

State of Iowa
Board of Pharmacy

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BOARD MEMBERS

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Storm Lake

MINUTES

November 18-19, 2014

The Iowa Board of Pharmacy met on November 18-19, 2014, in the conference room at 400 SW Eighth Street, Des Moines, Iowa. Chairperson Maier called the meeting to order at 9:00 a.m.

MEMBERS PRESENT

Edward L. Maier, Chairperson
James Miller, Vice-Chair
Susan M. Frey
LaDonna Gratias
Edward J. McKenna (left at 5:00 p.m.
on 11-19-14)
Sharon K. Meyer
Judith M. Trumpy

STAFF PRESENT

Lloyd Jessen, Executive Director
Meghan Gavin, Esq., Assistant Attorney
General
Laura Cathelyn, Esq., Assistant Attorney
General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary

SPEAKERS

Brett Barker, NuCara
Helen Eddy, Hy-Vee
Megan Myers, IPA
Anthony Pudlo, IPA
Joel Kurzman, NACDS
Lisa Ploehn, Main at Locust
Michelle Garvin, Wester Drug
Cheri Schmit, Medicap
Mike Fuller, Walgreens
Chris Clayton, Unity Point Health
David Scofield, Hartig Drug
Patrick Shanahan, Hopkinton Drug
Stephanie Fawkes-Lee, FL & R

Compliance Officers Present:

Andrew Funk
Curt Gerhold
Mark Mather
Sue Mears
Jean Rhodes
Jennifer Tiffany
Jennifer O'Toole
Jim Wolfe

I. Administrative Hearing.

A. Medicap Pharmacy, Controlled Substance Registration No. 1106533 of Oskaloosa.

On May 28, 2014, the Iowa Board of Pharmacy found probable cause to file Statement of Charges and Notice of Hearing, and issued an Order to Show Cause against the above-named individual.

Laura Lockard, Administrative Law Judge for the State, presided. Assistant Attorney General Meghan Gavin represented the Board. Medicap Pharmacy did not appear nor did counsel represent the pharmacy. The hearing was open to the public.

The Board examined the exhibits.

II. Closed Session.

Motion (Frey/Trumpy) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Frey/McKenna) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Gratias/Miller) to direct Administrative Law Judge Lockard to draft the decision of the Board in the Medicap Pharmacy case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

III. Closed Session.

Motion (Frey/Trumpy) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges; 21.5(1)(a) to review records required by state or federal law to be kept confidential, such as medical, mental health, or substance abuse records relating to non-licensee disciplinary issues; 21.5(1)(f) to discuss the decision to be rendered in a contested case; and 21.5(1)(d) to discuss the contents of a licensing examination. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Frey/Meyer) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

IV. Administrative Hearing.

A. Matthew Biggerstaff, Controlled Substance Registration No. 1306092 of Ankeny.

On August 26, 2014, the Iowa Board of Pharmacy issued an Order to Show Cause against the above-named individual.

Laura Lockard, Administrative Law Judge for the State, presided. Assistant Attorney General Meghan Gavin represented the Board. Matthew Biggerstaff was represented by Michael Sellers. The hearing was closed to the public.

The Board heard testimony of witnesses and examined the exhibits.

Motion (Miller/Frey) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

B. James Nielcen, Pharmacist License No. 14579, Waterloo.

On November 5, 2013, the Iowa Board of Pharmacy found probable cause to file Statement of Charges and Notice of Hearing against the above-named individual. On January 14, 2014, the Board placed Mr. Nielcen's pharmacist license on indefinite suspension. On November 18, 2014, Mr. Nielcen appeared before the Board for the purpose of requesting reinstatement of his pharmacist license.

Laura Lockard, Administrative Law Judge for the State, presided. Assistant Attorney General Meghan Gavin represented the Board. Mr. Nielcen appeared without counsel. The hearing was closed to the public.

The Board heard testimony of a witness and examined the exhibits.

Motion (Miller/McKenna) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

V. Approval of Minutes.

The Minutes of the August 26, 2014, meeting; the August 27, 2014, meeting; the September 11, 2014, teleconference meeting; the September 18, 2014, teleconference meeting; the October 2, 2014, teleconference meeting; the October 14, 2014, teleconference meeting; the October 16, 2014, teleconference meeting; and the October 28, 2014, teleconference meeting were read.

Motion (Frey/McKenna) to approve the minutes of the August 26, 2014, meeting. Passed: 7-0-0-0.

Motion (Miller/Gratias) to approve the minutes of the August 27, 2014, meeting. Passed: 7-0-0-0.

Motion (Miller/McKenna) to approve the minutes of the September 11, 2014, teleconference meeting. Passed: 7-0-0-0.

Motion (Frey/Miller) to approve the minutes of the September 18, 2014, teleconference meeting. Passed: 7-0-0-0.

Motion (Miller/McKenna) to approve the minutes of the October 2, 2014, teleconference meeting. Passed: 7-0-0-0.

Motion (Miller/Gratias) to approve the minutes of the October 14, 2014, teleconference meeting. Passed: 7-0-0-0.

Motion (Miller/Trumpy) to approve the minutes of the October 16, teleconference meeting.
Passed: 7-0-0-0.

Motion (Trumpy/McKenna) to approve the minutes of the October 28, 2014, teleconference meeting. Passed: 7-0-0-0.

VI. Amended Statement of Charges.

A. 2012-174 Kimberly Robertson, Pharmacist License No. 15845 of Des Moines.

Motion (Miller/Trumpy) to approve Amended Statement of Charges. Passed: 6-0-1-0.
Abstain: Frey. A copy of the Amended Statement of Charges is attached as Addendum A.

VII. Reports.

Executive Director's Report.

A. Financial.

FY15 as of 10/31/14 (33.33% of FY completed)

| | |
|---------------------------------|--------------------|
| Revenue Anticipated: | \$ 3,833,933 |
| Revenue Actual | \$ 2,009,327 (52%) |
| Carry-over from FY13 | \$ 1,504,637 |
| FY15 Fee Receipts | \$ 504,690 |
| Budget Allocation | \$ 3,833,933 |
| Obligations Actual | \$ 1,059,819 (28%) |
| Fines/Civil Penalties Collected | \$ 32,750 |

B. Meeting and Travel.

1. The January Board Meeting is scheduled for January 5-7, 2015, at the Board office in Des Moines. The meeting will begin at 1:00 p.m. on January 5, and conclude by 2:00 p.m. on January 7.
2. An Administrative Hearing for PCM Venture, LLC, Sandy, Utah, is scheduled for January 28-29, 2015, at the Board office in Des Moines.
3. The IPA Legislative Day will be held on January 29, 2015, in Des Moines.
4. The 2015 Midwest Pharmacy Expo will be held in Des Moines on February 13-15, 2015. The Board will present a pharmacy law presentation on Sunday, February 15.
5. The March Board Meeting is scheduled for March 10-11, 2015, at the Board office in Des Moines.
6. The next Rules Committee Meeting is scheduled for January 27, 2015, at the Board office in Des Moines.

C. Baum Harmon Mercy Hospital, Primghar -- Quarterly Waiver Report.

Baum Harmon Mercy Hospital submitted their Quarterly Waiver Report for review. The Board requested the pharmacy provide additional documentation in their reports regarding how the pharmacy is improving their practice of pharmacy and working to eliminate errors.

D. Iowa Board of Medicine Votes to Establish Standards for Physicians Who Use Telemedicine. Informational item.

E. Allen Hospital, Waterloo – Tech-Check-Tech Quarterly Update.

Allen Hospital submitted their Tech-Check-Tech Quarterly Report for review.

F. NuCara Pharmacy 10, Pharmacy License No. 78, Story City – Tech-Check-Tech Report.

NuCara Pharmacy submitted their Tech-Check-Tech Report for review.

G. Hy-Vee Pharmacy Fulfillment Center Third Quarter Error Report.

Hy-Vee Pharmacy Fulfillment Center submitted their third Quarterly Error Report for review.

H. Phase One – Second Quarterly Report -- New Practice Model – Megan Myers, Iowa Pharmacy Association.

The Iowa Pharmacy Association and Drake University College of Pharmacy provided their second Quarterly New Practice Model Report for review.

I. Pharmacy Meeting with Wellmark.

Susan Frey and Sharon Meyer attended the meeting. Wellmark is seeking pharmacist input into their next round of contract negotiations. The Board discussed sending a letter, as an informational piece, to Wellmark regarding issues they have encountered.

J. TakeAway Program Update – Anthony Pudlo, Iowa Pharmacy Association.

Discussion was held regarding the TakeAway Medication Disposal Program; Federal Legislation and Regulations; MedSafe and Yellow Jug as future options for the program; projected growth of the TakeAway Program with the addition of controlled substances; and projected annual cost of an Iowa Medication Disposal Program.

K. Point-of-Care Testing Presentation – Anthony Pudlo, Iowa Pharmacy Association, and Joel Kurzman, Director, State Government Affairs National Association of Chain Drug Stores.

The definition of Point-of-Care Testing was discussed and how pharmacists play an active role in the designing, implementing, and monitoring of therapeutic plans to produce specific therapeutic outcomes for patients. Discussion was held regarding if Point-of-Care Testing would be allowed under the Iowa Board of Pharmacy rules; if pharmacists could provide this level of Point-of-Care Testing; and how pharmacists could work within the current rules with collaborative practice agreements or if it would be expanded through a state-wide protocol opportunity. The Rules Committee will review this issue.

VIII. Requests.

A. Petition to Request Reclassification of Marijuana – Carl Olsen, Des Moines.

Motion (Miller/Trumpy) to table the Board's 2015 Recommendation for the Scheduling of Marijuana. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

B. Annual Review of Fees.

Motion (Frey/Trumpy) to approve the annual review of licensing and registration fees for FY15 and to continue licensing and registration fees at the current level. Passed: 7-0-0-0.

C. Request for Waiver -- 657 I.A.C. 8.35 Pharmacy License – Dr. Nathan Harold, PharmD, RPh, Clinical Pharmacy Manager, Pharmacist License No. 21780, Dubuque.

A letter will be sent to Mr. Harold notifying him a waiver request is not necessary.

D. License Reactivation – Sumitra Patel, Pharmacist License No. 14334, Bowling Green, Kentucky.

Motion (Miller/Frey) Ms. Patel complete 1,000 hours of internship, take and pass the NAPLEX and MPJE Examinations within 18 months, beginning November 19, 2014. Passed: 7-0-0-0.

E. Request for Internship Credit for Life Experience – Emma Awad, Bettendorf.

Motion (Miller/Gratias) to grant 1,000 hours of internship in lieu of life experience and require Ms. Awad to complete an additional 500 hours of internship. Passed: 7-0-0-0.

F. Phase Two – A Pharmacy Pilot or Demonstration Research Project for a New Practice Model for Community Pharmacy – Megan Myers, Iowa Pharmacy Association.

Motion (Miller/Trumpy) to approve the request. Passed: 6-1-0-0. No: Frey.

- G. Request to Have Charges Stricken from Website – Kevin Christians, Pharmacist License No. 18426, Coralville.

Motion (Frey/Trumpy) to deny the request. Passed: 7-0-0-0.

IX. Licensure/Registration.

- A. Initial Pharmacy Support Person Registration Application – Rhonda Macy, Des Moines.

Motion (Miller/Frey) to deny the application. Passed: 7-0-0-0.

- B. Initial Pharmacy Support Person Registration Application – Jacqueline Cobb, Sioux City.

Motion (Miller/Trumpy) to approve the application. Passed: 7-0-0-0.

- C. Application for Pharmacy Technician Trainee Registration/Initial Pharmacy Support Person Registration Application -- Stephanie Wadell, Orange City.

Motion (Frey/Trumpy) to deny the applications. Passed: 6-1-0-0. No: Miller.

- D. Iowa Wholesale Drug License Application – Sun Pharmaceutical Industries, Inc., Cranbury, New Jersey.

Motion (Frey/Miller) to deny the application. Passed: 7-0-0-0.

- E. Withdrawal of Nonresident Pharmacy Application – Hopkinton Drug, Hopkinton, Massachusetts.

Motion (Frey/Trumpy) to close due to application being withdrawn. Passed: 7-0-0-0.

- F. New Nonresident Pharmacy Application Review – Edge Pharmacy Services, Colchester, Vermont.

Motion (Miller/Gratias) to approve the application. Passed: 7-0-0-0.

- G. Application for Pharmacy Technician Trainee Registration – Michelle Heidebrink, Oskaloosa.

Motion (Miller/Gratias) to deny the application. Passed: 7-0-0-0.

X. Rules.

- A. Proposed for Adoption and Filing – Chapter 3, “Pharmacy Technicians.”

Motion (Frey/Gratias) to approve for Adoption and Filing. Passed: 7-0-0-0. A copy is attached as Addendum B.

- B. Proposed for Adoption and Filing – Chapter 4, “Pharmacist Interns,” and Chapter 8, “Universal Practice Standards.”

Motion (Trumpy/Frey) to approve for Adoption and Filing. Passed: 7-0-0-0. A copy is attached as Addendum C.

- C. Proposed for Adoption and Filing – Chapter 10, “Controlled Substances.”

Motion (Miller/Frey) to approve for Adoption and Filing as amended. Passed: 7-0-0-0. A copy is attached as Addendum D.

- D. Proposed for Adoption and Filing – Chapter 19, “Nonresident Pharmacy Practice.”

Motion (Frey/Miller) to approve for Adoption and Filing. Passed: 7-0-0-0. A copy is attached as Addendum E.

- E. Proposed for Adoption and Filing – Chapter 33, “Military Service and Veteran Reciprocity.”

Motion (Miller/Trumpy) to approve for Adoption and Filing. Passed: 7-0-0-0. A copy is attached as Addendum F.

- F. Notice of Intended Action – Chapter 8, “Universal Practice Standards.”

Motion (Frey/McKenna) to approve for filing Notice of Intended Action. Passed: 7-0-0-0. A copy is attached as Addendum G.

- G. Notice of Intended Action – Chapter 3, “Pharmacy Technicians,” Chapter 6, “General Pharmacy Practice,” and Chapter 7, “Hospital Pharmacy Practice”; to Rescind Chapter 13, “Sterile Compounding Practices”; and to Rescind Chapter 20, “Pharmacy Compounding Practices,” and adopt a new Chapter 20, “Compounding Practices.”

Motion (Trumpy/Miller) to approve for filing Notice of Intended Action. Passed: 7-0-0-0. A copy is attached as Addendum H.

