of learning and skill ordinarily possessed and applied by other Iowa pharmacies, (b) failure to exercise in a substantial respect that degree of care which is ordinarily exercised by an Iowa pharmacy and (c) willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by Respondent's failure to maintain adequate controls over controlled substances.



COUNT II – VIOLATION OF CONTROLLED SUBSTANCES LAWS

Respondent is charged with a failure to comply with controlled substances laws, in violation of Iowa Code §§ 124.306, 124.308, 124.402 and 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(j).

COUNT III – FAILURE TO MAINTAIN AND PROVIDE RECORDS

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

COUNT IV – FAILURE TO GIVE NOTICE OF CLOSURE TO BOARD

Respondent is charged under Iowa Code §§ 155A.15(2)(c) and 155A.19(1)(a) (2011), and 657 Iowa Administrative Code § 8.35(7), with failing to give two weeks prior notice to the Board of Respondent's intention to close a pharmacy.

COUNT V – VIOLATING RULES OF THE BOARD

Respondent is charged with violating the rules of the Board, including 657 IAC 3.21(1) and 3.23(6) (delegation of functions to a pharmacy support person); 6.14(3) (suitable counseling area); 657 IAC 8.3(3) (pharmacist-documented verification); 657 IAC 8.8 (out of date drugs); 657 IAC 8/16(1) regarding confidentiality; 657 IAC 10.31(5) (record book for Schedule V controlled substances); 657 IAC 10.33 (perpetual inventory of Schedule II controlled substances); 10.34(7) (ordering or distributing Schedule I or II controlled substances); 657 IAC 10.35(6) (change of registered location of controlled substances); and 10.35(8) (inventory of newly controlled substances).

B. CIRCUMSTANCES

An investigation was commenced on November 3, 2010 which revealed the following:

1. At all times material to this Statement of Charges, Respondent was operating a general pharmacy at 4029 Floyd Boulevard, Sioux City, Iowa 51108 with Thomas Dodds as the pharmacist in charge.
2. Respondent dispensed Actos 15mg to a patient, rather than the prescribed Celexa 30mg, resulting in the patient experiencing severe edema.
3. An inspection of Respondent on March 23, 2011 revealed the following:

- a. Respondent did not assign prescription numbers to some prescription hard copies.
 - b. Respondent did not keep documentation of the pharmacist responsible for checking cassettes and bubble packs before they were dispensed.
 - c. The refrigerator temperature was below freezing.
 - d. Respondent had no policy or procedure regarding drug recalls; no policy or procedure for giving notice of a recall to patients in nursing facilities.
 - e. Receipts for controlled substances were not signed by a responsible person. Respondent was not creating an electronic record of receipt of Schedule II controlled substances.
 - f. Respondent had no policy covering how a proper temperature will be maintained during delivery of drugs and devices that are temperature sensitive.
 - g. Respondent did not have a formal Continuous Quality Improvement program.
 - h. Respondent has not documented destruction of returned controlled substances.
 - i. Respondent did not maintain an inventory record of Schedule III, IV and V controlled substances.
 - j. Respondent did not have a policy or procedure relating to receipt and identification of returned drugs.
 - k. Respondent has been re-packaging medication originally dispensed to long term care patients by other pharmacies. The medications were stored by Respondent in bins designated for individual patients, then dispensed in unit dose packages.
4. Respondent failed to give the Board 30 days notice of the closing of the pharmacy.

A second investigation was commenced in February 2012, which revealed the following:

5. Leeds Pharmacy allowed a pharmacy technician to delegate technical functions to a pharmacy support person.
6. Leeds Pharmacy dispensed Furosemide (Lasiz) to a patient, rather than the prescribed Fluoxetine (Prozac).
7. Leeds Pharmacy allowed confidential patient information and prescription medication to be available in a public access area.
8. Leeds Pharmacy did not keep a conversation with a patient confidential.
9. An inspection of Leeds Pharmacy on March 14, 2012, revealed the following:
 - a. Leeds Pharmacy had not updated its Schedule II perpetual inventory since 1/2/12.
 - b. Leeds Pharmacy had not inventoried refrigerated controlled substances after

- it relocated its business on 10/31/11.
- c. Leeds Pharmacy does not currently have a usable counseling room.
 - d. Leeds Pharmacy failed to document the final verification of medications for long term care facilities.
 - e. Leeds Pharmacy maintained numerous outdated medications.
 - f. Leeds Pharmacy did not maintain the confidentiality of patient information and prescription medication in a public access area.
 - g. Leeds Pharmacy did not maintain an appropriate bound record book for dispensing Schedule V controlled substances.
 - h. Leeds Pharmacy did not electronically register receipts of Schedule II medications.
 - i. Leeds Pharmacy did not inventory Carisoprodol after it became a schedule IV medication in 1/12/12.

