# State of Iowa

# Board of Pharmacy

400 S.W. Eighth Street, Suite E, Des Moines, IA 50309-4688

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BOARD MEMBERS LADONNA GRATIAS EDWARD MCKENNA EDWARD MAIER

JAMES MILLER

Board Chair

ANDREW FUNK Executive Director JASON HANSEL SHARON MEYER JUDITH TRUMPY

### MINUTES

# November 3-4, 2015

The Iowa Board of Pharmacy met on November 3-4, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

### **TUESDAY, NOVEMBER 3, 2015**

#### MEMBERS PRESENT

James Miller, Chairperson Sharon K. Meyer, Vice-Chair LaDonna Gratias Jason Hansel Edward L. Maier Edward J. McKenna

# MEMBERS ABSENT

Judith M. Trumpy

### STAFF PRESENT

Andrew Funk, Executive Director
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney
General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O'Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Jennifer Tiffany, Compliance Officer
James Wolfe, Compliance Officer

#### Call to Order & Announcements

At 9:00 a.m., James Miller, Chairperson called the meeting of the Iowa Board of Pharmacy to order on Tuesday, November 3, 2015.

Meghan Gavin and Laura Steffensmeier left the room.

#### **State's Motion To Dismiss**

Postal Prescription Services, Nonresident Pharmacy License No. 3298, Portland, Oregon.

Motion by Edward Maier, seconded by Sharon Meyer, to approve State's Motion to Dismiss Statement of Charges for Postal Prescription Services, Nonresident Pharmacy License No. 3298 of Portland, Oregon. Motion approved unanimously. A copy of Ruling on State's Motion to Dismiss Statement of Charges is attached as Addendum A.

#### **Closed Session**

At 9:05 a.m., motion by Edward Maier, seconded by LaDonna Gratias, to go into closed session to review Closed Session Minutes pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required by state or federal law to be kept confidential, specifically to review or discuss information that is confidential under Iowa Code § 21.5(4).

At 9:08 a.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session, the following action was taken:

Motion by LaDonna Gratias, seconded by Jason Hansel, to approve the closed session minutes for the August 31-September 2, 2015, meeting; the September 1, 2015, deliberations; and the closed session minutes for the October 23, 2015, Emergency Teleconference meeting. Motion approved unanimously.

### **Administrative Hearing**

1. 2015-25, Inie Clement, Pharmacist License No. 16963 of Des Moines.

At 9:10 a.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Inie Clement did not appear nor did counsel represent her. The hearing was conducted in the presence of the Board. The hearing was open to the public.

The Board heard testimony of witnesses and examined exhibits.

At 9:30 a.m., the record was closed.

At 9:31 a.m., motion by Jason Hansel, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 9:43 a.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

Motion by LaDonna Gratias, seconded by Jason Hansel, to direct Administrative Law Judge LaMarche to draft the Order consistent with the Board's deliberations in case 2015-25, Inie Clement.

#### **Closed Session**

At 9:55 a.m., motion by Edward Maier, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session for the following reasons:

For Follow-Up Investigative Information pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically to review or discuss information that is confidential under Iowa Code § 272C.6(4).

For Settlement Agreement and Final Orders pursuant to Iowa Code § 21.5(1)(f) to discuss the decision to be rendered in a contested case.

For Notice of Hearings and Statement of Charges pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigation or proceedings.

For Complaints and Investigate Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically information that is confidential under Iowa Code § 272C.6(4).

At 12:00 p.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

### **Administrative Hearing**

1. Kevin O'Rourke, Pharmacist License No. 15064 of Iowa Falls.

At 1:05 p.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Kevin O'Rourke appeared without counsel. The hearing was conducted in the presence of the Board. The hearing was closed to the public.

The Board examined exhibits.

At 1:38 p.m., the record was closed.

At 1:40 p.m., motion by Edward Maier, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 2:15 p.m., while still in closed session, LaDonna Gratias moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

Motion by Edward Maier, seconded by Edward McKenna, to direct Administrative Law Judge LaMarch to draft the Order consistent with the Board's deliberations in the case of Kevin O'Rourke.

#### **Closed Session**

At 2:32 p.m., motion by Edward McKenna, seconded by Jason Hansel, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Complaints and Investigate Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a)

to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically information that is confidential under Iowa Code § 272C.6(4).

At 3:08 p.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session the following actions were taken:

1. Close With No Action.

Motion by Jason Hansel, seconded by Edward McKenna, to close with no further action the following investigative files in complaint numbers: 2013-3403, 2015-116, 2015-165, 2015-166, 2015-167, 2015-168, 2015-169, 2015-170, 2015-138, 2015-144, 2015-23, 2015-51, 2015-84, 2015-127, 2015-135, 2015-125, 2015-137, 2015-141, and 2015-146. Motion approved unanimously.

2. Settlement Agreement and Final Order.

Motion by Edward McKenna, seconded by Sharon Meyer, to approve the Settlement Agreement and Final Order in the following cases. Motion approved unanimously.

- A. Juanita Durham, ARNP, CSA Registration No. 5201466 of Chariton. A copy of the Settlement Agreement and Final Order is attached as Addendum B.
- B. Weatherford Compounding Pharmacy, Nonresident Pharmacy License No. 4075 of Weatherford, Texas. A copy of the Settlement Agreement and Final Order is attached as Addendum C.
- C. David Kroner, D.D.S., CSA Registration No. 1417820 of Urbandale. A copy of the Settlement Agreement and Final Order is attached as Addendum D.
- D. Leeds Pharmacy, Pharmacy License No. 227 of Sioux City. A copy of the Settlement Agreement and Final Order is attached as Addendum E.
- E. Karen Bean, Pharmacy Support Person Registration No. 3456 of Cedar Rapids. A copy of the Settlement Agreement and Final Order is attached as Addendum F.
- 3. Combined Notice of Hearing and Statement of Charges.