- H. Notice of Intended Action – Chapter 36, “Discipline.”

Motion (Frey/Trumpy) to approve for filing Notice of Intended Action. Passed: 7-0-0-0. A copy is attached as Addendum I.

- I. Notice of Intended Action – Chapter 6, “General Pharmacy Practice,” Chapter 7, “Hospital Pharmacy Practice,” Chapter 8, “Universal Practice Standards,” Chapter 9, “Automated Medication Distribution Systems and Telepharmacy Services,” Chapter 15, “Correctional Pharmacy Practice,” Chapter 18, “Centralized Prescription Filing and Processing,” Chapter 19, “Nonresident Pharmacy Practice,” Chapter 22, “Unit Dose, Alternative Packaging, and Emergency Boxes,” and Chapter 23, “Long-Term Care Pharmacy Practice.”

Motion (Frey/McKenna) to approve for filing Notice of Intended Action. Passed: 7-0-0-0.
A copy is attached as Addendum J.

XI. Legislation.

A. Proposed Legislative Changes Relating to Pharmacy Practice.

An Act relating to nonresident pharmacy and outsourcing facility licensure, pharmacist supervision of pharmacy technicians, alternate board members, enforcement authority, and various definitions regarding pharmacy practice.

Motion (Trumpy/Frey) to approve legislative changes. Passed: 7-0-0-0.

B. Proposed Legislative Changes Relating to Controlled Substances.

An Act making changes to controlled substances schedules and making penalties applicable.

Motion (Trumpy/Frey) to approve legislative changes. Passed: 7-0-0-0.

C. Establishment of Prescription Monitoring Program's Task Force/Advisory Group.

The Board discussed establishing a Prescription Monitoring Program (PMP) Task Force/Advisory Group in 2015. The Board directed staff to move forward with forming an Advisory Group composed of interested parties, including the law enforcement community.

XII. Closed Session.

Motion (Frey/Meyer) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; and 21.5(1)(a) to review records required by state or federal law to be kept confidential, such as medical, mental health, or substance abuse records relating to non-licensee disciplinary issues. Roll call vote. Yes: Frey, Gratias, Maier, Meyer, Miller, Trumpy; No: None; Abstain: McKenna; Absent: None. Passed: 6-0-1-0.

Motion (Frey/Trumpy) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, Meyer, Miller, Trumpy; No: None; Abstain: McKenna; Absent: None. Passed: 6-0-1-0.

XIII. Closed Session.

Motion (Frey/Miller) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Gratias/Miller) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Frey/Trumpy) to direct Administrative Law Judge Lockard to draft the decision of the Board in the Nielcen case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Frey/Trumpy) to direct Administrative Law Judge Lockard to draft the decision of the Board in the Biggerstaff case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

XIV. Complaints Against Non-Licensees.

A. 2014-113 – CanineCare US, Collegeville, Pennsylvania.

Motion (Miller/Gratias) to close with no action. Passed: 7-0-0-0.

B. 2014-131 – Better Off Healthy, Boca Raton, Florida.

Motion (Frey/Trumpy) to close with no action. Passed: 7-0-0-0.

C. 2014-134 – K-Mart Pharmacy No. 7306, Sioux Falls, South Dakota.

Motion (Miller/Frey) to close with no action. Passed: 7-0-0-0.

D. 2014-154 – Enovachem Manufacturing, Torrance, California.

Motion (Trumpy/McKenna) to close with no action. Passed: 7-0-0-0.

E. 2014-164 -- Iowa Medicaid Enterprise, Des Moines.

Motion (Frey/Trumpy) to refer to the Iowa Medicaid Drug Utilization Review Commission. Passed: 7-0-0-0.

XV. Closed Session.

Motion (Frey/Trumpy) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges; 21.5(1)(a) to review records required by state or federal law to be kept confidential, such as medical, mental health, or substance abuse records relating to non-licensee disciplinary issues; and 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

Motion (Trumpy Frey) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller, Trumpy; No: None; Abstain: None; Absent: None. Passed: 7-0-0-0.

In open session the following actions were taken.

A. Administrative Warning.

Motion (Miller/Frey) to send an Administrative Warning to the pharmacy in 2013-149, pharmacies in 2014-3, pharmacy in 2014-4, pharmacist in 2014-117, pharmacy and pharmacist in charge in 2014-135, pharmacy and pharmacist in charge in 2014-136, and pharmacy and pharmacist in charge in 2014-152. Passed: 6-0-0-1. Absent: McKenna.

B. Administrative Warning.

Motion (Frey/Gratias) to send an Administrative Warning to the CSA Registrant in 2014-149. Passed: 5-0-1-1. Abstain: Miller; Absent: McKenna.

C. Letter of Education.

Motion (Miller/Gratias) to send a letter of Education to the pharmacy and pharmacist in charge in 2014-128, pharmacy and pharmacist in charge in 2014-151, pharmacist in charge and technician in 2014-153, pharmacy and pharmacist in charge in 2014-161, pharmacy and pharmacist in charge in 2014-162, pharmacy and pharmacist in charge in 2014-163, and pharmacy in 2014-165. Passed: 6-0-0-1. Absent: McKenna.

D. Settlement Agreement and Final Order.

Motion (Miller/Frey) to approve the Settlement Agreement and Final Order in the following cases. Passed: 6-0-0-1. Absent: McKenna.

1. Excellence, Nonresident Pharmacy License No. 3435 of Memphis, Tennessee. A copy of the Settlement Agreement and Final Order is attached as Addendum K.
2. Thomas Snyder, Pharmacist License No. 13427 of Sheldon. A copy of the Settlement Agreement and Final Order is attached as Addendum L.
3. Peggy Ashby, Pharmacy Technician Registration No. 15487 of North Liberty. A copy of the Settlement Agreement and Final Order is attached as Addendum M.
4. Belmar Pharmacy, Nonresident Pharmacy License No. 3975 of Lakewood, Colorado. A copy of the Settlement Agreement and Final Order is attached as Addendum N.
5. Katie Meldrem-Ferneau, Pharmacy Technician Registration No. 20489 of Pella. A copy of the Settlement Agreement and Final Order is attached as Addendum O.
6. Kate Klingborg, Pharmacy Support Person Registration No. 2268 of Muscatine. A copy of the Settlement Agreement and Final Order is attached as Addendum P.

E. Combined Notice of Hearing and Statement of Charges.

Motion (Miller/Frey) to approve the Combined Notice of Hearing and Statement of Charges in the following cases. Passed: 6-0-0-1. Absent: McKenna.

1. Matthew Sherrow, Pharmacist License No. 18612 of Springfield, Illinois. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum Q.

2. Robert Osborn, Pharmacist License No. 19079 of Rock Island, Illinois. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum R.
3. Dutch Mill Pharmacy, Pharmacy License No. 445 of Orange City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum S.
4. Brent Plender, Pharmacist License No. 17651 of Orange City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum T.
5. Dwayne A. Plender, Pharmacist License No. 13561 of Orange City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum U.
6. Leeds Pharmacy, Pharmacy License No. 227 of Sioux City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum V.
7. Thomas B. Dodds, Pharmacist License No. 12951 of Dakota Dunes, South Dakota. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum W.
8. Rashid LTC Pharmacy, Pharmacy License No. 1129 of Fort Madison. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum X.
9. David Tracey King, Pharmacist License No. 19586 of Burlington. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum Y.
10. Brady Rolfes, Pharmacy Technician Registration No. 18729 of Iowa City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum Z.
11. OK Compounding LLC, Nonresident Pharmacy License No. 4204 of Skiatook, Oklahoma. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum AA.

F. Confidential Order for Evaluation.

Motion (Frey/Gratias) to approve the Confidential Order for Evaluation in 2013-167. Passed: 6-0-0-1. Absent: McKenna.

G. Closed With No Action.

Motion (Miller/Gratias) to close with no further action the investigative file in complaint numbers: 2012-195, 2013-3643, 2013-3779, 2014-76, 2014-107, 2014-139, 2014-140, 2014-141, 2014-142, 2014-146, 2014-148, 2014-155, 2014-157, 2014-160, and 2014-176. Passed: 6-0-0-1. Absent: McKenna.

H. Draft Statement of Charges.

Motion (Miller/Frey) to draft Statement of Charges against the stated individuals in the following complaints: technician trainee in 2014-116, technician in 2014-144, technician in 2014-147, pharmacist in 2014-156, and pharmacist in 2014-175. Passed: 6-0-0-1. Absent: McKenna.

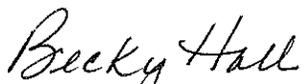
I. Draft Confidential Order for Evaluation.

Motion (Gratias/Trumpy) to draft a Confidential Order for Evaluation against the pharmacist in 2014-119 and pharmacist in 2014-151. Passed: 6-0-0-1. Absent: McKenna.

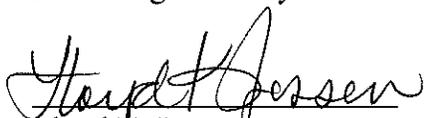
J. Draft Order to Show Cause.

Motion (Miller/Gratias) to draft an Order to Show Cause against the CSA registrant in 2014-145 and CSA registrant in 2014-172. Passed: 6-0-0-1. Absent: McKenna.

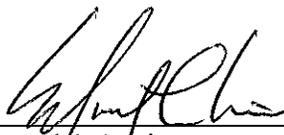
Meeting adjourned at 5:40 p.m. on November 19, 2014.



Becky Hall
Recording Secretary



Lloyd K. Jessen
Executive Director



Edward L. Maier
Board Chair

APPROVED THIS 6th DAY OF January, 2015.

ADDENDUM A

AMENDED STATEMENT OF CHARGES

**KIMBERLEY R. ROBERTSON
PHARMACIST LICENSE NO. 15845
DES MOINES, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-------------------------------|---|------------------------------|
| Re: |) | Case Nos. 2012-52 & 2012-174 |
| Pharmacist License of |) | |
| KIMBERLEY R. ROBERTSON |) | AMENDED STATEMENT |
| License No. 15845, |) | OF CHARGES |
| Respondent. |) | |

COMES NOW, the Board of Pharmacy and adopts the following Amended Statement of Charges.

A. 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.

B. CHARGES

Count I

PROFESSIONAL INCOMPETENCY

Respondent is charged with failing 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 in violation of Iowa Code sections 147.55(2) and 155A.12(1) and 657 Iowa Administrative Code rule 36.1(4)(b)(3).

Count II

**UNETHICAL BEHAVIOR OR
PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC**

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(3) and 155A.12(2) and 657 Iowa Administrative Code rules 8.11(4); (8) and 36.1(4)(c).

Count III

AIDING THE UNLAWFUL PRACTICE OF PHARMACY

Respondent is charged with knowingly aiding, assisting, procuring, or advising another

person to unlawfully practice pharmacy in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rule. 36.1(4)(I).

Count IV
FAILURE TO REPORT

Respondent is charged with failing to report the acts or omissions committed by another licensee in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 36.1(4)(g) and 36.2(3).

Count V
FAILURE TO MAINTAIN SECURITY

Respondent is charged with failing to maintain security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.7, 8.5(3), and 36.1(4)(u).

Count VI
VIOLATING THE DUTIES OF A PHARMACIST-IN-CHARGE

Respondent is charged with violating the duties of a pharmacist-in-charge in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.2(15), 8.3(1), and 36.1(4)(u).

C. FACTUAL CIRCUMSTANCES

1. At all times material to this Amended Statement of Charges, Respondent was self-employed as a pharmacist and co-owner of Bauder Pharmacy in Des Moines, Iowa.
2. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP tablets or hydrocodone-containing products, Schedule III controlled substances. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration and comparing it with data from the State prescription monitoring program (PMP). ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level.
3. For the same audit period (January 1, 2008 through March 21, 2012), prescription monitoring program (PMP) records submitted by Bauder Pharmacy indicate that the pharmacy dispensed 358,012 tablets of hydrocodone-containing products to customers. ARCOS data, comparatively, revealed that during the same audit period, Bauder Pharmacy had ordered more than 1.1 million tablets of hydrocodone-containing products from various wholesalers.

4. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 tablets of hydrocodone-containing products are not accounted for in the pharmacy's PMP dispensing records. The pharmacy has received, from wholesalers, 740,888 more tablets of hydrocodone-containing products than the pharmacy had dispensed.

5. Shortages of tablets of hydrocodone-containing products at Bauder Pharmacy occurred as follows:

Calendar Year 2008: 229,846 tablets;
Calendar Year 2009: 163,185 tablets;
Calendar Year 2010: 155,436 tablets;
Calendar Year 2011: 182,732 tablets;
January-March 21, 2012: 9,689 tablets.

6. Following a contested case, the Board issued its Findings of Fact, Conclusions of Law, Decision, and Order in a disciplinary case against Bauder Pharmacy and Mark Graziano. The Board found that Bauder Pharmacy and Mark Graziano could not account for at least 689,987 tablets of hydrocodone-containing products during the audit period.

7. During the audit period, Respondent was responsible for signing controlled substances invoices. Many of the controlled substance invoices for the audit period are unaccounted for or were unsigned. Of the invoices that were signed, all were signed by the Respondent.

8. In 2010 and 2011, Respondent signed invoices for approximately 121,000 tablets of hydrocodone APAP 7.5-500mg, almost a hundred thousand *more* tablets than the pharmacy dispensed during the same period. For example, the Respondent signed invoices for 11,500 hydrocodone APAP 7.5-500mg tablets in March 2011, while the PMP records provide that Bauder Pharmacy lawfully dispenses only 802 tablets of the drug.

9. A typical pharmacy would not order five times the number of tablets it was dispensing.

10. Respondent has worked at Bauder Pharmacy for more than a decade as a staff pharmacist.

11. Annual inventories from 2010 and 2011 are missing entries for most hydrocodone-containing products. No documented annual controlled substance inventory was completed by the pharmacy in 2012. Respondent conducted and signed each of the annual inventories.

12. On multiple occasions, the Respondent was personally informed by an individual of the hydrocodone diversion at Bauder Pharmacy.

13. In a signed statement to the Board, Respondent reported that Bauder used three wholesalers for purchases of controlled substances. During the audit period, Bauder used fourteen wholesalers for purchases of controlled substances, including numerous instances where

the pharmacy used multiple wholesalers on the same day for the same commercially available product. In 2011, the Respondent signed invoices from nine different wholesalers for tablets of hydrocodone-containing products.