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 ____ day of _____ 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: Theresa O'Connell Weeg
Assistant Attorney General
2nd Floor Hoover State Office Building
Des Moines, Iowa 50319

Connie Diekema
FINLEY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut St., Suite 1900
Des Moines, IA 50309-3905

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF :

LEEDS PHARMACY)	CASE NOS. 2010-138,
License No. 227, and)	2011-169, and 2012-33
)	
THOMAS B. DODDS)	CASE NOS. 2010-138 and
Pharmacist License No. 12951)	2012-33
)	
RESPONDENTS)	RULING GRANTING STATE'S
)	MOTIONS TO AMEND

On March 7, 2012, the Iowa Board of Pharmacy (Board) found probable cause to file Statements of Charges against Leeds Pharmacy and Thomas B. Dodds (Respondents). On August 22, 2012, the state of Iowa filed Motions to Amend both Statements of Charges to add one additional legal count and additional factual circumstances, which relate to a second investigation conducted in February 2012. Both Motions to Amend included a copy of the proposed First Amended Statement of Charges.

On September 14, 2012, Respondents' attorney filed an Answer to Amended Statement of Charges on behalf of both Respondents. Respondents deny all charges contained in the Amended Statement of Charges. Respondents did not file any resistance to the Amended Statements of Charges.

The Board has delegated ruling on the Motions to Amend to the undersigned administrative law judge. Respondents have been afforded sufficient opportunity to prepare a defense to the additional charges. It is in the interest of judicial economy for the Board to hear and determine all pending charges in one disciplinary proceeding. IT IS THEREFORE ORDERED that the State's Motions to Amend the Statement of Charges filed against Respondents Leeds Pharmacy and Thomas Dodds are hereby GRANTED.

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IOWA BOARD OF PHARMACY

Dated this 29th day of November, 2012.

Margaret LaMarche

Margaret LaMarche
Administrative Law Judge
Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building-Third Floor
Des Moines, Iowa 50319
[For the Iowa Board of Pharmacy]

cc: Connie L. Diekema, Finley, Alt, Smith, 699 Walnut Street, Suite 1900, Des Moines, Iowa 50309-3905 (CERTIFIED)
Theresa O'Connell Weeg, Department of Justice, Hoover Bldg, 2nd Fl. (LOCAL)
Lloyd Jessen and Debbie Jorgenson, Iowa Board of Pharmacy, 400 SW 8th Street, Suite C, Des Moines (LOCAL)

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2010-138, 2011-169
Pharmacy License of)	And 2012-33
LEEDS PHARMACY)	
License No. 227)	SETTLEMENT AGREEMENT
)	AND FINAL ORDER

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy and Leeds Pharmacy, 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. 227. That license is active and current until December 31, 2012.
2. A Statement of Charges was filed against Respondent on March 7, 2012. An Amended Statement of Charges was later filed.
3. Respondent was at all times relevant to the Amended Statement of Charges operating a general pharmacy at 4029 Floyd Boulevard, Sioux City, Iowa 51108, with Thomas Dodds as the pharmacist in charge.
4. The Board has jurisdiction over the parties and the subject matter of these proceedings.

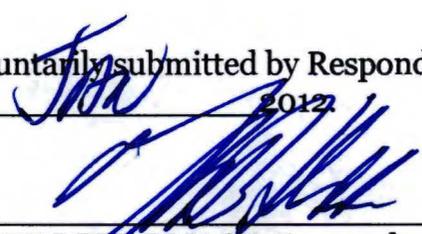
5. Respondent has chosen not to contest the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
6. On the date of the Board's approval of this Settlement Agreement and Final Order, Respondent's license shall be placed on probation for a period of three (3) years, subject to the following terms:
 - a. Respondent shall submit a \$2000.00 civil penalty to the Board. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within ten (10) days of the date this Settlement Agreement is approved by the Board. All civil penalty payments shall be deposited into the State of Iowa's general fund.
 - b. Respondent shall within thirty (30) days of the date this Settlement Agreement is approved by the Board complete a current, accurate and complete controlled substance inventory and submit it to the Board for review and approval.
 - c. Respondent shall within thirty (30) days of the date this Settlement Agreement is approved by the Board establish and implement a continuous quality improvement (CQI) program for the pharmacy and submit it to the Board for its review and approval.
 - d. Respondent shall within thirty (30) days of the date this Settlement Agreement is approved by the Board establish a patient counseling area which provides privacy for patients.