Motion by LaDonna Gratias, seconded by Edward Maier, to approve the Combined Notice of Hearing and Statement of Charges in the following cases. Motion approved unanimously.

- A. Pharmacy Creations, LLC, Nonresident Pharmacy License No. 4185 of Randolph, New Jersey. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum G.
- B. Wells Pharmacy Network, LLC, Nonresident Pharmacy License No. 3385 of Ocala, Florida. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum H.
- C. Downing Labs, LLC, Nonresident Pharmacy License No. 4030 of Dallas, Texas. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum I.
- D. Keysource Medical Inc., Wholesale Drug License No. 6272 of Cincinnati, Ohio. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum J.
- E. Adam D. Castle, Pharmacy Technician Registration No. 19952 of Clinton. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum K.

- F. Lisa A. Gray, Pharmacist License No. 18401 of Urbandale. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum L.
- G. Remedies Inc., Pharmacy License No. 611 of Sibley. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum M.
- H. Alan R. Hoppe, Pharmacist License No. 18117 of Sibley. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.
- I. Minnesota Independent Cooperative, Inc., Wholesale Drug License No. 6464 of Eagan, Minnesota. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum O.
- J. Hy-Vee Pharmacy 1068, Pharmacy License No. 811 of Cherokee. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum P.
- K. Dawn Ruehle, Pharmacist License No. 16618 of Cherokee. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum Q.
- L. Priority Pharmaceuticals, Inc., Wholesale Drug License No. 5989 of San Diego, California. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum R.
- 4. Voluntary Surrender of Pharmacist License.

Motion by Jason Hansel, seconded by Edward Maier, to approve the Order Accepting Surrender of Pharmacist License for Steven J. Johnson, Pharmacist License No. 18278 of Clarinda. Motion approved unanimously. A copy of the Order Accepting Surrender of Pharmacist License is attached as Addendum S.

5. Refer to Another Agency.

Motion by Sharon Meyer, seconded by Edward McKenna, to refer 2015-142 to another agency. Motion approved unanimously.

6. Draft Statement of Charges.

Motion by Edward Maier, seconded by Jason Hansel, to draft Statement of Charges against the pharmacy in 2013-4139, technician in 2015-150, pharmacy and pharmacist in charge in 2015-123, and pharmacist in 2015-66. Motion approved unanimously.

7. Letter of Education.

Motion by Sharon Meyer, seconded by Edward Maier, to issue a Letter of Education to the technician in 2015-118 and pharmacist in charge in 2015-158. Motion approved unanimously.

8. Close With No Action.

Motion by Edward Maier, seconded by Jason Hansel, to close with no further action the following investigative files in complaint numbers: 2014-49 and 2015-75. Motion approved unanimously.

Meghan Gavin and Laura Steffensmeier left the room.

#### **Closed Session**

At 3:15 p.m., motion by Jason Hansel, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Findings of Fact, Conclusions of Law, Decision and Order pursuant to Iowa Code § 21.5(5)(f) to discuss the decision to be rendered in the following case.

At 3:38 p.m., while still in closed session, Jason Hansel moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session, the following action was taken:

1. Findings of Fact, Conclusions of Law, Decision and Order.

Motion by Edward Maier, seconded by Jason Hansel, to approve the Findings of Fact, Conclusions of Law, Decision and Order for Amanda Latta, Pharmacist License No. 19669 of Springville. Motion approved unanimously. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum T.

At 3:30 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, November 4, 2015, at 9:00 a.m.

### WEDNESDAY, NOVEMBER 4, 2015

#### MEMBERS PRESENT

Edward L. Maier, Chairperson James Miller, Vice-Chair LaDonna Gratias Jason Hansel Edward J. McKenna Sharon K. Meyer

### MEMBERS ABSENT

Judith M. Trumpy

#### **SPEAKERS**

Amanda Lattas, IPRN
Helen Eddy, Hy-Vee
Amy Van Maanen, Board of Medicine
Brianne Bakken, University of Iowa
Todd Thompson, Kalona
Roby Miller, Telepharm
Adam Chesler, Telepharm
Pat R., Sioux Rapids
Chris Finnell, Winfield
Jim Bollig, Bancroft
Josh Hveem, Nora Springs
Russell Yoder, Wayland

#### STAFF PRESENT

Andrew Funk, Executive Director
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney
General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O'Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Jennifer Tiffany, Compliance Officer
Jim Wolfe, Compliance Officer

Marie Matthiesen, Lake Park Dale Woolery, ODCP Anthony Pudlo, IPA

#### **Call to Order and Announcements**

At 9:00 a.m., James Miller, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

### Acknowledgement

Edward Maier was acknowledged for his leadership and service as past Chair of the Board.

### **Public Comments**

No public comments.

### **Approval of Minutes**

The minutes of the August 31-September 2, 2015, meeting and October 23, 2015, Emergency Teleconference meeting were reviewed.

Motion by Edward Maier, seconded by Edward McKenna, to approve the open session minutes of the August 31-September 2, 2015, meeting as presented. Motion approved unanimously.

Motion by Sharon Meyer, seconded by Jason Hansel, to approve the open session minutes of the October 23, 2015, Emergency Teleconference meeting as presented. Motion approved unanimously.

### Reports

1. Executive Director's Report –

#### A. Financial.

#### FY16 as of 9/30/15 (25% of FY completed)

Carry-over from FY15: \$1,335,215 (Includes \$850,000 reserve for new database)

FY16 Receivables: 344,378

Total FY16 Revenue: 1,679,593 (45.83% of anticipated revenue)

Fines and Civil Penalties: 12,000 (paid to General Fund)

Total FY16 Obligations: 675,899 (18.47%)

PMP Program Fund Obligations: 26,700 (25%)

IPRN Program Fund Obligations: 28,374 (25%)

Anticipated Carry-over to FY17: 318,289

A minimum of \$500,000 is needed for carry-over to ensure financial obligations are met.