14. An average pharmacist with the Respondent's experience, knowledge of the number of hydrocodone tablets received by Bauder Pharmacy, knowledge of the number of hydrocodone tablets legally dispensed, knowledge of the number of wholesalers used by the pharmacy, and knowledge of the allegations of diversion would have a reasonable belief that diversion had been or was occurring.

15. At no time did the Respondent inform the Board of the diversion allegations or the large amount of hydrocodone being ordered by the pharmacy.

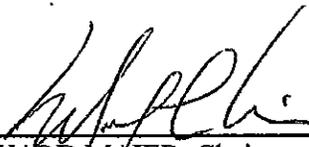
16. On April 5, 2013, the Board issued its Findings of Fact, Conclusions of Law, Decision, and Order in a disciplinary case against Bauder Pharmacy and Mark Graziano. Under the Order, Bauder Pharmacy's license was placed on indefinite probation subject to numerous terms and conditions.

17. Respondent assumed the position of Pharmacist-in-Charge at Bauder Pharmacy in late 2013.

18. Bauder Pharmacy has failed to comply with several requirements of the Board's April 5th Order, including prohibiting Mark Graziano from having access to the pharmacy department and prescription drugs, complying with all the recommendations of the Board-approved consultant, and submitting quarterly reports by the pharmacy and the consultant. Mark Graziano has access to the pharmacy department by virtue of his access to the keys and alarm codes for the building because there is no secure, physical barrier between the pharmacy and the drug store/soda fountain.

D. PROBABLE CAUSE FINDING

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



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Iowa Board of Pharmacy
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cc: Meghan Gavin
Assistant Attorney General

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ATTORNEY FOR THE RESPONDENT

ADDENDUM B

ADOPTED AND FILED

CHAPTER 3, "PHARMACY TECHNICIANS"

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 3, "Pharmacy Technicians," Iowa Administrative Code.

The amendments provide updated language to remove all references to uncertified pharmacy technicians. Current rules require all pharmacy technicians to obtain national certification, but the rules provide an extended deadline for compliance under certain conditions. As of December 31, 2013, the provision for extension of the deadline to attain national certification has expired. These amendments eliminate all references to the extended deadline for national certification and all references to uncertified pharmacy technicians because national certification is required of all pharmacy technicians following one-year registration as a technician trainee.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1653C**. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the November 19, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 147.72, 147.107, 155A.6A, 155A.23, 155A.33, and 155A.39.

These amendments will become effective on January 14, 2015.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these amendments [amendments to Ch 3] is being omitted. These amendments are identical to those published under Notice as **ARC 1653C**, IAB 10/1/14.

[Filed 11/19/14, effective 1/14/15]

[Published 12/10/14]

[For replacement pages for IAC, see IAC Supplement 12/10/14.]

ADDENDUM C

ADOPTED AND FILED

CHAPTER 4, "PHARMACIST INTERNS,"
AND
CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS"

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 147.76 and 155A.6, the Board of Pharmacy hereby amends Chapter 4, "Pharmacist Interns," and Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The amendments provide for the delegation of immunization administration by an authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist. This provision was inadvertently omitted when the immunization rule was amended in September 2013. The amendments also define "authorized pharmacist-intern" and require continued cardiac life support certification and documentation of such certification beyond initial qualification of the authorized pharmacist or authorized pharmacist-intern. The amendments also require that the prescriber authorizing the administration of immunizations via protocol must identify, by name or classification, any pharmacists or other qualified health professionals that may administer immunizations pursuant to the specific protocol.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1652C**. The Board received one written comment regarding the proposed amendments. The commenter expressed concern that the amendments would effectively limit immunization activities by pharmacist-interns if the protocol required the identification by name of each pharmacist-intern. The Board's intent of the rule making is to alleviate that burden by allowing in a signed protocol the identification of immunizers by category. The Board reviewed the language of the proposed amendments and determined that the intent is provided. The adopted amendments are identical to those published under Notice.

The amendments were approved during the November 19, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 155A.6 and 155A.13.

These amendments will become effective on January 14, 2015.

The following amendments are adopted.

ITEM 1. Amend subrule 4.6(2) as follows:

4.6(2) Supervision and authorized functions. A licensed pharmacist shall be on duty in the pharmacy and shall be responsible for the actions of a pharmacist-intern during all periods of internship training. At the discretion of the supervising pharmacist, the following judgmental functions, usually restricted to a pharmacist, may be delegated to pharmacist-interns registered by the board:

- a. and b. No change.
- c. Patient counseling;
- d. Administration of vaccines pursuant to rule 657—8.33(155A).

ITEM 2. Amend rule 657—8.33(155A) as follows:

657—8.33(155A) Vaccine administration by pharmacists. An authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

8.33(1) Definitions. For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 8.33(2).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 8.33(2) "a" and "c."

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Protocol" means a standing order for a vaccine to be administered by an authorized pharmacist.

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

8.33(2) Authorized pharmacist training and continuing education. An authorized pharmacist shall document successful completion of the requirements in paragraph 8.33(2) "a" and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 8.33(2) "b."

a. and b. No change.

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in the American Heart Association or the Red Cross basic cardiac life support protocol for health care providers.

8.33(3) Protocol requirements. A pharmacist may administer vaccines pursuant to CDC protocols. A protocol shall be unique to a pharmacy and, The prescriber who signs a protocol shall identify all within the protocol, by name or category, those pharmacists authorized or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. Links to CDC protocols shall be provided on the board's Web site at www.iowa.gov/ibpe. A protocol:

a. to d. No change.

e. Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

8.33(4) to 8.33(7) No change.

[Filed 11/19/14, effective 1/14/15]

[Published 12/10/14]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/10/14.

ADDENDUM D
ADOPTED AND FILED
CHAPTER 10, "CONTROLLED SUBSTANCES"
NOVEMBER 19, 2014

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.301, the Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendments temporarily classify as Schedule IV controlled substances products containing tramadol, alfaxalone, and suvorexant and temporarily remove the classification of hydrocodone combination products from Schedule III, effectively classifying all hydrocodone-containing products in Schedule II of the Controlled Substances Act in conformance with recent control of these same substances by the U.S. Department of Justice, Drug Enforcement Administration (DEA).

The amendments also provide clearer direction for the notification process when a registrant has experienced a theft or loss of controlled substances. The amendment regarding the reporting of a theft or loss of controlled substances requires immediate notification to the DEA and, in certain circumstances, to the Board, upon discovery of a theft or loss of a significant quantity of controlled substances, followed by submission to the Board and to the DEA of a formal report within 14 days of discovery of the theft or loss.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1647C**. The Board received written comments objecting to the proposed temporary scheduling of tramadol and hydrocodone-containing products and requesting that the Board terminate the rule making. Regardless of whether the Board proceeded with the rule making, the drugs identified in the comments have been scheduled under federal law, and where federal and state laws differ regarding controlled substances schedules, the more stringent scheduling action prevails. The Board also received a request for clarification of the 14-day time period specified in subrule 10.16(3), questioning whether that period refers to calendar days or business days. In response to that question, the adopted amendment has been changed to require reporting within 14 calendar days of discovery of the theft or loss.

Although the Notice of Intended Action proposed to rescind current rule 657—10.38(124), the temporary scheduling provisions of the rule are still necessary. Therefore, the proposed rescission of rule 657—10.38(124) was not adopted, and the new temporary scheduling provisions have been included in the rule as new subrules 10.38(4) through 10.38(6).

The amendments were approved during the November 19, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.201(4) and 124.301.

These amendments will become effective on January 14, 2015.

The following amendments are adopted.

ITEM 1. Rescind rule 657—10.16(124) and adopt the following **new** rule in lieu thereof:

657—10.16(124) Report of theft or loss. A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

10.16(1) Immediate notice to board. If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from whom the controlled substances were stolen shall notify the board

immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

10.16(2) Immediate notice to DEA. A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

10.16(3) Timely report submission. Within 14 calendar days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA Web site at <http://www.deadiversion.usdoj.gov/>. A copy of the report that was completed and submitted to the DEA shall be immediately submitted to the board via facsimile, e-mail attachment, or personal or commercial delivery.

10.16(4) Record maintained. A copy of the report shall be maintained in the registrant's files for a minimum of two years following the date the report was completed.

ITEM 2. Adopt the following **new** subrules 10.38(4) to 10.38(6):

10.38(4) Amend Iowa Code subsection 124.208(5), paragraph "a," by rescinding subparagraphs (3) and (4) and by renumbering remaining subparagraphs (5) through (8) as subparagraphs (3) through (6).

10.38(5) Amend Iowa Code subsection 124.210(2) by adding the following new paragraph:
c. 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol).

10.38(6) Amend Iowa Code subsection 124.210(3) by adding the following new paragraphs:

bb. Alfaxalone.

bc. Suvorexant.

[Filed 11/19/14, effective 1/14/15]

[Published 12/10/14]

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ADDENDUM E

ADOPTED AND FILED

CHAPTER 19,
“NONRESIDENT PHARMACY PRACTICE”

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 19, "Nonresident Pharmacy Practice," Iowa Administrative Code.

The amendment reorganizes the provisions of rule 657—19.2(155A) into subrules, requires notification to Iowa patients when a nonresident pharmacy intends to cease business in Iowa, and provides that a nonresident pharmacy may not cancel its license as a means of avoiding disciplinary action.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1651C**. The Board received no written comments regarding the proposed amendments. The Board, however, removed from the initially proposed amendments the requirement that a nonresident pharmacy comply with the rules in Chapter 13 for sterile compounding. The Board is proposing in **ARC 1791C** herein a Notice of Intended Action that would rescind Chapter 13, effectively negating the need for the amendment proposed in Item 2 of **ARC 1651C**. The amendment to rule 657—19.2(155A) adopted in this rule making is identical to that published under Notice of Intended Action.

The amendment was approved during the November 19, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code sections 155A.13A and 155A.19.

This amendment will become effective on January 14, 2015.

The following amendment is adopted.

Amend rule 657—19.2(155A) as follows:

657—19.2(155A) Application and license requirements. A nonresident pharmacy shall apply for and obtain, pursuant to provisions of 657—8.35(155A), a nonresident pharmacy license from the board prior to providing prescription drugs, devices, or pharmacy services to an ultimate user in this state.

19.2(1) Pharmacy license changes. Change of pharmacy name, ownership, location, or pharmacist in charge shall require a new completed application and license fee pursuant to 657—subrule 8.35(6).

19.2(2) Pharmacy discontinuing Iowa operations. A nonresident pharmacy intending to close or discontinue provision of prescription drugs, devices, and pharmacy services to Iowa patients shall notify the board and Iowa patients as provided in 657—subrule 8.35(7). The license of a nonresident pharmacy that provides such notice of intent to close or discontinue provision of services to patients in Iowa and that has returned to the board the nonresident pharmacy's Iowa pharmacy license certificate shall be administratively canceled within 30 days of the board's receipt of the notice and license certificate. A nonresident pharmacy licensee that is under investigation or pending administrative charges shall not be permitted to cancel the nonresident pharmacy license in lieu of discipline.

[Filed 11/19/14, effective 1/14/15]

[Published 12/10/14]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/10/14.

ADDENDUM F

ADOPTED AND FILED

**CHAPTER 33,
“MILITARY SERVICE
AND
VETERAN RECIPROCITY”**

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby adopts new Chapter 33, "Military Service and Veteran Reciprocity," Iowa Administrative Code.

The new chapter fulfills the directive of the 85th General Assembly in 2014 Iowa Acts, chapter 1116, division VI, by enacting rules that provide for priority application status for veterans and the opportunity to receive credit, as appropriate, towards licensing and registration qualifications for education, training, and service obtained by those who have served honorably in the military.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1641C**. The Board received no written comments regarding these rules. The adopted rules are identical to those published under Notice.

These rules were approved during the November 19, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, there may be a minimal impact on jobs as a result of adoption of these rules. The provisions of these rules include prioritizing an application for license or registration submitted by a veteran or other military service applicant which may result in an applicant's earlier entry into the Iowa workforce.

These rules are intended to implement 2014 Iowa Acts, chapter 1116, section 34.

These rules will become effective on January 14, 2015.

The following amendment is adopted.

Adopt the following new 657—Chapter 33:

CHAPTER 33
MILITARY SERVICE AND VETERAN RECIPROCITY

657—33.1(85GA, ch1116) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Military service" means honorably serving on federal active duty, state active duty, or national guard duty, as defined in Iowa Code section 29A.1; in the military services of other states, as provided in 10 U.S.C. Section 101(c); or in the organized reserves of the United States, as provided in 10 U.S.C. Section 10101.

"Military service applicant" means an individual requesting credit toward licensure or registration requirements for education, training, or service obtained or completed in military service.

"Veteran" means an individual who meets the definition of "veteran" in Iowa Code section 35.1(2).

657—33.2(85GA, ch1116) Military education, training, and service credit. A military service applicant may apply for credit for verified military education, training, or service toward any experiential or educational requirement for pharmacist licensure, pharmacist-intern registration, or technician registration by submitting a military service credit application form to the board office. The board shall make available an application for military service credit.

33.2(1) Military service credit application. A military service credit application may be submitted with an application for licensure, examination, or registration or may be submitted prior to the submission of an application for licensure, examination, or registration. No fee is required with submission of a military service credit application.

33.2(2) Credit identified. The applicant shall identify the experiential or educational licensure or registration requirement to which the credit would be applied if granted. Credit shall not be applied to

an examination requirement.

33.2(3) *Submission of verification documentation.* The applicant shall provide documents, military transcripts, a certified affidavit, or forms that verify completion of the relevant military education, training, or service, which may include, when applicable, the applicant's Certificate of Release or Discharge from Active Duty (DD Form 214) or Verification of Military Experience and Training (VMET) (DD Form 2586).

33.2(4) *Credit determination.* Upon receipt of a completed military service credit application, the board shall promptly determine whether the verified military education, training, or service will satisfy all or any part of the identified experiential or educational qualifications for licensure or registration.

33.2(5) *Granting of credit.* The board shall grant credit requested in the application in whole or in part if the board determines that the verified military education, training, or service satisfies all or part of the experiential or educational qualifications for licensure or registration.

33.2(6) *Notification of credit determination.* The board shall inform the military service applicant in writing of the credit, if any, given toward an experiential or educational qualification for licensure or registration or explain why no credit was granted. The applicant may request reconsideration of the board's determination upon submission of additional documentation or information.