- e. Respondent shall within sixty (60) days of the date this Settlement Agreement is approved by the Board, submit to the Board for its approval policies and procedures for the following areas of practice. Respondent agrees to comply with these policies and procedures while operating its pharmacy.
- i. patient counseling
 - ii. drug recalls
 - iii. drugs returned to the pharmacy
 - iv. proper storage of drugs
 - v. proper repackaging of drugs
 - vi. proper transport of temperature-sensitive drugs
 - vii. pharmacy technician duties
 - viii. pharmacy support person duties
 - ix. handling of confidential patient information
 - x. documentation of final verification of dispensed medications
 - xi. checking for outdated medications and how close to expiration they will be left on the dispensing shelf
 - xii. disposal of expired medications
 - xiii. proper recordkeeping for the dispensing of prescription drugs and controlled substances
 - xiv. proper recordkeeping for the sale of non-prescription, Schedule V controlled substances
 - xv. proper recordkeeping for the destruction of controlled substances.

- f. Respondent shall comply with all applicable Iowa pharmacy law and rules and all related federal requirements for controlled substances while operating its pharmacy.
 - g. Respondent shall submit quarterly reports to the Board. The reports shall be filed not later than December 5, March 5, June 5 and September 5 of each calendar year. These reports shall include a narrative discussing Respondent's current compliance with the terms of this Settlement Agreement and Final Order and any other information requested by the Board.
 - h. Only the periods of time during which Respondent is actively operating a pharmacy in Iowa shall apply to the duration of the probation, unless otherwise approved by the Board.
7. Should Respondent violate or fail to comply with any of the terms and conditions of this Settlement Agreement and Final Order, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacy license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011) and 657 IAC 36.
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.

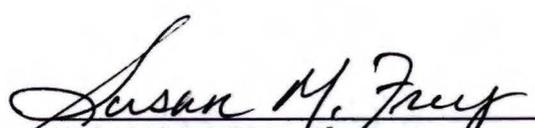
10. This Settlement Agreement and Final Order is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full 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 10 day of July 2012.


LEEDS PHARMACY, Respondent
By Thomas B. Dodds, R.Ph.
Pharmacist in Charge

By his signature Thomas Dodd acknowledges he is the pharmacist in charge of Leeds Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Leeds Pharmacy.

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the 16th day of January 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

Connie Diekema
FINLEY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut St., Suite 1900
Des Moines, IA 50309

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2014-86
Pharmacy License of)	
LEEDS PHARMACY)	STATEMENT OF CHARGES
License No. 227)	& NOTICE OF HEARING
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent was issued Iowa license 227. Respondent's license is currently active, but on probation until January 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 6, 2015, before the Board. The hearing shall be held during the afternoon session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover State Office Building
Des Moines, Iowa 50319.

Ms. Gavin can also be reached by phone at (515)281-6736 or e-mail at Meghan.Gavin@iowa.gov.

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistance Attorney General Meghan Gavin at (515)281-6736.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction over this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 155A, and 272C and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

C. CHARGES

Count I

FAILURE TO MAINTAIN A CONTINUOUS QUALITY IMPROVEMENT PROGRAM

Respondent is charged with failing to maintain a continuous quality improvement program in violation of Iowa Code sections 147.55(9) and 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 8.3(1), 8.26, and 36.1(4)(u).

Count II

FAILURE TO PROPERLY VERIFY THE ACCURACY OF A PRESCRIPTION

Respondent is charged with failing to properly verify the accuracy of a prescription in violation of Iowa Code sections 147.55(9) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 6.10(1), 8.3(1), (3), and 36.1(4)(u).

Count III

FAILURE TO HAVE SUFFICIENT POLICIES AND PROCEDURES

Respondent is charged with failing to have sufficient policies and procedures in violation of Iowa Code section 147.55(9) and 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 6.2, 8.3(1), and 36.1(4)(u).

Count IV
VIOLATION OF THE TERMS OF ITS PROBATION

Respondent is charged with violating of the terms of its probation violation of Iowa Code sections 147.55(9) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(i).

D. FACTUAL CIRCUMSTANCES

1. Respondent is an Iowa-licensed pharmacy doing business at 2729 Outer Drive North, Sioux City, Iowa 51101.
2. In January 2013, Leeds Pharmacy entered into a settlement agreement with the Board. Leeds Pharmacy's license was placed on probation for three years subject to a number of terms and conditions. Amongst those conditions were requirements for Leeds Pharmacy to establish and implement a Continuous Quality Improvement Program (CQI), complete a current, accurate, and complete controlled substance inventory, establish a patient counseling area which provides privacy for patients, and submit for Board approval policies and procedures in a number of practice areas.
3. On May 1, 2014, the Board received notification from Pharmacists Mutual Insurance Company regarding the settlement of a claim with the Respondent. The settlement was due to a dispensing error committed by a staff pharmacist at Leeds. The patient was dispensed amitriptyline 100mg tablets instead of the prescribed 10mg tablets. As a result of the error, the patient was woozy and unable to work for two days.
5. The dispensing error was not recorded in a CQI program.
6. When questioned by a Board compliance officer, Respondent's employees did not appear to know what a CQI program entailed.
7. Respondent lacked sufficient policies and procedures. Upon request, Respondent was only able to produce a policy and procedure manual for Rx HealthMart Pharmacy Operations. This manual was not specific to Leeds Pharmacy. Moreover, while the manual did contain procedures for "Dispensing Error Risk Management" and "Documenting Dispensing Errors," Leeds had not actually implemented a CQI program.
8. Respondent failed to submit policies and procedures as required by the settlement agreement.
9. Respondent failed to complete a current, accurate, and complete controlled substance inventory and submit it to the Board for review and approval as required by the settlement agreement.
10. Respondent failed to establish a patient counseling area which provides privacy for patients as required by the settlement agreement.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this the 19th day of November, 2014, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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