#### 2. Meetings.

- A. A committee of the Board will meet with the Iowa Pharmacy Association Board of Trustees for an annual dinner meeting the evening of November 4, at the Iowa Pharmacy Association's (IPA) office in Urbandale.
- B. IPRN will hold its Fall Meeting on November 11, 2015, from 4:30-6:30 p.m. at IPA's office in Urbandale.
- C. Terry Witkowski and Andrew Funk will be attending the Heroin & Opiods: A Community Crisis Seminar at the University of Iowa, College of Public Health on November 12, 2015.
- D. The National Association of Boards of Pharmacy (NABP) will be hosting a Pharmacist Assessment for Remediation Evaluation (PARE) Item Development Workshop on November 12-13, 2015, in Mount Prospect, Illinois. Jennifer O'Toole plans to attend the workshop.
- E. The Federal Drug Administration (FDA) will be holding an Intern-Governmental Meeting on Pharmacy Compounding and Drug Supply Chain Security in Silver Spring, Maryland on November 16-17, 2015. Andrew Funk and Sue Mears plan to attend the meeting.
- F. An Interactive Compliance Officer and Legal Counsel Forum will be hosted by NABP on December 1-2, 2015, in Northbrook, Illinois. Jennifer Tiffany and Laura Steffensmeier plan to attend the forum.
- G. ASHP Midyear Clinical Meeting will be held in New Orleans, Louisiana, on December 6-10, 2015. Jean Rhodes plans to attend the meeting.
- H. The January board meeting is scheduled for January 12-13, 2016, in Des Moines at the board office.
- I. The 2016 Midwest Pharmacy Expo will be held in Des Moines on February 12-14, 2016.
- J. The APhA Annual Meeting will be held in Baltimore, Maryland, on March 4-7, 2016.
- 3. Office/Program Updates.
  - A. Open Positions.

The Board of Pharmacy is currently working on seeking to fill two positions:

- Program Planner/Administrative Assistance/Administrative Intern position. The primary function of this position will be Prescription Monitoring Program administration. Andrew Funk and Terry Witkowski are currently working on designing and assigning job duties to this position.
- Pharmacist position to serve as a Compliance Officer.
- B. Database Licensing System Options.

Andrew Funk, Terry Witkowski, and Debbie Jorgenson have attended two presentations regarding potential database licensing system options.

• Option 1: eLicense - \$260,000 up-front, with \$3,900 a month for on-going support fees. eLicense is not an approved database option by the Office of the Chief Information Officer (OCIO). The Board is currently seeking approval of this option.

• Option 2: Salesforce – approximately \$700,000 up-front, with \$6,500 a month for on-going support fees. Salesforce is a state approved database option and is preferred by OCIO.

#### C. New Website.

The redesign of the Board's new website is complete. On September 24, 2015, the new website <a href="https://pharmacy.iowa.gov">https://pharmacy.iowa.gov</a> went live.

D. Committees for 2016.

Discussion was held regarding forming committees for the following:

- 2016 Board of Pharmacy Strategic Planning.
- Review and assess the Iowa Pharmacy Recovery Network (IPRN).
- E. 2016 Board of Pharmacy Outreach.

The Board discussed holding a series of Outreach meetings in 2016. The purpose of the meetings would be to engage pharmacists and pharmacy staff in meaningful dialogue regarding any issues and concerns they may have. A definite decision was not made at this time.

4. Proposed 2016 Calendar of Board Meetings and Conferences.

The Proposed 2016 Calendar of Board Meetings and Conferences was reviewed.

5. Nominations for Awards to be Presented at the National Association of Boards of Pharmacy's (NABP) 112<sup>th</sup> Annual Meeting.

Informational item.

- 6. Multistate Pharmacy Jurisprudence Examination (MPJE) Program Updates 2016 NABP. Informational item.
- 7. Litigation Update Laura Steffensmeier.

The Board currently has one judicial review in District Court.

8. USP 797 Proposed Revisions.

Proposed revisions to USP Chapter 797 for sterile compounding were published for comment on November 2, 2015, and comments will be accepted until January 31, 2016. Compliance Officers provided a brief summary of the proposed changes.

9. California Legislature Passed Bill Requiring Multilingual Medication Instructions.

Informational item.

10. \$750,000 Settlement Points to the Need for Strong HIPPA Policies – Health IT Pulse (September 17, 2015 - online).

Informational item.

11. Denver Area Pharmacy Draws Penalty for HIPAA Privacy Violation – ModernMedicine Network (August 10, 2015 – online).

Informational item.

12. New Practice Model Site Feedback Regarding Pharmacy Technician Certification Board (PTCB) 2020 Requirement.

Megan Myers had an opportunity through conference calls and a meeting to seek input from pharmacists and technicians at New Practice Model sites regarding the proposed requirement for technicians to complete an accredited program in order to be eligible for the PTCB certification exam. Feedback from pharmacists and currently certified pharmacy technicians was provided for review and discussion.

13. IPRN Welcomes Amanda Latta as IPRN Monitor.

Amanda Lattas was welcomed as the new monitor for IPRN.

14. IPRN Third Quarter Report.

Amanda Latta provided the IPRN Third Quarter Report.

15. Hy-Vee Pharmacy Fulfillment Center's 2015 Quarter Two Error Report.

Hy-Vee Pharmacy Fulfillment Center submitted their 2015 Quarter Two Error Report for review.

#### **IPRN Discussion**

Comparison information regarding who administers and funds the Pharmacist Recovery Network program for the states of Missouri, Kansas, Wisconsin, Illinois, Minnesota, Nebraska, North Dakota, and South Dakota was provided for review.