33.2(7) *Consideration of applications.* The board shall grant or deny the military service credit application prior to ruling on the application for licensure, examination, or registration. The applicant shall not be required to submit any fees in connection with the license or registration application until the board issues a determination on the military service credit application. If the board does not grant the military service credit application, the applicant may withdraw any license or registration application and application fee, if submitted, or the applicant may request that the application be placed in pending status. The withdrawal of a license or registration application and fee shall not preclude subsequent applications supported by additional documentation or information.

657—33.3(85GA, ch1116) *Veteran licensure or registration.* A veteran with an unrestricted pharmacist license in another jurisdiction may apply for pharmacist licensure in Iowa by license transfer/reciprocity pursuant to rule 657—2.9(147,155A) and this chapter. A veteran must pass any required examinations to be eligible for pharmacist licensure by license transfer/reciprocity. A veteran may submit an application for pharmacist-intern registration pursuant to 657—Chapter 4 and this chapter. A veteran may submit an application for technician registration pursuant to 657—Chapter 3 and this chapter. A veteran may submit an application for pharmacy support person registration pursuant to 657—Chapter 5 and this chapter.

33.3(1) *Priority application status.* A fully completed application for licensure or registration submitted by a veteran under this chapter shall be given priority status and shall be expedited.

33.3(2) *Application requirements.* Such an application shall contain all of the information required of all applicants for licensure or registration who hold unrestricted licenses or registrations in other jurisdictions and who are applying for licensure or registration, including, but not limited to, completion of all required forms, payment of applicable fees, disclosure of criminal or disciplinary history, and, if applicable, a criminal history background check. In addition, the applicant shall provide such documentation as is reasonably needed to verify the applicant's status as a veteran under Iowa Code section 35.1(2).

33.3(3) *Equivalency determination.* Upon receipt of a fully completed application for licensure or registration, the board shall promptly determine if the requirements for licensure or registration of the jurisdiction where the veteran is licensed or registered are substantially equivalent to the requirements for licensure or registration in Iowa. The board may consider the following factors in determining substantial equivalence: scope of practice, education and coursework, degree requirements, and post-graduate experiences.

33.3(4) *Licensure or registration approval.* The board shall promptly grant a license or registration, as appropriate, to the veteran if the veteran is licensed or registered in another jurisdiction whose licensure or registration requirements are substantially equivalent to those required in Iowa, unless the applicant is ineligible for licensure or registration based on other grounds, for example, the

applicant's disciplinary or criminal background.

33.3(5) Notification of additional requirements and provisional licensure or registration. If the board determines that the veteran is licensed or registered in another jurisdiction whose licensure or registration requirements are not substantially equivalent to those required in Iowa, the board shall promptly inform the veteran of the additional experience, education, or examinations required for licensure or registration in Iowa. Unless the applicant is ineligible for licensure or registration based on other grounds, such as disciplinary or criminal background, the following shall apply:

a. If a veteran has not passed the required examination(s) for licensure or registration, the applicant may request that the application be placed in pending status.

b. If additional experience or education is required in order for the applicant's qualifications to be considered substantially equivalent, the applicant may request that the board issue a provisional license or registration for a specified period of time upon such conditions as the board deems reasonably necessary to protect the health, welfare, and safety of the public unless the board determines that the deficiency is of a character that the public health, welfare, or safety will be adversely affected if a provisional license or registration is granted.

c. If a request for a provisional license or registration is denied, the board shall issue an order fully explaining the decision and shall inform the applicant of the steps the applicant may take in order to receive a provisional license or registration.

d. If a provisional license or registration is issued, the application for full licensure or registration shall be placed in pending status until the necessary experience or education has been successfully completed or the provisional license or registration expires, whichever occurs first. The board may extend a provisional license or registration on a case-by-case basis for good cause.

657—33.4(85GA, ch1116) Request for contested case. A military service applicant or a veteran who is aggrieved by the board's decision to deny all or part of the military service credit application, a request for a license transfer/reciprocal license, a request for a registration, or a request for provisional license or registration, or is aggrieved by the terms under which a provisional license or registration will be granted, may request a contested case (administrative hearing) and may participate in a contested case by telephone. A request for a contested case shall be made within 30 days of issuance of the board's decision pursuant to 657—subrule 35.26(1). There shall be no fees or costs assessed against the veteran in connection with a contested case conducted pursuant to this chapter.

These rules are intended to implement 2014 Iowa Acts, chapter 1116, section 34.

[Filed 11/19/14, effective 1/14/15]

[Published 12/10/14]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/10/14.

ADDENDUM G

NOTICE OF INTENDED ACTION

**CHAPTER 8,
“UNIVERSAL PRACTICE STANDARDS”**

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendment was approved at the November 19, 2014, regular meeting of the Board of Pharmacy.

The proposed amendment requires the owner or the owner’s authorized representative and the temporary pharmacist in charge to provide written notification to the Board in the event that a pharmacist in charge has been identified to fill a temporary need. The amendment also removes the requirement for a signature of the owner or corporate officer on the notification.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on January 15, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code sections 155A.13, 155A.13A, 155A.13B, 155A.15, and 155A.19.

The following amendment is proposed.

Amend subrule 8.35(6) as follows:

8.35(6) Pharmacy license changes. When a pharmacy changes its name, location, ownership, or pharmacist in charge, a new pharmacy license application with a license fee as provided in subrule 8.35(4) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new pharmacy license certificate. The old license certificate shall be returned to the board office within ten days of the change of name, location, ownership, or pharmacist in charge.

a. and b. No change.

c. *Pharmacist in charge.* A change of pharmacist in charge shall require completion and submission of the application and fee for a new pharmacy license.

(1) If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge, ~~signed by the pharmacy owner or corporate officer and the temporary pharmacist in charge,~~ shall be submitted to the board by the pharmacy owner or the pharmacy owner’s authorized representative and by the temporary pharmacist in charge within 10 days following the vacancy.

(2) Within 90 days following the vacancy, a permanent pharmacist in charge shall be identified, and an application for pharmacy license, including the license fee as provided in subrule 8.35(4), shall be submitted to the board office.

ADDENDUM H

NOTICE OF INTENDED ACTION

**CHAPTER 3, "PHARMACY TECHNICIANS,"
CHAPTER 6, "GENERAL PHARMACY PRACTICE,"
AND CHAPTER 7, "HOSPITAL PHARMACY PRACTICE";
TO RESCIND CHAPTER 13, "STERILE COMPOUNDING
PRACTICES"; AND TO RESCIND CHAPTER 20,
"PHARMACY COMPOUNDING PRACTICES," AND
ADOPT A NEW CHAPTER 20, "COMPOUNDING
PRACTICES"**

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 3, “Pharmacy Technicians,” Chapter 6, “General Pharmacy Practice,” and Chapter 7, “Hospital Pharmacy Practice”; to rescind Chapter 13, “Sterile Compounding Practices”; and to rescind Chapter 20, “Pharmacy Compounding Practices,” and adopt a new Chapter 20, “Compounding Practices,” Iowa Administrative Code.

The amendments were approved at the November 19, 2014, regular meeting of the Board of Pharmacy.

The proposed amendments are intended to combine the requirements currently in Chapters 13 and 20 for the compounding of drug products into a single chapter, Chapter 20, that fully adopts national minimum practice standards for compounding found in General Chapters 795 and 797 of the United States Pharmacopeia. The proposed amendments also incorporate new federal regulations as established in the Drug Quality and Security Act of 2013, also known as the Compounding Quality Act, with respect to compounding and outsourcing facilities. Current Chapter 13 will be rescinded and reserved.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 15, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

A public hearing will be held on January 15, 2015, at 1 p.m. in the shared conference room at the Board of Pharmacy office, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, for the purpose of receiving oral and written comments. Interested persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

After analysis and review of this rule making, the Board has been unable to determine any impact on jobs.

These amendments are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

The following amendments are proposed.

ITEM 1. Amend rule 657—3.22(155A) as follows:

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, the following technical functions, in addition to any of the functions authorized for a pharmacy support person pursuant to 657—Chapter 5, may be delegated to a pharmacy technician as specified in the following subrules.

3.22(1) Certified pharmacy technician. Under the supervision of a pharmacist, a certified pharmacy technician may perform technical functions delegated by the supervising pharmacist including, but not limited to, the following:

- a. to h. No change.
- i. Perform drug compounding processes for ~~nonsterile compounding~~ as provided in 657—Chapter 20.
- ~~j. Perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

~~k. l.~~ As provided in rule 657—3.24(155A), accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent.

3.22(2) Pharmacy technician trainee. Under the supervision of a pharmacist, a pharmacy technician trainee may perform only the following technical functions delegated by the supervising pharmacist:

- a. to g. No change.
- h. Under the supervision of a pharmacist who provides training and evaluates and monitors trainee competence in the compounding processes, perform drug compounding processes for ~~nonsterile compounding~~ as provided in 657—Chapter 20.
- ~~i. Under the supervision of a pharmacist who provides training and evaluates and monitors trainees, and contingent on successful completion of appropriate media fill testing processes, perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

ITEM 2. Amend subrule 6.10(2) as follows:

6.10(2) Exceptions. The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A); ~~sterile products, 657—Chapter 13;~~ and patient med paks, 657—22.5(126,155A).

ITEM 3. Amend paragraph 7.8(1)“b” as follows:

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter ~~13~~ 20.

ITEM 4. Rescind and reserve ~~657—Chapter 13~~.

ITEM 5. Rescind 657—Chapter 20 and adopt the following new chapter in lieu thereof:

CHAPTER 20
COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals.

657—20.2(124,126,155A) Definitions. For purposes of this chapter, the following definitions apply:

“*Anticipatory compounding*” means the compounding of preparations in advance of receiving a patient-specific prescription.

“*Batch preparation compounding*” means anticipatory compounding, compounding preparations intended for multiple disbursements or compounding preparations in a multiple-dose container for administration to more than one patient.

“*Beyond-use date*” means the date after which a compounded preparation should not be used, determined from the date that the preparation is compounded.

“*Bulk drug substance*” means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a

finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

"Compounding" means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions.

"FDA" means the Food and Drug Administration of the U.S. Department of Health and Human Services.

"Outsourcing facility" means a facility that is located at a single geographic location and has registered with the FDA in accordance with Section 503B of the Federal Food, Drug, and Cosmetic Act as an outsourcing facility.

"USP" means United States Pharmacopeia.

657—20.3(124,126,155A) Nonsterile compounding. Iowa-licensed pharmacies that compound nonsterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 795 standards. Additional USP chapters incorporated by reference into USP Chapter 795 shall also be followed.

657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.

657—20.5(126,155A) Delayed compliance. A pharmacy that is unable to meet full compliance with these rules and with USP Chapter 795 or USP Chapter 797 by [six months following the effective date of these rules] shall, prior to that date, request and obtain from the board a waiver of the specific requirement or requirements that the pharmacy is unable to meet. A pharmacy that cannot meet full compliance with these rules, including applicable USP chapters, and that has not obtained from the board a waiver of the specific requirement or requirements shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved a waiver of the specific requirement or requirements.

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for hospitals, practitioners, or patients in the state of Iowa.

657—20.7 and 20.8 Reserved.

657—20.9(124,155A) Prescriber/patient/pharmacist relationship. All compounded preparations shall be dispensed pursuant to a patient-specific prescription unless the compounded preparation is distributed pursuant to rule 657— 20.15(124,126,155A) or 657—20.16(124,126,155A). A prescription for a compounded preparation shall be authorized by the prescriber for a specific patient. Prescriptions for all compounded preparations shall be maintained on file at the dispensing pharmacy.

657—20.10(126,155A) Anticipatory compounding.

20.10(1) Outsourcing facilities. Outsourcing facilities are authorized to engage in anticipatory compounding. Outsourcing facilities are not required to obtain patient-specific prescriptions in order to distribute compounded preparations.

20.10(2) Pharmacies. Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely

within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.

657—20.11(126,155A) Prohibition on resale of compounded preparations. The sale of compounded preparations to other pharmacies, prescribers, or facilities, except as explicitly authorized by this chapter, is considered manufacturing.

657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on the FDA Web site <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

657—20.13 and 20.14 Reserved.

657—20.15(124,126,155A) Compounding for office use.

20.15(1) Human compounded preparations. Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) Veterinary compounded preparations. Veterinary compounded preparations may be sold to a practitioner for office use if compounded by an Iowa-licensed pharmacy and sold directly to the practitioner by the compounding pharmacy.

20.15(3) Office administration. Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to an individual patient in the practitioner's office. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or to patients for administration outside of the office.

20.15(4) Labeling. Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) By an FDA-registered outsourcing facility. Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) By a pharmacy that is not an FDA-registered outsourcing facility. Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

657—20.17 and 20.18 Reserved.

657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to

the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) General pharmacy or outpatient dispensing. The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

- a. The name and concentration of each active ingredient.
- b. The date that the preparation was compounded.
- c. The beyond-use date of the compounded preparation.
- d. Special storage and handling instructions, if applicable.
- e. FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor Web site or telephone number) to facilitate adverse event reporting.
- f. The statement “COMPOUNDED PREPARATION” or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.
- g. If the compounded preparation is sterile, the word “STERILE.”
- h. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) Hospital pharmacy or inpatient administration. The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

- a. The name and concentration of each active ingredient.
- b. The date that the preparation was compounded.
- c. The beyond-use date of the compounded preparation.
- d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.
- e. Special storage and handling instructions, if applicable.

20.19(3) Outsourcing facility distribution or dispensing. The label, or auxiliary labeling if necessary, shall include the following information:

- a. The statement “THIS IS A COMPOUNDED DRUG” or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.
- b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.
- c. The established name of the preparation.
- d. The dosage form and strength.
- e. The quantity of the preparation.
- f. The date that the preparation was compounded.
- g. The beyond-use date of the compounded preparation.
- h. Storage and handling instructions.
- i. The lot or batch identification or control number.
- j. The national drug code number, if available.
- k. The statement “Not for resale” and, if the preparation is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement “OFFICE USE ONLY.”
- l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information

- (1) Directions for use including, as appropriate, dosage and administration;
- (2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;
- (3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor Web site or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label

requirements in subrule 20.15(4).