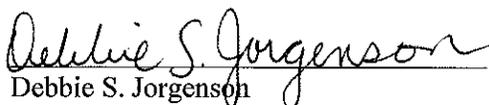
cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- personal service
- certified mail, return receipt requested
- Article Number 9171999991703106755807
- first class mail
- facsimile
- other _____

on the 19th day of November, 2014.

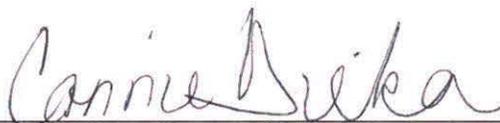
I declare that the statements above are true to the best of my information, knowledge and belief.


Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
)
Pharmacy License of) Case No.: 2014-86
)
LEEDS PHARMACY)
) APPEARANCE AND ANSWER
License No.: 227)
)
Respondent.)

COMES NOW, Connie L. Diekema, who hereby enters her Appearance for the Respondent, Leeds Pharmacy, and denies all charges contained in the Statement of Charges.



Connie L. Diekema AT # 0001987
FINLEY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut Street, Ste 1900
Des Moines, IA 50309
Telephone: (515) 288-0145
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ATTORNEYS FOR RESPONDENT

Original filed.

Copy to:

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, IA 50319
Phone: 515-281-6736
Email: Meghan.gavin@iowa.gov

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on December 12, 2014

By: U.S. Mail FAX
 Hand Delivered Overnight Courier
 Certified Mail Other:

Signature Leah Swanson

RECEIVED

DEC 15 2014

IOWA BOARD OF PHARMACY

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-86
Pharmacy License of)	
)	SETTLEMENT AGREEMENT
LEEDS PHARMACY)	AND FINAL ORDER
License No. 227)	
Respondent.)	

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), the Iowa Board of Pharmacy ("Board") and Leeds Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case 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:

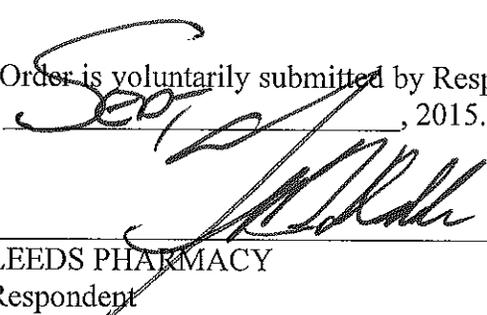
1. Respondent's license #227 is currently active, but is on probation until January 16, 2016 .
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. A Statement of Charges was filed against Respondent on November 19, 2014.
4. Respondent admits the allegations contained 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.
5. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent is freely and voluntarily entering into this Order.
7. Respondent acknowledges that he has the right to be represented by counsel on this matter.
8. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
9. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

10. This Order shall be part of the permanent record of Respondent and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
11. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse, as applicable.
12. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.
13. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

14. Respondent is hereby **CITED** for violating the terms of its probation and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.
15. Respondent's license shall remain on **PROBATION** until January 16, 2016.
16. Respondent agrees to pay a civil penalty in the amount of one-thousand dollars (\$1000). This civil penalty shall be made payable to the Treasurer of Iowa and paid within thirty (30) 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.
17. Respondent's agrees to provide the Board proof within ninety (90) days of the Board's approval of this Settlement Agreement and Final Order of the *implementation* of a continuous quality improvement program.
18. Respondent agrees that a Board compliance officer shall conduct a training with *all* licensed and registered staff on medication errors, the use of a continuous quality improvement program, and any other topic chosen by the Board within ninety (90) days of the Board's approval of this Settlement Agreement and Final Order.
19. The civil penalty and the documentation required to be submitted to the Board under paragraphs 17 should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.
20. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 17 day of September, 2015.


LEEDS PHARMACY
Respondent

By his signature _____ acknowledges he is authorized to this Settlement Agreement and Final Order on behalf of Leeds Pharmacy.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 4th day of November, 2015.


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

cc: Meghan Gavin
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

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ATTORNEY FOR THE RESPONDENT