Amy Van Maanen, Iowa Physician Health Program Project Manager with the Iowa Board of Medicine provided a presentation on the Iowa Physicians Health Program (IPHP). IPHP was established to support physicians who self-report mental health issues, physical disabilities or substance use disorders. The advocacy and confidential monitoring program is administered by the Iowa Physician Health Committee, which is appointed by the Board of Medicine.

A committee will be formed to review and assess the IPRN program.

### **TakeAway Program Discussion**

Current TakeAway Program and possible expansion of the program were discussed. The current contract cannot be renewed so a Request for Proposal will be prepared and submitted for competitive bid.

#### Requests

1. University of Iowa Hospitals and Clinics Intelliguard® Kit and Tray Management System Implementation – Brianne Bakken.

The Intelliguard® Kit and Tray Management System offers an automated solution for the medication restocking and checking of emergency kits and trays.

Clarification regarding registering Intelliguard® technicians on a temporary basis, if the Intelliguard® Kit and Tray Management System is considered to be an "Automated

Medication Distribution System," requirements of I.A.C. Chapter 9, and reporting were discussed.

2. Request for Waiver – 657 I.A.C. 2.11(1) Late Payment Penalty – Matthew J. Kolb, Chicago, Illinois.

Motion by Jason Hansel, seconded by Edward McKenna, to deny the request. Motion approved unanimously.

3. Roadrunner Pharmacy's Request for Board's Opposition to FDA's Proposed "Guidance for Industry-Compounding Animal Drugs from Bulk Drug Substances."

The Board will not be making a position statement on this issue.

4. Request for Waiver – 657 I.A.C. 9.3(2) Telepharmacy – Thompson & Thompson LTC – Todd Thompson, Victor Drug, West Liberty Pharmacy, and Brooklyn Pharmacy.

Motion by Edward Maier, seconded by LaDonna Gratias, to approve the waiver request extending the pilot project for 12 months for the Victor, West Liberty, and Brooklyn locations. Motion approved unanimously.

5. Telepharmacy Pilot Project – TelePharm, Roby Miller and Adam Chesler.

Roby Miller and Adam Chesler presented a proposal for a pilot/search demonstration project to establish telepharmacies in rural Iowa communities. TelePharm requested to create pilot projects in Lake Park, Nora Springs, Wayland, and Winfield. Representatives from these communities addressed the Board regarding the proposed telepharmacy sites.

Motion by LaDonna Gratias, seconded by Edward McKenna, to table this request pending further review. Motion approved unanimously.

#### **Closed Session**

At 11:42 a.m., motion by LaDonna Gratias, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Requests pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required or authorized by state or federal law to be kept confidential under Iowa Code § 272C.6 and 22.7(2).

Sharon Meyer left the room.

At 11:55 a.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session the following actions were taken:

A. Modification to Board Order.

Motion by Edward Maier, seconded by Edward McKenna, to grant request to modify Board Order for early termination of probation for Janee Anderson. Motion passed. Sharon Meyer abstained.

Sharon Meyer rejoined the meeting.

B. NAPLEX Examination and Internship Request.

Motion by Edward Maier, seconded by Edward McKenna, to authorize Belkis McCarthy to take and pass the NAPLEX Examination with a deadline of May 4, 2016, to approve pharmacist-intern registration, and grant a 12 month extension to complete 500 hours of internship by November 4, 2016. Motion approved unanimously.

### **Rules and Legislation**

1. Naloxone Dispensing and Classification.

Naloxone is a prescription drug that may only be dispensed by a pharmacist on the order of a qualified and authorized prescriber. The Board is interested in further dialogue regarding this topic.

2. Notice of Intended Action to Amend Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses," and Chapter 23, Long-Term Care Pharmacy Practice.

Motion by Jason Hansel, seconded by Sharon Meyer, to approve for filing Notice of Intended Action. A copy is attached as Addendum U. Motion approved unanimously.

3. Notice of Intended Action to Amend Chapter 7, "Hospital Pharmacy Practice."

Motion by Edward Maier, seconded by Edward McKenna, to approve for filing Notice of Intended Action. A copy is attached as Addendum V. Motion approved unanimously.

4. Notice of Intended Action to Amend Chapter 4, "Pharmacist-Interns."

Motion by Edward McKenna, seconded by LaDonna Gratias, to approve for filing Notice of Intended Action. A copy is attached as Addendum W. Motion approved unanimously.

5. Review of Fees and Notice of Intended Action to Amend Chapter 2, "Pharmacist Licenses," Chapter 4, "Pharmacist-Interns," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses,", and Chapter 24, Pharmacy Internet Sites."

There is a provision in the Iowa Code that directs boards that are fee-based to review their revenues and expenditures and make adjustments if necessary so that the amount of revenues being brought in equals the amount of expenditures going out. Alternative proposals for fee increases were discussed as possible options.

Motion by Sharon Meyer, seconded by Edward Maier, to approve for filing Notice of Intended Action to change rules as needed to implement new licensing fees. Copies are attached as Addendum X (Notice of Intended Action) and Addendum Y (Adopted Proposal for Fee Increases). Motion approved unanimously.

6. Proposed Telepharmacy Pilot Project Petition Criteria.

Suggested petition criteria were distributed to the Board. No dialogue was held regarding this topic.

7. Proposed Legislation – Iowa Code Chapter 124, Controlled Substance Scheduling Actions. The Bill modifies the controlled substances schedules and provides penalties.

Motion by Edward Maier, seconded by Sharon Meyer, to approve the proposed legislation.

8. Proposed Legislation – Senate File 453, Iowa Code Chapter 155A, Pharmacy Practice Act.

A Bill for an Act relating to the Board of Pharmacy, including Nonresident pharmacy and Outstanding Facility Licensure, pharmacist supervision of pharmacy technicians, alternate board members, and enforcement authority.