657—20.20(126,155A) Labeling for batch preparation compounding. Compounded preparations resulting from batch preparation compounding shall be labeled with the following information until such time as they are labeled pursuant to rule 657—20.19(124,126,155A) for distribution to hospitals or practitioners or for dispensing or administration to patients:

1. The date that the preparation was compounded.
2. Compounded preparation name or formula.
3. Dosage form.
4. Strength.
5. Quantity per container.
6. Unique internal batch identification or control number.
7. Beyond-use date.
8. Special storage and handling instructions, if applicable.

657—20.21 and 20.22 Reserved.

657—20.23(124,126,155A) Records. All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record. Records shall allow for the identification of all ingredients used in compounding, all personnel involved in compounding, and all personnel involved in reviewing compounded preparations. The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

ADDENDUM I

NOTICE OF INTENDED ACTION

CHAPTER 36, "DISCIPLINE"

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 36, “Discipline,” Iowa Administrative Code.

This amendment was approved at the November 19, 2014, regular meeting of the Board of Pharmacy.

The proposed amendment provides clearer and more direct references to certain common violations by licensees or registrants for use by the Board when initiating and hearing disciplinary action. With respect to the addition of the submission of a false certification of continuing education as a ground for discipline, pharmacist licensees are now required to utilize the CPE Monitor for documenting the completion of continuing education requirements for licensure, and upon license renewal, pharmacists may now submit a certification of completion in lieu of reporting each educational program completed.

This rule does not provide for waiver or variance. The Board simply, by means of deciding not to initiate disciplinary action against a licensee or registrant based on any of the listed grounds for disciplinary action, implies a waiver or variance of the specific ground for disciplinary action.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on January 15, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

A public hearing will be held on January 15, 2015, at 11 a.m. in the shared conference room at the Board of Pharmacy office, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, for the purpose of receiving oral and written comments. Interested persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendment.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code sections 147.55, 272C.3, 272C.5, 155A.15, 155A.23, 126.3, 124.304, and 124.401 to 124.407.

The following amendment is proposed.

Amend subrule 36.1(4) as follows:

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

a. to n. No change.

o. Submission of a false report of continuing education, submission of a false certification of completion of continuing education, or failure to submit biennial reports of continuing education as directed by the board.

p. to t. No change.

u. Violating any of the grounds for revocation or suspension of a license or registration listed in Iowa Code sections section 147.55, 155A.12, and 155A.15 Iowa Code chapter 155A, or any of the

rules of the board.

v. to *ah*. No change.

ai. Failure to notify the board of a criminal conviction within 30 days of the action, regardless of the jurisdiction where it occurred.

aj. Obtaining, possessing, or attempting to obtain or possess prescription drugs without lawful authority.

ak. Diverting prescription drugs from a pharmacy for personal use or for distribution.

al. Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of alcohol or illicit substances.

am. Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of prescription drugs or substances for which the licensee or registrant does not have a lawful prescription or while impaired by the use of legitimately prescribed pharmacological agents, drugs, or substances.

an. Forging or altering a prescription.

ao. Practicing outside the scope of the profession.

ap. Dispensing, or contributing to the dispensing of, an incorrect prescription, which includes, but is not limited to, the incorrect drug, the incorrect strength, the incorrect patient or prescriber, or the incorrect or incomplete directions.

aq. Failing to comply with a confidential order for evaluation.

ADDENDUM J

NOTICE OF INTENDED ACTION

**CHAPTER 6, "GENERAL PHARMACY PRACTICE,"
CHAPTER 7, "HOSPITAL PHARMACY PRACTICE,"
CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"
CHAPTER 9, "AUTOMATED MEDICATION
DISTRIBUTION SYSTEMS AND TELEPHARMACY
SERVICES," CHAPTER 15, "CORRECTIONAL
PHARMACY PRACTICE," CHAPTER 18, "CENTRALIZED
PRESCRIPTION FILING AND PROCESSING,"
CHAPTER 19, "NONRESIDENT PHARMACY PRACTICE,"
CHAPTER 22, "UNIT DOSE, ALTERNATIVE
PACKAGING, AND EMERGENCY BOXES," AND
CHAPTER 23, "LONG-TERM CARE PHARMACY
PRACTICE"**

NOVEMBER 19, 2014

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 9, "Automated Medication Distribution Systems and Telepharmacy Services," Chapter 15, "Correctional Pharmacy Practice," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 19, "Nonresident Pharmacy Practice," Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the November 19, 2014, regular meeting of the Board of Pharmacy.

The proposed amendments update and clarify the persons responsible for various activities required by Board rules including responsibilities shared by a pharmacy, by and through its owner or license holder, the pharmacist in charge (PIC), and staff pharmacists. The purpose for the proposed amendments is to assign responsibility for pharmacy activities and functions to the party or parties that have the ability to control those activities and functions. The proposed amendments are a result of recommendations made by the 2014 PIC Task Force. The PIC Task Force was established at the recommendation of the 2013 Patient Safety Task Force. In developing its recommendations to the Board, the PIC Task Force reviewed current Board rules and the rules and regulations of other state licensing authorities, in addition to discussing responsibility issues and current pharmacy management and practice issues and standards.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 15, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

A public hearing will be held on January 15, 2015, at 9 a.m. in the shared conference room at the Board of Pharmacy Office, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, for the purpose of receiving oral and written comments. Interested persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.301, 126.11, 147.107, 155A.13, 155A.13A, 155A.15, 155A.19, and 155A.33.

The following amendments are proposed.

ITEM 1. Amend rule 657—6.2(155A) as follows:

657—6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, ~~the following:~~ the responsibilities identified in rule 657—8.3(155A).

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).
5. Ensuring that a pharmacist provides patient counseling as specified in rule 657—6.14(155A).
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).
9. Training pharmacy technicians and pharmacy support persons.
10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
11. Distributing and disposing of drugs from the pharmacy.
12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.
14. Establishing, implementing, and periodically reviewing and revising written policies and procedures to reflect changes in processes, organization, and other functions for all operations of the pharmacy and ensuring that all pharmacy personnel are familiar with those policies and procedures.
15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.

ITEM 2. Amend rule 657—7.2(155A) as follows:

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule responsibilities identified in rule 657—8.3(155A). A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

- ~~7. Delivering drugs to the patient or the patient's agent.~~
- ~~8. Ensuring that patient medication records are maintained as specified in rule 657—7.10(124,155A).~~
- ~~9. Training pharmacy technicians and pharmacy support persons.~~
- ~~10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and pharmacy support persons.~~
- ~~11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.~~
- ~~12. Distributing and disposing of drugs from the pharmacy.~~
- ~~13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.~~
- ~~14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.~~
- ~~15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.~~
- ~~16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.~~

ITEM 3. Amend rule 657—7.8(124,126,155A) as follows:

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge established pursuant to rule 657—8.3(155A) with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) Drug preparation. ~~The pharmacist shall institute the control~~ Control and adequate quality assurance procedures needed to ensure that patients receive the correct drugs at the proper times shall be established pursuant to rule 657—8.3(155A). ~~Adequate quality assurance procedures shall be developed.~~

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacist pharmacy for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) ~~The pharmacist in charge shall establish~~ Established policies and procedures that shall identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter ~~13~~ 20.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) Drug formulary. ~~The pharmacist in charge shall maintain~~ Established policies and procedures shall include a current formulary of drug products approved for use in the institution and shall be responsible for include specifications for those drug products and ~~for selecting their source of supply.~~

7.8(3) to 7.8(6) No change.

7.8(7) Drugs brought into the institution. ~~The pharmacist in charge~~ Established policies and

procedures shall determine those circumstances when patient-owned drugs brought into the institution may be administered to a hospital patient and shall ~~establish policies and~~ identify procedures governing the use and security of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(8) and 7.8(9) No change.

7.8(10) *Hazardous drugs and chemicals.* ~~The pharmacist, in cooperation with other hospital staff, shall establish policies~~ Policies and procedures for handling drugs and chemicals that are known occupational hazards shall be established pursuant to rule 657—8.3(155A). The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the ~~pharmacy~~ pharmacist shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) No change.

ITEM 4. Amend rule 657—7.9(124,155A) as follows:

~~657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with~~ Established policies and procedures shall include the provision to the institution's staff and patients of accurate, comprehensive information about drugs and their use ~~and shall serve as its center for drug information. The pharmacy shall serve as the institution's center for drug information.~~

7.9(1) and 7.9(2) No change.

ITEM 5. Amend rule 657—7.10(124,155A) as follows:

~~657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies~~ Policies and procedures for ensuring the quality of drug therapy shall be established pursuant to rule 657—8.3(155A).

7.10(1) No change.

7.10(2) *Adverse drug events.* ~~The pharmacist, in cooperation with the appropriate patient care committee, shall develop~~ Established policies and procedures shall include a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

ITEM 6. Amend rule 657—7.11(124,126,155A) as follows:

~~657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed to patients in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription drug order shall be provided to the patient to be filled at a pharmacy of the patient's choice.~~

7.11(1) No change.

7.11(2) *Administration in the outpatient setting.* Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug

therapy ordered.

a. Accountability. ~~A Established policies and procedures shall include a system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's outpatient services committee, or a similar group or person responsible for policy in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.~~

b. and c. No change.

ITEM 7. Amend rule 657—7.12(124,126,155A) as follows:

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means an individual who is examined and evaluated in the emergency department.

7.12(1) Accountability. ~~A Established policies and procedures shall include a system of drug control and accountability shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in the emergency department. The system shall identify drugs of the nature and type to meet the immediate needs of emergency department patients. Drugs shall be administered or dispensed only in accordance with the system.~~

7.12(2) No change.

7.12(3) Drug dispensing. In those facilities with 24-hour pharmacy services, only a pharmacist or prescriber may dispense any drugs to an emergency department patient. In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, the provisions of this rule shall apply.

a. Pharmacist-in-charge responsibility Responsibility. ~~The pharmacist in charge is responsible for maintaining Pursuant to rule 657—8.3(155A), the accuracy and labeling of prepackaged drugs shall be ensured and accurate records of dispensing of drugs from the emergency department and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to this paragraph shall be maintained.~~

(1) and (2) No change.

b. No change.

7.12(4) No change.

ITEM 8. Amend rule 657—8.3(155A) as follows:

657—8.3(155A) Responsibility Responsible parties.

~~**8.3(1) Pharmacy operations.** The pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.~~

8.3(1) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

8.3(2) Pharmacy. Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally competent, legally qualified

pharmacist in charge.

8.3(3) Pharmacy and pharmacist in charge. The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.

8.3(4) Pharmacist in charge and staff pharmacists. The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:

a. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).

b. Ensuring that a pharmacist provides patient counseling as specified in rule 657—6.14(155A).

c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

d. Delivering drugs to the patient or the patient's agent.

e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).

f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.

g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

h. Distributing and disposing of drugs from the pharmacy.

i. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

j. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

8.3(5) Pharmacy, pharmacist in charge, and staff pharmacists. The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:

a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying with (by the pharmacist in charge and staff pharmacists) policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.

b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.

c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

8.3(2) 8.3(6) Practice functions. The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and pharmacy support persons.

8.3(3) 8.3(7) Pharmacist-documented verification. The pharmacist shall provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

ITEM 9. Amend rule 657—8.5(155A) as follows:

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) to 8.5(6) No change.

8.5(7) Other equipment. The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall ensure share the responsibility for ensuring the availability of any other equipment necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) Bulk counting machines. Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. ~~The pharmacy~~ Established policies and procedures shall ~~have~~ include a method to calibrate and verify the accuracy of the counting device, and The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

ITEM 10. Amend rule 657—8.14(155A) as follows:

657—8.14(155A) Training and utilization of pharmacy technicians or pharmacy support persons. ~~All Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review~~ have written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. ~~Pharmacy policies shall specify the frequency of review.~~ Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

ITEM 11. Amend subrule 8.15(2) as follows:

8.15(2) Policies and procedures required. ~~Every Pursuant to rule 657—8.3(155A), every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall develop and implement~~ have policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(4).

ITEM 12. Amend rule 657—8.26(155A) as follows:

657—8.26(155A) Continuous quality improvement program. ~~Each Pursuant to rule 657—8.3(155A), each~~ pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program ~~or~~ (CQI program). The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) No change.

8.26(2) Responsibility. ~~The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule.~~ The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) Policies and procedures. ~~Each Pursuant to rule 657—8.3(155A), each~~ pharmacy shall develop, implement, and adhere to have written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and

policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

- a. to f. No change.
- 8.26(4) to 8.26(6)** No change.

ITEM 13. Amend rule 657—9.3(147,155A) as follows:

657—9.3(147,155A) Pharmacist in charge responsibilities Responsibilities.

9.3(1) AMDS. ~~The pharmacist in charge of~~ In any pharmacy utilizing an AMDS, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities described in rule 657—8.3(155A), shall be responsible for the following in addition to other responsibilities assigned under federal and state laws and regulations as follows:

a. ~~Implementing~~ The pharmacy and the pharmacist in charge shall share responsibility for establishing, the pharmacist in charge shall be responsible for implementing, and the pharmacist in charge and staff pharmacists shall share responsibility for utilizing an ongoing quality assurance program the purpose of which purpose is to monitor and improve performance of each AMDS as provided in rule 657—9.10(147,155A).

~~b. Establishing and ensuring compliance with all policies and procedures relating to the AMDS.~~

~~e. b.~~ Assigning The pharmacist in charge shall be responsible for assigning, discontinuing, or changing drug and information access to the AMDS.

~~d. c.~~ The pharmacist in charge and staff pharmacists shall share responsibility for:

(1) Ensuring that drug access, including access to controlled substances, is in compliance with state and federal laws, rules and regulations.

(2) Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.

(3) Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.

(4) Ensuring that confidentiality of patient-specific information is maintained.

(5) Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.

~~e. Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.~~

~~f. Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.~~

~~g. d.~~ Ensuring The pharmacy, by and through its owner or license holder, pharmacist in charge, and staff pharmacists shall share responsibility for ensuring that the AMDS has adequate security safeguards regarding drug access and information access.

~~h. Ensuring that confidentiality of patient-specific information is maintained.~~

~~i. Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.~~

~~j. e.~~ Ensuring that the board is provided The pharmacy shall provide the board with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:

- (1) to (6) No change.

9.3(2) No change.

ITEM 14. Amend rule 657—9.10(147,155A) as follows:

657—9.10(147,155A) Quality assurance and performance improvement. The goal of any AMDS is the accurate dispensing of drugs. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy. Quality assurance data shall be utilized to monitor and improve systems.