- Motion by Edward Maier, seconded by Sharon Meyer, to continue to proceed with the proposed legislation for Senate File 453.
- 9. Proposed Legislation Iowa Code Chapter 124, Information Program for Drug Prescribing and Dispensing.

An Act making changes to the drug prescribing and dispensing information program.

Motion by Jason Hansel, seconded by Edward McKenna, to approve the proposed legislation.

### Licensure/Registrations

- Professional Partners, Inc., Nonresident Pharmacy Application, Newport Beach, California.
   Motion by Edward Maier, seconded by Jason Hansel, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.
- 2. Grove Professional Pharmacy, Inc., Nonresident Pharmacy Application, Springfield, Missouri. Motion by Edward Maier, seconded by Jason Hansel, to table this item. Motion approved unanimously.
- G & K Pharmacy, Nonresident Pharmacy Application, Allentown, Pennsylvania.
   Motion by Edward Maier, seconded by Jason Hansel, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.
- HDK Enterprises Inc., Nonresident Pharmacy Application, Houston, Texas.
   Motion by Edward Maier, seconded by Edward McKenna, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.
- 5. Request to Obtain Internship Registration Jisoo Lee, Iowa.

Motion by Edward Maier, seconded by Jason Hansel, to grant an internship registration to Ms. Lee once she has obtained an Individual Tax Identification Number in lieu of required social security number. Motion approved unanimously.

Motion by Edward Maier, seconded by Sharon Meyer, to adjourn at 2:03 p.m. on November 4, 2015.

Becky Hall	
Recording Secretary	

Andrew Funk		James Miller	
Executive Director		Board Chair	
APPROVED THIS	DAY OF	, 20 .	

# **ADDENDUM A**

# RULING ON STATE'S MOTION TO DISMISS STATEMENT OF CHARGES

POSTAL PRESCRIPTION SERVICES NONRESIDENT PHARMACY LICENSE NO. 3298 PORTLAND, OREGON

#### BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2012-168
Nonresident License of	)	
POSTAL PRESCRIPTION SERVICES	)	<b>RULING ON STATE'S</b>
License No. 3298	)	MOTION TO DISMISS
Respondent.	)	STATEMENT OF CHARGES

On March 13, 2013, the Iowa Board of Pharmacy (Board) found probable cause to file Statement of Charges against Postal Prescription Services (Respondent).

On October 20, 2015, the state of Iowa filed a Motion to Dismiss against Respondent. The circumstances supporting the State's motion included:

- 1. Following issuance of the Statement of Charges & Notice of Hearing, the State and Respondent informally agreed to a settlement and the matter was removed from the Board's hearing schedule.
- 2. Upon further review, the State believes that the above-captioned matter should be dismissed for the following reasons:
  - a. The sole charge was based upon a 2012 Consent Agreement between the Respondent and the Oregon Board of Pharmacy. In the Consent Order, Respondent acknowledged employing an unlicensed individual to perform the duties of a pharmacy technician. The Respondent agreed to pay a civil penalty in the amount of \$5000.
  - b. There was no allegation that the Respondent failed to timely notify the Iowa Board of Pharmacy of this Consent Agreement.
  - c. The State believes that the Oregon Consent Agreement more than adequately protects the public, making further disciplinary action unnecessary.
- 3. Given the totality of circumstances, the undersigned believes that it is in the interest of justice to dismiss the above-captioned matter.

The Board considered the State's Motion on November <u>3</u>, 2015. IT IS THEREFORE ORDERED that the State's Motion to Dismiss Statement of Charges against Postal Prescription Services is hereby GRANTED.

Dated this 4th day of November, 2015.

JAMES MILLER, Chairperson Iowa Board of Pharmacy

400 SW Eighth Street, Suite E

Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorneys General
Hoover State Office Building
Des Moines, IA 50319

Postal Prescription Services 3500 SE 26<sup>th</sup> Ave. Portland, OR 97202

# **ADDENDUM B**

# SETTLEMENT AGREEMENT AND FINAL ORDER

JUANITA DURHAM, ARNP CSA REGISTRATION NO. 5201466 CHARITON, IOWA

### BEFORE THE IOWA BOARD OF PHARMACY

_	)	Case No. 2013-147
Re:	)	
Controlled Substance Registration of	)	SETTLEMENT AGREEMENT
JUANITA DURHAM, ARNP	)	AND
Registration No. 5201466	)	FINAL ORDER
Respondent	)	

**COME NOW** the Iowa Board of Pharmacy ("Board") and Juanita Durham, ARNP ("Respondent"), and enter into this Settlement Agreement and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2015) to settle a licensee disciplinary proceeding currently pending before the Board.

The allegations contained in the Order to Show Cause against the Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

- 1. Respondent holds Iowa controlled substance registration number 5201466, which is currently active.
- 2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
- 3. An Order to Show Cause the Respondent's Controlled Substance Act registration was issued on August 12, 2014.
- 4. Respondent has chosen not to contest the charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
- 5. 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.
- 6. 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.
- 7. Respondent is freely and voluntarily entering into this Agreement. Respondent further 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.

- 8. 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.
- 9. 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.
- 10. 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.
- 11. This Agreement shall be reported to the National Practitioners Data Bank and the National Association of Boards of Pharmacy's Disciplinary Clearinghouse as applicable.
- 12. This Agreement shall not be binding as to any new complaints received by the Board.
- 13. The Board's approval of this Agreement shall constitute a FINAL ORDER of the Board.

### IT IS THEREFORE ORDERED:

14. Respondent is hereby CITED for having her federal registration to distribute or dispense controlled substances restricted and WARNED that Respondent's failure to comply with the laws governing the distribution and dispensing of controlled substances could result in further discipline.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 20 day of October 2015.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the Hinday of November 2015.

EDWARD MAJER, Chairperson Iowa Board of Pharmacy

400 SW Eighth Street, Suite E Des Moines, Iowa 50309-4688

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# **ADDENDUM C**

# SETTLEMENT AGREEMENT AND FINAL ORDER

WEATHERFORD COMPOUNDING PHARMACY NONRESIDENT PHARMACY LICENSE NO. 4075 WEATHERFORD, TEXAS

# BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of	) CASE NOS. 2013-4075 & 2014-100	
WEATHERFORD COMPOUNDING PHARMACY License No. 4075 Respondent.	SETTLEMENT AGREEMENT AND FINAL ORDER  )	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Weatherford Compounding Pharmacy ("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 the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

- 1. The Board filed a Notice of Hearing and Statement of Charges on March 10, 2015.
- 2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
- 3. 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.
- 4. 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 Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
- 5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
- 6. 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.
- 7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
- 8. This Order 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.

- 9. This Order shall not be binding as to any new complaints received by the Board.
- 10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.
- 11. 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.
  - 12. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

# IT IS THEREFORE ORDERED:

- 13. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license effective December 31, 2015, and pay a **CIVIL PENALTY** in the amount of sixthousand dollars (\$6000) no later than November 30, 2015, to resolve this matter.
- 14. This voluntary surrender has the same force and effect as an order of revocation under 657 IAC 36.15 for purposes of reinstatement. Reinstatement requests are governed by 657 IAC 36.13. Respondent agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.
- 15. The civil penalty and the license should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.
- 16. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is yoluntarily submitted by Respondent to the Board for its consideration on the 2 day of 2015.

WEATHERFORD COMPOUNDING

PHARMACY

Respondent

By this signature, acknowledges s/he is the for Weatherford Compounding Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Weatherford Compounding Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the day of November, 2015.
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Chairperson

Iowa Board of Pharmacy

## Copies to:

Charles K. Aris Byrne, Cardenas & Aris, LLP 7557 Rambler Road, Suite 1400 Dallas, TX 75231 ATTORNEY FOR RESPONDENT

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2<sup>nd</sup> Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

# **ADDENDUM D**

# SETTLEMENT AGREEMENT AND FINAL ORDER

DAVID KRONER, D.D.S. CSA REGISTRATION NO. 1417820 URBANDALE, IOWA

### BEFORE THE IOWA BOARD OF PHARMACY

	)	Case No. 2014-35
Re:	)	
Controlled Substance Registration of	)	SETTLEMENT AGREEMENT
DAVID KRONER, DDS	)	AND
Registration No. 1417820	)	FINAL ORDER
Respondent	)	

**COME NOW** the Iowa Board of Pharmacy ("Board") and David Kroner, DDS ("Respondent"), and enter into this Settlement Agreement and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2015) to settle a licensee disciplinary proceeding currently pending before the Board.

The allegations contained in the Order to Show Cause against the Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

- 1. Respondent holds Iowa controlled substance registration number 1417820, which is currently active.
- 2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
- 3. An Order to Show Cause concerning the Respondent and his alleged failure to renew his Controlled Substance Act registration was issued on August 26, 2014.
- 4. Respondent has chosen not to contest the charges, but 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 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.
- 6. 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 65736.
- 7. Respondent is freely and voluntarily entering into this Agreement. Respondent further 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.

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- 8. 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.
- 9. 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.
- 10. 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.
- 11. This Agreement shall not be reported to the National Practitioners Data Bank and the National Association of Boards of Pharmacy's Disciplinary Clearinghouse.
- 12. This Agreement shall not be binding as to any new complaints received by the Board.
- 13. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

#### IT IS THEREFORE ORDERED:

14. Within thirty (30) days of the Board's approval of this Settlement Agreement and Final Order, Respondent shall pay a civil penalty in the amount of \$1000. The civil penalty shall be sent to the Board's executive director. The civil penalty shall be made payable to the Treasurer of Iowa to be deposited in the State's general fund.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 26 day of AUGUST, 2015.

DAVID KRONER, DDS

Respondent

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

James Miller EDWARD 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

Craig Sieverding Davis Brown Law Firm 215 10th Street, Suite 1300 Des Moines, Iowa 50309 ATTORNEY FOR THE RESPONDENT

# **ADDENDUM E**

# SETTLEMENT AGREEMENT AND FINAL ORDER

LEEDS PHARMACY PHARMACY LICENSE NO. 227 SIOUX CITY, IOWA

#### BEFORE THE IOWA BOARD OF PHARMACY

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

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

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

- 1. Respondent's license #227 is currently active, but is on probation until January16, 2016.
- 2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
- 3. A Statement of Charges was filed against Respondent on November 19, 2014.
- 4. Respondent admits the allegations contained in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
- 5. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
- 6. Respondent is freely and voluntarily entering into this Order.
- 7. Respondent acknowledges that he has the right to be represented by counsel on this matter.
- 8. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
- 9. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

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

### IT IS THEREFORE ORDERED:

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

This Settlement Agreement and Fin for its consideration on the day	al Order is voluntarily submitted by Respondent to the Board of
	Respondent
	respondige
By his signature and Final Order on behalf of Leeds I	acknowledges he is authorized to this Settlement Agreement Pharmacy.
This Settlement Agreement and Fin	al Order is accepted by the Iowa Board of Pharmacy on the, 2015.
	a Mills
	Chairperson
	Iowa Board of Pharmacy
	400 SW Eighth Street, Suite E
	Des Moines, Iowa 50309-4688

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

> Connie Diekema FINLEY, ALT, SMITH, SCHARNBERG, CRAIG, HILMES & GAFFNEY, P.C. 699 Walnut Street, Ste. 1900 Des Moines, IA 50309 ATTORNEY FOR THE RESPONDENT

# **ADDENDUM F**

# SETTLEMENT AGREEMENT AND FINAL ORDER

KAREN BEAN
PHARMACY SUPPORT PERSON
REGISTRATION NO. 3456
CEDAR RAPIDS, IOWA

#### BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy Support Person Registration of	)	CASE NO. 2015-43
Tharmacy Support I cison Registration of	)	SETTLEMENT AGREEMENT AND FINAL ORDER
KAREN BEAN,	)	
Registration No. 3456,	)	
Respondent.	)	

**COME NOW** the Iowa Board of Pharmacy ("Board") and Karen Bean ("Respondent"), and enter into this Settlement Agreement and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2015) 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 pharmacy support person registration number 3456.
- 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 September 1, 2015.
- 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. 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.
- 6. 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.
- 7. 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.
- 8. 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.