9.10(1) AMDS. Pharmacies utilizing an AMDS shall develop have a written quality assurance and

monitoring plan pursuant to rule 657—9.3(147,155A) prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to, the following:

a. to d. No change.

9.10(2) to 9.10(4) No change.

ITEM 15. Amend rule 657—9.11(147,155A) as follows:

657—9.11(147,155A) Policies and procedures. Notwithstanding rule 657—8.3(155A), policies and procedures for an AMDS shall be required pursuant to this chapter. All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS or, if a telepharmacy practice, shall be maintained at both the managing pharmacy and the remote site. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years following the date of the change. The policy and procedure manual and retained changes shall be available for inspection and copying by the board or an agent of the board.

9.11(1) AMDS. ~~All pharmacies utilizing AMDS shall develop, implement, and adhere to policies and procedures that address Pursuant to rule 657—8.3(155A) and this chapter, a pharmacy shall have policies and procedures for an AMDS that provide, at a minimum, the following:~~

a. to k. No change.

9.11(2) No change.

ITEM 16. Amend rule 657—15.3(155A) as follows:

657—15.3(155A) Pharmacist in charge Responsibilities. ~~One professionally competent, legally qualified pharmacist who is licensed to practice pharmacy in Iowa shall be the pharmacist in charge of the In any correctional pharmacy and, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities as described in rule 657—8.3(155A), shall be responsible for, at a minimum, the following assigned as follows:~~

~~1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;~~

~~2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy;~~

~~3. 1. Ensuring The pharmacist in charge or designee shall ensure that a quarterly inspection of all pharmaceuticals located at the correctional facility, including any emergency/first dose drug supply located outside the confines of the pharmacy, is completed and documented;~~

~~4. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;~~

~~5. Preparing written policies and procedures governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; ensuring that policies and procedures are consistent with board rules; and ensuring that all pharmacy personnel are familiar with the policies and procedures;~~

~~6. Ensuring that a pharmacist performs prospective drug use reviews as specified in rule 657—8.21(155A);~~

~~7. 2. Ensuring that The pharmacist in charge or a pharmacist provides shall provide drug information to other health professionals, to other caregivers, and to patients as required or requested;~~

~~8. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;~~

~~9. Delivering drugs to the patient or the patient's agent;~~

~~10. Ensuring that patient drug records are maintained as specified in rule~~

657—15.8(124,126,155A);

11. Training pharmacy technicians and pharmacy support persons;
12. Establishing policies and procedures for the procurement and storage of prescription drugs and devices and other products dispensed from the pharmacy;
13. Disposing of and distributing drugs from the pharmacy;
14. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;
15. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;
16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

ITEM 17. Amend subrule 15.5(2) as follows:

15.5(2) Access when pharmacist absent. ~~The pharmacist in charge, with the concurrence of the department, shall establish and implement~~ Pursuant to rule 657—8.3(155A), the pharmacy shall have policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy.

ITEM 18. Amend rule 657—15.7(124,126,155A) as follows:

657—15.7(124,126,155A) Training and utilization of pharmacy technicians or pharmacy support persons. ~~All correctional pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of the review. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.~~

ITEM 19. Amend rule 657—15.10(124,126,155A) as follows:

657—15.10(124,126,155A) Policies and procedures. ~~The pharmacist in charge shall develop and implement written policies and procedures for the pharmacy drug distribution system consistent with board rules and department policies and procedures pertaining to pharmaceutical services. Pharmacy policies and procedures, established, implemented, and complied with pursuant to rule 657—8.3(155A), shall address, but not be limited to, the following:~~

1. to 22. No change.

ITEM 20. Amend rule 657—18.10(155A) as follows:

657—18.10(155A) Policy and procedures.

18.10(1) Manual maintained. ~~A~~ Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) No change.

ITEM 21. Amend rule 657—19.7(155A) as follows:

657—19.7(155A) Confidential data. ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure patient confidentiality and to protect patient identity and

patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of 657—8.16(124,155A).

ITEM 22. Amend rule 657—19.8(124,155A) as follows:

657—19.8(124,155A) Storage and shipment of drugs and devices. ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A) and USP standards for the storage and shipment of drugs and devices. Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method, and all records of such shipment and delivery to Iowa patients shall be maintained for a minimum of two years from date of delivery.

ITEM 23. Amend rule 657—19.9(155A) as follows:

657—19.9(155A) Patient record system, prospective drug use review, and patient counseling.

19.9(1) and 19.9(2) No change.

19.9(3) *Patient counseling.* ~~The pharmacist in charge shall be responsible for developing, implementing, and enforcing~~ Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).

ITEM 24. Amend subrule 22.7(6) as follows:

22.7(6) *Notifications.* Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. ~~Policy must be developed by the provider pharmacist to~~ Pursuant to rule 657—8.3(155A), established policies and procedures shall address notification, record keeping, and documentation procedures for use of the supply.

ITEM 25. Amend subrule 22.7(7) as follows:

22.7(7) *Procedures.*

a. ~~The consultant or provider pharmacist~~ The pharmacy shall, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, develop and implement and as provided in rule 657—8.3(155A), have written policies and procedures to ensure compliance with this rule.

b. to d. No change.

ITEM 26. Amend subrule 22.9(6) as follows:

22.9(6) *Policies and procedures.* ~~The pharmacist in charge of the provider pharmacy and The pharmacy,~~ pursuant to rule 657—8.3(155A) and in coordination with the home health agency or hospice, shall ~~develop~~ have policies and procedures to address storage conditions and security for drugs and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.

ITEM 27. Amend subrule 22.9(7) as follows:

22.9(7) *Responsibility for compliance.* ~~The provider pharmacy is responsible to ensure The pharmacist in charge and staff pharmacists shall share responsibility for~~ compliance with this rule, and any abuse or misuse of the intent of this rule shall be immediately reported to the board.

ITEM 28. Amend rule 657—23.4(124,155A) as follows:

657—23.4(124,155A) Pharmacy responsibilities Responsibilities. ~~The long-term care pharmacy pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to long-term care facility patients shall be responsible~~ share responsibility for:

1. to 4. No change.

5. Developing Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents including immediate discontinuation

of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility.

6. Providing a 24-hour emergency service procedure either directly or by contract with another pharmacy.

7. to 9. No change.

ITEM 29. Amend rule 657—23.6(124,155A) as follows:

657—23.6(124,155A) Space, equipment, and supplies. ~~Each~~ Pursuant to rule 657—8.3(155A), each pharmacy serving a long-term care facility shall have adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy and to meet the needs of the residents served. The pharmacy shall also comply with all reference, environment, and equipment requirements contained in rules 657—6.3(155A) and 657—8.5(155A).

ITEM 30. Amend rule 657—23.7(124,155A) as follows:

657—23.7(124,155A) Policies and procedures. ~~Policies and procedures shall be formulated to cover the provider~~ Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of the long-term care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. to 4. No change.

ITEM 31. Amend rule 657—23.10(124,155A) as follows:

657—23.10(124,155A) Stop orders. ~~The consultant pharmacist, in consultation with the provider pharmacist, the medical director, and the appropriate committee or representative of the facility, shall develop and implement an automatic stop order policy. To ensure that drug orders are not continued inappropriately, drugs~~ the pharmacy's policies and procedures, established pursuant to rule 657—8.3(155A) and in consultation with the medical director and the appropriate committee or representative of the facility, shall include an automatic stop order policy. ~~Drugs~~ not specifically limited when ordered as to duration of therapy or number of doses shall be controlled by the automatic stop order policy in accordance with the status of the patient.

ITEM 32. Amend subrule 23.13(4) as follows:

23.13(4) Leave meds. Labeling of prescription drugs for residents on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

ITEM 33. Amend subrule 23.13(5) as follows:

23.13(5) Discharge meds. Drugs authorized for a resident being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the resident removes those drugs from the facility premises. The dispensing ~~pharmacy~~ pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

ITEM 34. Amend rule 657—23.16(124,155A) as follows:

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. ~~The consultant pharmacist, in consultation with the provider pharmacist and a facility representative, shall develop and implement~~ The pharmacy shall, pursuant to rule 657—8.3(155A) and in consultation with a facility representative, have written policies and procedures to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Drugs shall be destroyed by means that will ensure protection against unauthorized possession or use.

ADDENDUM K

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**EXCELLERX
NONRESIDENT PHARMACY LICENSE NO. 3435
MEMPHIS, TENNESSEE**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
Nonresident Pharmacy License of)
EXCELLERX)
License Nos. 3435, 3631 and 3638)
)

Case Nos. 2012-184
**SETTLEMENT AGREEMENT
AND FINAL ORDER**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy and excelleRx, 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 Nonresident Pharmacy License No. 3435 for its Memphis, TN facility. That license is active and current until December 31, 2014.
2. Respondent was issued Nonresident Pharmacy License No. 3631 for its Sharon Hill, PA facility. That license is active and current until December 31, 2014.
3. Respondent was issued Nonresident Pharmacy License No. 3838 for its Philadelphia, PA facility. That license is active and current until December 31, 2014.
4. Respondent at all times relevant to the Statement of Charges operated a pharmacies at 2525 Horizon Lake Drive, Suite 101, Memphis, Tennessee 38133; 512 Elmwood Avenue, Sharon Hill, PA 19079, and 1601 Cherry Street, Suite 1700, Philadelphia, PA 19102
5. The Board has jurisdiction over the parties and the subject matter of these proceedings.

6. 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.

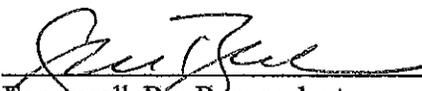
On the date of the Board's approval of this Settlement Agreement and Final Order, Respondent is hereby cited and warned that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline. Respondent shall submit a \$5000.00 civil penalty 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.

Respondent has submitted to the Board for its approval policies and procedures for the dispensing of controlled substances, including verification of the completeness of controlled drug prescriptions.

- a. Respondent shall comply with all applicable Iowa pharmacy law and rules and related federal requirements for controlled substances while operating its pharmacies.
- b. Additionally, at this time Respondent is in settlement discussions with several other states related to the same underlying matters contained in the Statement of Charges. Respondent will self-report to the Iowa Board of Pharmacy upon final approval of any other settlement agreements resulting in disciplinary action in connection with such underlying matters upon final resolution with the individual state Boards.

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 nonresident 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 27 day of October, 2014.



For excelleRx, Respondent

By this signature, Scott Beach acknowledges s/he is the Secretary for Respondent excelleRx and is authorized to sign this Settlement Agreement and Final Order on

behalf of Respondent.

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the 19th day of November 2014.



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

cc: Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319
Phone (515) 281-6736

Kate Woods, Esquire
Senior Director, Corporate Compliance
excellerx, Inc.
1601 Cherry Street
Suite 1700
Philadelphia, PA 19102

ADDENDUM L
SETTLEMENT AGREEMENT
AND
FINAL ORDER

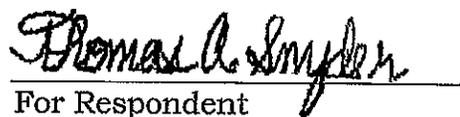
THOMAS SNYDER
PHARMACIST LICENSE NO. 13427
SHELDON, IOWA

13. The State's legal counsel may present this Settlement Agreement and Final Order to the Board *ex parte*

14. 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.

15. 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 17th day of November, 2014.


For Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 19th day of November, 2014.


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

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

Thomas J. Whorley
Security Professional Plaza
934 Third Avenue, Suite 200
P.O. Box 309
Sheldon, Iowa 51201
ATTORNEY FOR RESPONDENT

ADDENDUM M

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**PEGGY ASHBY
PHARMACY TECHNICIAN REGISTRATION NO. 15487
NORTH LIBERTY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-------------------------|---|---------------------------------|
| Re: |) | Case No. 2014-53 |
| Pharmacy Technician |) | |
| PEGGY ASHBY |) | SETTLEMENT AGREEMENT AND |
| Registration No.: 15487 |) | FINAL ORDER |
| Respondent. |) | |

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Peggy Ashby ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case 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 holds Iowa Pharmacy Technician Registration No. 15487, which is currently active and expires on October 31, 2015.
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 August 26, 2014. A contested case hearing in this matter is scheduled for November 18, 2014.
4. Respondent admits 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.
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 she 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.
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 agrees to **VOLUNTARILY SURRENDER** her pharmacy technician registration to resolve this matter.
15. This voluntary surrender is considered a revocation under 657 IAC 36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least one year from the date of this Order.
16. Respondent may request reinstatement of her Iowa pharmacy technician registration by filing an application for reinstatement under 657 IAC 36.13. Respondent's registration shall not be reinstated except upon a showing by Respondent that the basis for suspension of her registration no longer exists, and that it is in the public interest for the registration to be reinstated.
17. Respondent agrees not to work in a pharmacy in any capacity unless her registration is reinstated.
18. Respondent shall immediately surrender her pharmacy technician registration to the Board.
19. 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 (2013) and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 17th day of November, 2014.



PEGGY ASHBY
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the
19 day of November, 2014.



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

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM N

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**BELMAR PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 3975
LAKEWOOD, COLORADO**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---------------------------------|---|-----------------------------|
| Re: |) | CASE NO. 2014-85 |
| Nonresident Pharmacy License of |) | |
| |) | SETTLEMENT AGREEMENT |
| BELMAR PHARMACY |) | AND FINAL ORDER |
| License No. 3975, |) | |
| Respondent. |) | |

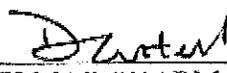
Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Belmar Pharmacy ("Respondent") enter into the following Settlement Agreement to settle a contested case currently pending before the Board.

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. The Board has jurisdiction over the parties and the subject matter of these proceedings.
2. A Statement of Charges was filed against Respondent on August 26, 2014. A contested case hearing on the matter is currently set for November 18, 2014.
3. Respondent admits the allegations, and acknowledges that, if proven in a contested case proceeding, the allegations would constitute grounds for the discipline described herein.
4. Upon the Board's approval of this Settlement Agreement and Final Order, Respondent is hereby **CITED** for out-of-state discipline and failing to report out-of-state discipline and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.
5. 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 mailed to the Executive Director of the Board 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.
6. Respondent agrees to report any discipline to the Board within thirty (30) days, as required by 657 IAC 36.1(4)"k".
7. This Settlement Agreement is the resolution of a contested case. By entering into this Settlement Agreement, 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.
8. Respondent is freely and voluntarily entering into this Settlement Agreement.
9. Respondent acknowledges that it has a right to be represented by counsel on this matter.
10. The State's legal counsel may present this Settlement Agreement to the Board *ex parte*.