- 9. 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.
- 10. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank, as applicable.
  - 11. This Agreement shall not be binding as to any new complaints received by the Board.
  - 12. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

#### IT IS THEREFORE ORDERED:

- 13. Respondent agrees to **VOLUNTARILY SURRENDER** her pharmacy support person registration.
- 14. 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.
- 15. Respondent may request reinstatement of her Iowa pharmacy 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.
- 16. Respondent agrees not to engage in any aspect of the practice of pharmacy until her registration has been reinstated.
- 17. 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 (2015) and Iowa Administrative Code chapter 657—36.

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

KAREN BEAN

Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the Hinday of November, 2015.

JAMES MILLER, 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, 2<sup>nd</sup> Floor Des Moines, IA 50319

# ADDENDUM G

# NOTICE OF HEARING AND STATEMENT OF CHARGES

PHARMACY CREATIONS, LLC NONRESIDENT PHARMACY LICENSE NO. 4185 RANDOLPH, NEW JERSEY

Re: Nonresident Pharmacy License of	)	CASE NO. 2015-6
PHARMACY CREATIONS, LLC License No. 4185 Respondent.	) ) )	NOTICE OF HEARING AND STATEMENT OF CHARGES

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Pharmacy Creations, LLC ("Respondent"), 540 Route 10 West, Randolph, New Jersey, 07869, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license number 4185 is currently active through December 31, 2015.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings</u>. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications</u>. 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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".

#### COUNT II FAILURE TO NOTIFY OF DISCIPLINE

Respondent is charged with failing to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"k".

#### **COUNT III**

#### FAILURE TO NOTIFY OF PHARMACY LICENSE CHANGE

Respondent is charged with failing to timely submit an application for a change in pharmacist in charge, or failing to appoint or notify the board of a temporary pharmacist in charge, in violation of 657 IAC 8.35(6)"c", pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

#### D. FACTUAL CIRCUMSTANCES

- 1. Respondent became licensed as an Iowa nonresident pharmacy in May 2013. When initially licensed, Respondent was a limited liability company co-owned by two individuals.
- 2. On October 17, 2013, the Indiana State Board of Pharmacy granted Respondent an Indiana nonresident pharmacy permit, but placed it on probation for a minimum period of 16 months. The probationary period was based on Respondent's shipment of medications into Indiana prior to licensure. Respondent reported the discipline to the Board in December 2014.
- 3. On April 1, 2014, Imprimis Pharmaceuticals Inc. acquired 100% of the membership interests of the limited liability company.
- 4. On April 22, 2014, the Ohio State Board of Pharmacy granted Respondent's Ohio nonresident pharmacy permit, but placed it on probation for 12 months and imposed a \$2000 fine. The probationary period and fine were based on Respondent's shipment of medication into Ohio prior to licensure. Respondent reported the discipline to the Board in August 2014.
- 5. The New Jersey Board of Pharmacy issued two Interim Consent Orders, on May 14, 2014, and on July 21, 2014, that related to inspection deficiencies identified by inspectors in June 2013, but neither Consent Order was disciplinary in nature. These Consent Orders were not reported to the Board.
- 6. On June 5, 2014, the North Carolina Board of Pharmacy denied Respondent's application for a North Carolina nonresident pharmacy permit. The denial was based on inspection deficiencies noted by the New Jersey Board of Pharmacy in June 2013. Respondent reported the denial to the Board in December 2014.
- 7. On September 19, 2014, the Missouri Board of Pharmacy denied Respondent's application for a Missouri nonresident pharmacy permit. The denial was based on Respondent's prior discipline. Respondent reported the denial to the Board in December 2014.
- 8. In September 2014, the Board received notification from the pharmacist in charge that he was resigning effective October 10, 2014. The Board received Respondent's renewal indicating a change in pharmacist-in-charge on December 16, 2014. The Board did not receive any information regarding the appointment of a permanent or temporary pharmacist in charge between these two dates.
- 9. On March 16, 2015, the Alabama Board of Pharmacy granted Respondent's Alabama nonresident pharmacy permit, but placed it on probation for a period of one year. The

probationary period was based on Respondent's prior discipline. Respondent reported the discipline to the Board on June 1, 2015.

- 10. On July 28, 2015, the Colorado Board of Pharmacy issued a Letter of Admonition to Respondent for failing to provide timely notification of the Alabama discipline. Respondent timely reported the discipline to the Board on August 6, 2015.
- 11. On August 4, 2015, the Texas State Board of Pharmacy granted Respondent's Texas nonresident pharmacy permit, but placed it on probation for a period of two years and imposed a \$2,200 fine. The probationary period and fine were based on prior discipline and Respondent's failure to disclose all prior discipline. Respondent timely reported the discipline to the Board on September 2, 2015.