11. This Settlement Agreement is subject to approval by a majority of the full Board. If the Board fails to approve this Settlement Agreement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement, it shall be the full and final resolution of this matter.
12. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse.
13. This Settlement Agreement, 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.
14. The Board's approval of this Settlement Agreement shall constitute a **FINAL ORDER** of the Board.

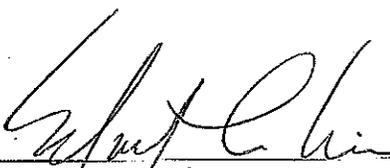
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 8 day of September, 2014.



 BELMAR PHARMACY
 Respondent

By this signature, Dave Hill acknowledges s/he is the Managing member for Belmar Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Belmar Pharmacy.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 19 day of November, 2014.



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

cc: Laura Steffensmeier
 Assistant Attorney General
 Hoover State Office Building
 Des Moines, Iowa

ADDENDUM O

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**KATIE MELDREM-FERNEAU
PHARMACY TECHNICIAN REGISTRATION NO. 20489
PELLA, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|------------------------------|---|---------------------------------|
| Re: |) | Case No. 2014-94 |
| Pharmacy Technician |) | |
| KATIE MELDREM-FERNEAU |) | SETTLEMENT AGREEMENT AND |
| Registration No.: 20489 |) | FINAL ORDER |
| Respondent. |) | |

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Katie Meldrem-Ferneau ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case 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 holds Iowa Pharmacy Technician Registration No. 20489, which is currently active and expires on January 31, 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 August 26, 2014. A contested case hearing in this matter is scheduled for November 18, 2014.
4. Respondent admits 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.
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 she 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.
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.

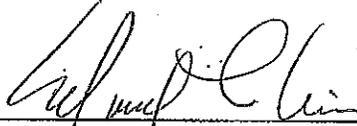
IT IS THEREFORE ORDERED:

14. Respondent agrees to **VOLUNTARILY SURRENDER** her pharmacy technician registration to resolve this matter.
15. This voluntary surrender is considered a revocation under 657 IAC 36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least one year from the date of this Order.
16. Respondent may request reinstatement of her Iowa pharmacy technician registration by filing an application for reinstatement under 657 IAC 36.13. Respondent's registration shall not be reinstated except upon a showing by Respondent that the basis for suspension of her registration no longer exists, and that it is in the public interest for the registration to be reinstated.
17. Respondent agrees not to work in a pharmacy in any capacity unless her registration is reinstated.
18. Respondent shall immediately surrender her pharmacy technician registration to the Board.
19. 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 (2013) and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 17 day of NOV, 2014.


KATIE MELDREM-FERNEAU
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the
19 day of November, 2014.



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

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM P

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**KATE KLINGBORG
PHARMACY SUPPORT PERSON
REGISTRATION NO. 2268
MUSCATINE, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2014-101
Pharmacist Support Person)
Registration of) **SETTLEMENT AGREEMENT**
) **AND FINAL ORDER**
KATE KLINGBORG,)
Registration No. 2268,)
Respondent.)

COME NOW the Iowa Board of Pharmacy ("Board") and Kate Klingborg ("Respondent"), and enter into this Settlement Agreement and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2013) to settle a licensee disciplinary proceeding currently pending before the Board.

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

1. Respondent holds Iowa pharmacist support person registration number 2268, which expired on August 31, 2014.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. A Statement of Charges was filed against the Respondent on August 26, 2014.
4. Respondent admits to 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.
5. Respondent agrees to **VOLUNTARILY SURRENDER** her pharmacist support person registration.
6. This voluntary surrender is considered a revocation of license under Iowa Administrative Code rule 657—36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least one year from the date of this Order.
7. Respondent may request reinstatement of her Iowa pharmacist support person registration by filing an application for reinstatement under Iowa Administrative Code rule 657—36.13. Respondent's registration shall not be reinstated except upon a showing by Respondent that the basis for revocation of her registration no longer exists, and that it is in the public interest for the registration to be reinstated.

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IOWA BOARD OF PHARMACY

8. Respondent agrees not to engage in any aspect of the practice of pharmacy until her registration has been reinstated.

9. Should Respondent violate the terms of this Settlement Agreement and Final Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and Iowa Administrative Code chapter 657—36.

10. Execution of this Settlement Agreement and Final 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 Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.

11. Respondent is freely and voluntarily entering into this Agreement. Respondent agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.

12. This Agreement shall be part of Respondent's permanent record 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.

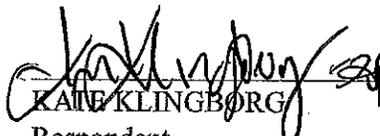
13. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

14. This Agreement, 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.

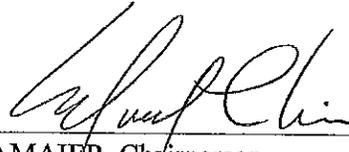
15. This Agreement shall not be binding as to any new complaints received by the Board.

16. The Board's approval of this Agreement 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 30 day of October, 2014.


KATE KLINGBORG
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the 19 day of November, 2014.



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

Copies to:

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

ADDENDUM Q

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**MATTHEW SHERROW
PHARMACIST LICENSE NO. 18612
SPRINGFIELD, ILLINOIS**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|------------------------|---|------------------------------|
| Re: |) | CASE NO. 2010-133 |
| Pharmacist License of |) | |
| |) | NOTICE OF HEARING AND |
| MATTHEW SHERROW |) | STATEMENT OF CHARGES |
| License No. 18612 |) | |
| Respondent. |) | |

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Matthew Sherrow (“Respondent”), 1754 W. Ash, Springfield, Illinois 62704, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa pharmacist license number 18612 is currently active and expires on June 30, 2015.

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 morning session, beginning at 9:00 a.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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General’s Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not

contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I VIOLATING A BOARD ORDER

Respondent is charged with violating a board order, pursuant to Iowa Code sections 147.55(9) and 155A.12(1), and 657 IAC 36.1(4)“i”.

D. FACTUAL CIRCUMSTANCES

1. On January 19, 2012, the Board approved a Stipulation and Consent Order to resolve disciplinary charges against Respondent. The Order imposed a \$500 civil penalty on Respondent, to be paid promptly.
2. To date, Respondent has not paid the \$500 civil penalty.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board’s settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

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 Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

PROOF OF SERVICE

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

personal service first class mail
 certified mail, return receipt requested facsimile
Article Number 917199999170310675729 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

ADDENDUM R
NOTICE OF HEARING
AND
STATEMENT OF CHARGES

ROBERT OSBORN
PHARMACIST LICENSE NO. 19079
ROCK ISLAND, ILLINOIS

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-----------------------|---|------------------------------|
| Re: |) | Case No. 2014-34 |
| Pharmacist License of |) | |
| ROBERT OSBORN |) | NOTICE OF HEARING AND |
| License No. 19079, |) | STATEMENT OF CHARGES |
| 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). Respondent was issued Iowa pharmacist license number 19709. Respondent's license is currently active and will expire on June 30, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 6, 2015, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.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 in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2013).

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 (2013) 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

VIOLATION OF A BOARD RULE

Respondent is charged with failing to comply with a Board order for a mental and physical examination as required by Board rule 657 Iowa Administrative 36.17 in violation of Iowa Code sections 147.55(9) and 155A.12(1),(3) and 657 Iowa Administrative Code rule 36.1(4)(u); .

Count II

VIOLATION OF A LAW RELATED TO THE PRACTICE OF PHARMACY

Respondent is charged with violation of a law of another state related to the practice of pharmacy or the distribution of controlled substances in violation of Iowa Code sections 147.55(5) and 155A.12(1), (3) and 657 Iowa Administrative Code rules 8.11(4); (8) and 36.1(4)(f).

D. FACTUAL CIRCUMSTANCES

1. Respondent is an Iowa-licensed pharmacist, living and working primarily in Rock Island, Illinois.

2. On August 27, 2014, the Board issued the Respondent a Confidential Order for Evaluation. The Order required the Respondent to obtain a complete physical and mental health

evaluation, including substance abuse evaluation, within thirty days. Alternatively, Respondent could file an objection to the Board's Order within thirty days.

3. More than two months have now passed since issuance of the Board's Confidential Order for Evaluation. Respondent has neither objected to the Order nor submitted copies of the required evaluations.

4. In October 2014, Respondent pled guilty to the attempted unlawful possession of a controlled substance, a Class A misdemeanor. Respondent was sentenced to two years conditional discharge, four days in county jail, a \$2000 fine, and required to participate in and successfully complete a substance abuse evaluation within six months.

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 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

ADDENDUM S

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**DUTCH MILL PHARMACY
PHARMACY LICENSE NO. 445
ORANGE CITY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|----------------------------|---|--------------------------------|
| Re: |) | Case Nos. 2014-45 |
| Pharmacy License of |) | |
| DUTCH MILL PHARMACY |) | STATEMENT OF CHARGES |
| License No. 445 |) | & 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 445. Respondent's license is currently active.

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 COUNSEL A PATIENT ON A CHANGE IN DOSAGE

Respondent is charged with failing to counsel a patient on a change in dosage in violation of Iowa Code section 147.55(9) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 6.14(1), 8.3(1), and 36.1(4)(u).

Count IV

FAILURE TO NOTIFY THE BOARD OF A MALPRACTICE SETTLEMENT

Respondent is charged with failing to notify the board within 30 days of a settlement agreement in violation of Iowa Code sections 147.55(9) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(p).

D. FACTUAL CIRCUMSTANCES

1. On March 20, 2014, the Board received a complaint about a dispensing error at the Respondent pharmacy, Dutch Mill Pharmacy in Orange City, Iowa.

2. On March 13, 2014, the Respondent received an electronic prescription for lamotrigine for an eight-year-old patient. The patient had been taking 5mg chewable tablets (5 tablets, 2 times per day). The new prescription called for the patient to take 25mg tablets (1 tablet, 2 times per day).

4. On Friday, March 14, 2014, the patient's mother called the pharmacy to refill the prescription.

5. The prescription was filled by staff pharmacist, Dwayne Plender. The patient's mother picked up the prescription on March 17, 2014. The prescription's label read: "Take 5 tablets 2 times per day." The label further noted that the tablets were 5mg chewable tablets. The patient was given 5 tablets on the evening of March 17th and 5 tablets on the morning of March 18th.

6. It was later discovered that the prescription was correctly filled with the 25mg tablets, but the label incorrectly provided instructions for the 5mg tablet. As a result, the patient took two dosages of 125mg instead of the prescribed 25mg.

7. The patient was reported ill by her school on March 18, 2014.

8. The patient's mother was not counseled when picking up the prescription.

9. This dispensing error was not recorded in the Respondent's Continuous Quality Improvement Program.

10. During the course of this investigation, it was discovered that in 2009 a staff pharmacist at the Respondent pharmacy misfilled a prescription for tramadol. The patient was mistakenly given zolpidem. Due to the error, the patient experienced double vision, hallucinations, and incurred thousands of dollars in medical testing. The pharmacist's malpractice insurance settled with the patient in 2010 for \$86,117.60.

11. This settlement was not reported to the Board.

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

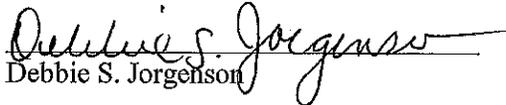
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 9171999991703106755774 | <input type="checkbox"/> 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

ADDENDUM T
NOTICE OF HEARING
AND
STATEMENT OF CHARGES

BRENT PLENDER
PHARMACIST LICENSE NO. 17651
ORANGE CITY, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-----------------------|---|--------------------------------|
| Re: |) | Case No. 2014-45 |
| Pharmacist License of |) | |
| BRENT PLENDER |) | STATEMENT OF CHARGES |
| License No. 17651, |) | & 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 17651. Respondent's license is currently active.

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

VIOLATING THE DUTIES OF A PHARMACIST-IN-CHARGE

Respondent is charged with violating the duties of a pharmacist-in-charge in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.2, 8.3(1), 8.26(3), and 36.1(4)(u).

D. FACTUAL CIRCUMSTANCES

1. On March 20, 2014, the Board received a complaint about a dispensing error at Dutch Mill Pharmacy in Orange City, Iowa.
2. At all times relevant to the complaint, the Respondent, an Iowa-licensed pharmacist, served as the pharmacist-in-charge at Dutch Mill Pharmacy.
3. On March 13, 2014, the pharmacy received an electronic prescription for lamotrigine for an eight-year-old patient. The patient had been taking 5mg chewable tablets (5 tablets, 2 times per day). The new prescription called for the patient to take 25mg tablets (1 tablet, 2 times per day).
4. On Friday, March 14, 2014, the patient's mother called the pharmacy to refill the prescription.
5. The prescription was filled by staff pharmacist, Dwayne Plender. The patient's mother picked up the prescription on March 17, 2014. The prescription's label read: "Take 5 tablets 2 times per day." The label further noted that the tablets were 5mg chewable tablets. The

patient was given 5 tablets on the evening of March 17th and 5 tablets on the morning of March 18th.

6. It was later discovered that the prescription was correctly filled with the 25mg tablets, but the label incorrectly provided instructions for the 5mg tablet. As a result, the patient took two dosages of 125mg instead of the prescribed 25mg.

7. The patient was reported ill by her school on March 18, 2014.

8. The patient's mother was not counseled when picking up the prescription.

9. This dispensing error was not recorded in the pharmacy's Continuous Quality Improvement Program.

10. During the course of this investigation, it was discovered that in 2009 a staff pharmacist at Dutch Mill misfilled a prescription for tramadol. The patient was mistakenly given zolpidem. Due to the error, the patient experienced double vision, hallucinations, and incurred thousands of dollars in medical testing. The pharmacist's malpractice insurance settled with the patient in 2010 for \$86,117.60.

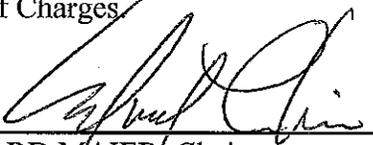
11. This settlement was not reported to the Board.

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

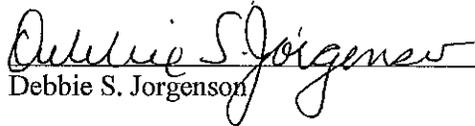
PROOF OF SERVICE

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 917199999170310675781
on the 19th day of November, 2014.

first class mail
 facsimile
 other _____

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


Debbie S. Jorgenson

ADDENDUM U

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**DWAYNE A. PLENDER
PHARMACIST LICENSE NO. 13561
ORANGE CITY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|-----------------------|---|--------------------------------|
| Re: |) | Case No. 2014-45 |
| Pharmacist License of |) | |
| DWAYNE PLENDER |) | STATEMENT OF CHARGES |
| License No. 13561, |) | & 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 13561. Respondent's license is currently active.

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 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.12(1) and 657 Iowa Administrative Code rules 6.10(1), 8.3(3) and 36.1(4)(u).

Count II

FAILURE TO COUNSEL A PATIENT ON A CHANGE IN DOSAGE

Respondent is charged with failing to counsel a patient on a change in dosage in violation of Iowa Code section 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.14(1) and 36.1(4)(u).

Count III

FAILURE TO NOTIFY BOARD OF A MALPRACTICE SETTLEMENT

Respondent is charged with failing to notify the Board of a malpractice settlement in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rule 36.1(4)(p).

D. FACTUAL CIRCUMSTANCES

1. On March 20, 2014, the Board received a complaint about a dispensing error at Dutch Mill Pharmacy in Orange City, Iowa.

2. At all times relevant to the complaint, the Respondent, an Iowa-licensed pharmacist, served as a staff pharmacist at Dutch Mill Pharmacy.

3. On March 13, 2014, the pharmacy received an electronic prescription for lamotrigine for an eight-year-old patient. The patient had been taking 5mg chewable tablets (5 tablets, 2 times per day). The new prescription called for the patient to take 25mg tablets (1 tablet, 2 times per day).

4. On Friday, March 14, 2014, the patient's mother called the pharmacy to refill the prescription.

5. Respondent filled and verified the prescription. The patient's mother picked up the prescription on March 17, 2014. The prescription's label read: "Take 5 tablets 2 times per day." The label further noted that the tablets were 5mg chewable tablets. The patient was given 5 tablets on the evening of March 17th and 5 tablets on the morning of March 18th.

6. It was later discovered that the prescription was correctly filled with the 25mg tablets, but the label incorrectly provided instructions for the 5mg tablet. As a result, the patient took two dosages of 125mg instead of the prescribed 25mg.

7. The patient was reported ill by her school on March 18, 2014.

8. The patient's mother was not counseled on the change in dosage when picking up the prescription.

9. This dispensing error was not recorded in the pharmacy's Continuous Quality Improvement Program.

10. During the course of this investigation, it was discovered that in 2009 Respondent misfiled a prescription for tramadol. The patient was mistakenly given zolpidem. Due to the error, the patient experienced double vision, hallucinations, and incurred thousands of dollars in medical testing. Respondent's malpractice insurance settled with the patient in 2010 for \$86,117.60.

11. This settlement was not reported to the Board.

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

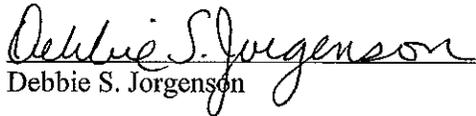
cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 917199999170310675798 | <input type="checkbox"/> 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

ADDENDUM V

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**LEEDS PHARMACY
PHARMACY LICENSE NO. 227
SIOUX CITY, IOWA**

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

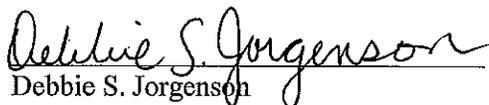
cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

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

ADDENDUM W

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**THOMAS B. DODDS
PHARMACIST LICENSE NO. 12951
DAKOTA DUNES, SOUTH DAKOTA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|------------------------|---|--------------------------------|
| Re: |) | Case No. 2014-86 |
| Pharmacist License of |) | |
| THOMAS B. DODDS |) | STATEMENT OF CHARGES |
| License No. 12951, |) | & 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 12951. Respondent's license is currently active, but on probation until January 12, 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

VIOLATING THE DUTIES OF A PHARMACIST-IN-CHARGE

Respondent is charged with violating the duties of a pharmacist-in-charge in violation of Iowa Code sections 147.55(9) and 155A.12(1), (4) and 657 Iowa Administrative Code rules 6.2, 8.3(1), 8.26(3), and 36.1(4)(u).

Count II

VIOLATING THE TERMS OF HIS PROBATION

Respondent is charged with violating the terms of his probation in violation of Iowa Code section 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 36.1(4)(i), (ac), (ag).

D. FACTUAL CIRCUMSTANCES

1. Respondent is an Iowa-licensed pharmacist. At all times relevant to this Statement of Charges, Respondent served as the pharmacist-in-charge at Leeds Pharmacy in Sioux City, Iowa.
2. In January 2013, Respondent entered into a settlement agreement with the Board to resolve pending disciplinary charges. The settlement agreement placed Respondent's pharmacist license on probation for three years subject to a number of terms and conditions. Amongst those conditions were requirements that Respondent abide by the laws and rules related to the practice

of pharmacy and that Respondent provide the Board notice of the completion of two (2) additional hours on continuing pharmacy education on medication dispensing errors.

3. Also in January 2013, Leeds Pharmacy entered into a settlement agreement with the Board. Leeds Pharmacy's license was also placed on probation 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.

4. On May 1, 2014, the Board received notification from Pharmacists Mutual Insurance Company regarding the settlement of a claim with Leeds Pharmacy. 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, the Respondent did not appear to know what a CQI program entailed.

7. Leeds Pharmacy 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. Leeds Pharmacy failed to submit policies and procedures as required by the settlement agreement.

9. Leeds Pharmacy failed to complete a current, accurate, and complete controlled substance inventory and submit it to the Board for review and approval.

10. Leeds Pharmacy failed to establish a patient counseling area which provides privacy for patients.

11. Respondent failed to submit evidence of his completion of two additional hours of continuing pharmacy education on medication dispensing errors.

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

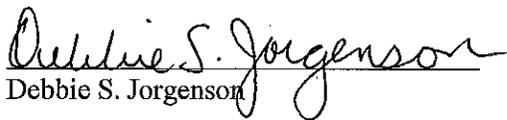
cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 9171999991703106755811 | <input type="checkbox"/> 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

ADDENDUM X
NOTICE OF HEARING
AND
STATEMENT OF CHARGES

RASHID LTC PHARMACY
PHARMACY LICENSE NO. 1129
FORT MADISON, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|----------------------------|---|------------------------------|
| Re: |) | CASE NO. 2014-102 |
| Pharmacy License of |) | |
| RASHID LTC PHARMACY |) | NOTICE OF HEARING AND |
| License No. 1129 |) | STATEMENT OF CHARGES |
| Respondent. |) | |

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Rashid LTC Pharmacy (“Respondent”), 2402 Avenue L, Fort Madison, IA 52627 pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa pharmacy license number 1129 is currently active and expires on December 31, 2014.

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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General’s Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I

FAILURE TO MEET THE REQUIREMENTS OF EMERGENCY PRESCRIPTIONS

Respondent is charged with failing to meet the requirements for emergency prescriptions in violation of 657 IAC 10.22(2), pursuant to Iowa Code sections 147.55(9), 155A.15(2)“c” and “h”, and 657 IAC 36.1(4)“u” and “ac”.

D. FACTUAL CIRCUMSTANCES

1. From May to July 2014, several doses of Schedule II controlled substances were removed from a StatSafe machine at a long-term care facility serviced by Respondent.
2. Respondent could not produce Schedule II emergency prescriptions for the Schedule II controlled substances removed from the StatSafe machine.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

Hearing. A disciplinary contested case hearing shall be held on January 13, 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.



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

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

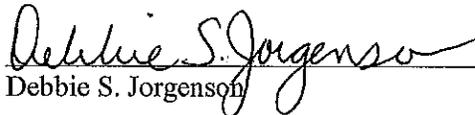
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 917199999170310675750 | <input type="checkbox"/> 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

ADDENDUM Y

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**DAVID TRACEY KING
PHARMACIST LICENSE NO. 19586
BURLINGTON, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|--------------------------|---|------------------------------|
| Re: |) | CASE NO. 2014-102 |
| Pharmacist License of |) | |
| DAVID TRACEY KING |) | NOTICE OF HEARING AND |
| License No. 19586 |) | STATEMENT OF CHARGES |
| Respondent. |) | |

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against David Tracey King (“Respondent”), 837 Monticello Drive, Burlington, IA 52601 pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa pharmacist license number 19586 is currently active and expires on June 30, 2015.

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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General’s Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I

FAILURE TO MEET THE REQUIREMENTS OF EMERGENCY PRESCRIPTIONS

Respondent is charged with failing to meet the requirements for emergency prescriptions in violation of 657 IAC 10.22(2), pursuant to Iowa Code sections 147.55(9), 155A.12(1) and (5), and 657 IAC 6.2(12), 6.2(15), 36.1(4)“u” and “ac”.

D. FACTUAL CIRCUMSTANCES

1. At all relevant times, Respondent was the pharmacist-in-charge at Rashid LTC Pharmacy.
2. From May to July 2014, several doses of Schedule II controlled substances were removed from a StatSafe machine at a long-term care facility serviced by Rashid LTC Pharmacy.
3. Rashid LTC Pharmacy could not produce temporary written records or written prescriptions for the Schedule II controlled substances removed from the StatSafe machine.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

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 Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

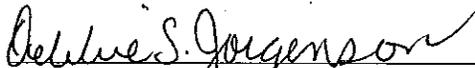
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested Article Number 917199999170310675743 | <input type="checkbox"/> facsimile |
| | <input type="checkbox"/> 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

ADDENDUM Z

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

BRADY ROLFES
PHARMACY TECHNICIAN REGISTRATION NO. 18729
IOWA CITY, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2014-109
Pharmacy Technician Registration of)
) **NOTICE OF HEARING AND**
BRADY ROLFES) **STATEMENT OF CHARGES**
Registration No. 18729)
Respondent.)

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Brady Rolfes (“Respondent”), 57 Westside Drive, Iowa City, Iowa 52246, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa pharmacy technician registration number 18729 is currently active and expires on June 30, 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 morning session, beginning at 9:00 a.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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General’s Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I

ENGAGING IN UNETHICAL BEHAVIOR—THEFT

Respondent is charged with engaging in unethical behavior—thrift in violation of 657 IAC 3.28(4), pursuant to Iowa Code sections 147.55(9) and 155A.6A(5), and 657 IAC 3.30, 36.1(4)“c”, and “u”.

Count II

UNLAWFUL POSSESSION OF A PRESCRIPTION DRUG

Respondent is charged with unlawful possession of a prescription drug in violation of Iowa Code section 155A.21(1), pursuant to Iowa Code sections 147.55(8), (9), and 155A.6A(5), and 657 IAC 3.30, 36.1(4)“j”, and “u”.

Count III

UNLAWFUL POSSESSION OF A CONTROLLED SUBSTANCE

Respondent is charged with unlawful possession of a controlled substance in violation of Iowa Code section 124.401(5), pursuant to Iowa Code sections 147.55(9) and 155A.6A(5), and 657 IAC 3.30, 36.1(4)“j”, and “u”.

D. FACTUAL CIRCUMSTANCES

1. At all relevant times, Respondent was employed as a pharmacy technician at Walgreens in Iowa City, Iowa.
2. In June, 2014, Respondent was seen on video taking hydrocodone from the pharmacy.

3. In June, 2014, Respondent admitted to taking drugs from the pharmacy since the summer of 2013. Respondent admitted to taking the following drugs from the pharmacy: tramadol, hydrocodone, alprazolam, Lyrica, gabapentin, Fiorinal with codeine, modafinil, and phentermine.

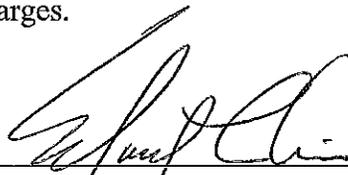
4. In June, 2014, Respondent was arrested and charged criminally in Johnson county with theft—5th degree, possession of controlled substances, and unlawful possession of prescription drugs. The following drugs were on Respondent's person when he was arrested: tramadol, Fioricet, Ultracet, clonazepam, and Midrin.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

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 Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

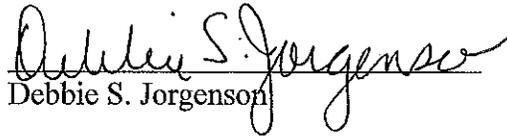
PROOF OF SERVICE

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

- personal service first class mail
 certified mail, return receipt requested facsimile
Article Number 917199999170310675712 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

ADDENDUM AA

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**OK COMPOUNDING LLC
NONRESIDENT PHARMACY LICENSE NO. 4204
SKIATOOK, OKLAHOMA**

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---------------------------------|---|------------------------------|
| Re: |) | CASE NO. 2014-121 |
| Nonresident Pharmacy License of |) | |
| OK COMPOUNDING LLC |) | NOTICE OF HEARING AND |
| License No. 4204 |) | STATEMENT OF CHARGES |
| Respondent. |) | |

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against OK Compounding LLC (“Respondent”), 102 N. Broadway, Skiatook, OK 74070, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa nonresident pharmacy license number 4204 is currently active and expires on December 31, 2014.

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 morning session, beginning at 9:00 a.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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General’s Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the 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.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 155A, and 272C (2013).

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 147, 155A, and 272C and under 657 IAC 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 IAC 35.21.

C. CHARGES

Count I

OUT-OF-STATE DISCIPLINE

Respondent is charged with violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)“ad”.

D. FACTUAL CIRCUMSTANCES

1. Respondent holds Iowa nonresident pharmacy license number 4204, which is currently active and expires on December 31, 2014.

2. In June, 2014, Respondent was disciplined by the Oklahoma State Board of Pharmacy for several violations of Oklahoma law.

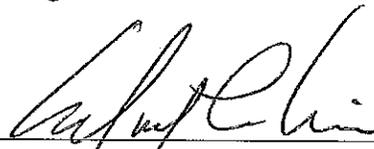
3. Respondent was fined \$520,200, ordered to cease business operations for 5 days, and placed on probation for 3 years.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board’s settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

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

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

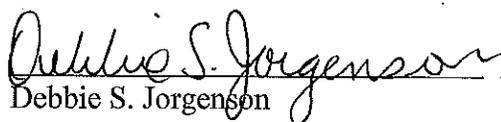
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 917199999170310675736 | <input type="checkbox"/> 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