#### 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 <u>Htw</u> day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

# ADDENDUM H

# NOTICE OF HEARING AND STATEMENT OF CHARGES

WELLS PHARMACY NETWORK LLC NONRESIDENT PHARMACY LICENSE NO. 3385 OCALA, FLORIDA

Re: Pharmacy License of WELLS PHARMACY NETWORK, LLC	)	Case Nos. 2015-37  STATEMENT OF CHARGES
License No. 3385 Respondent.	,	& NOTICE OF HEARING

**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) (2015). Respondent was issued Iowa license 3385. Respondent's license is currently active.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, before the Iowa Board of Pharmacy. 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. 8<sup>th</sup> Street, Des Moines, Iowa.

<u>Presiding Officer.</u> 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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**

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

<u>Legal Authority</u>. 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.

<u>Default.</u> 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 DISPENSING A PRESCRIPTION WITHOUT VERIFYING A VALID PATIENT-PRACTITIONER RELATIONSHIP

Respondent is charged with dispensing a prescription without verifying a valid patient-practitioner relationship in violation of Iowa Code sections 147.55(9) and 155A.13A(3) and 657 Iowa Administrative Code rules  $8.3(1)^1$ , 8.19(4), 19.3, and 36.1(4)(u).

#### Count II

# REGULARLY COMPOUNDING COMMERCIALLY AVAILABLE PRODUCTS AND/OR COMPOUNDING INORDINATE AMOUNTS OF DRUGS WHICH ARE ESSENTIALLY COPIES OF COMMERCIALLY AVAILABLE PRODUCT

Respondent is charged with regularly compounding commercially available products and/or compounding inordinate amounts of drugs which are essentially copies of commercially available product in violation of Iowa Code sections 147.55(9) and 155A.13A(3) and 657 Iowa Administrative Code rules 8.3(1), 19.3, 20.3(1), 20.3(5)(b), and 36.1(4)(u).

#### Count III

#### FAILING TO PROVIDE RECORDS TO THE BOARD IN A TIMELY MANNER

Respondent is charged with failing to provide records to the board in a timely manner in violation of Iowa Code section 147.55(9) and 155A.13A(3) and 657 Iowa Administrative Code rules 6.16(2), 8.3(1), 8.9, 19.3, and 36.1(4)(u), (ag).

<sup>&</sup>lt;sup>1</sup> Effective May 20, 2015, this rule was renumbered to rule 8.3(2).

#### Count IV

#### FAILURE TO PERFORM A PROSPECTIVE DRUG USE REVIEW

Respondent is charged with failing to perform a prospective drug use review in violation of Iowa Code sections 147.55(9) and 155A.13A(3) and 657 Iowa Administrative Code rules 8.3(1), 8.21, 19.3, 36.1(4)(u).

#### Count V

#### FAILING TO TIMELY REPORT OUT OF STATE DISCIPLINE

Respondent is charged with failing to report out of state discipline in violation of Iowa Code section 147.55(9) and 155A.3A(3) and 657 Iowa Administrative Code rule 36.1(4)(k).

#### Count VI

#### VIOLATING THE LAWS AND RULES OF ANOTHER STATE

Respondent is charged with violating the laws and rules of another state in violation of Iowa Code section 147.55(9) and 155A.3A(3) and 657 Iowa Administrative Code rule 36.1(4)(j).

#### D. FACTUAL CIRCUMSTANCES

- 1. Respondent is a non-resident pharmacy with its principle place of business at 1210 SW 33<sup>rd</sup> Avenue, Ocala, Florida 34474.
- 2. Wells Pharmacy was disciplined by the Maine Board of Pharmacy for not timely notifying that board of a change in their pharmacist-in-charge on November 6, 2014. Maine fined the Respondent \$750 for the violation.
- 3. Wells Pharmacy did not timely inform the Iowa Board of Pharmacy about the Maine discipline. Wells first reported the out-of-state discipline on their change of pharmacist-in-charge application, which was received by the Board on February 26, 2015.
- 4. Wells Pharmacy dispensed numerous prescriptions from Dr. Randall L. Sisam, whose Iowa medical license is inactive, to Iowa patients. The prescription indicates that Dr. Sisam resides in Maine, while Mr. Sisam's LinkedIn profile states that he resides in South Carolina and consults for Kingsberg Medical. Wells Pharmacy took no action to ensure that a valid, preexisting patient-prescriber relationship existed.
- 5. Wells Pharmacy compounded large quantities of testosterone in grape seed oil. Testosterone is commercially available in sesame seed oil. Individual patients would receive small portions of the compounded medication.
- 6. Wells Pharmacy compounded large quantities of testosterone cypionate in sesame seed oil. This product is commercially available in cottonseed oil. Individual patients would receive small portions of the compounded medication.

- 7. Wells Pharmacy did not perform a drug use review on prescriptions dispensed in Iowa, resulting in duplicative therapy.
- 8. On May 8, 2015, the Board requested copies of 32 prescriptions that were dispensed into Iowa from April 1, 2014 to April 1, 2015. Respondent was given until May 15, 2015 to provide the Board copies of the requests prescriptions. Respondent did not provide the requested records until May 27, 2015.

#### 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 36.6. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

#### F. PROBABLE CAUSE FINDING

On this the 3<sup>rd</sup> day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

JAMES MILLER, 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 I**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

DOWNING LABS, LLC NONRESIDENT PHARMACY LICENSE NO. 4030 DALLAS, TEXAS

Re: Nonresident Pharmacy License of	)	CASE NO. 2015-48
DOWNING LABS, LLC License No. 4030 Respondent.	) ) )	NOTICE OF HEARING AND STATEMENT OF CHARGES

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Downing Labs, LLC ("Respondent"), 4001 McEwen Road, Suite 110, Dallas, Texas 75244, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license number 4030 is currently active through December 31, 2015.

#### A. TIME, PLACE, AND NATURE OF HEARING

<u>Hearing.</u> A disciplinary contested case hearing shall be held on January <u>/2</u>, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications</u>. 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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".

#### COUNT II FAILURE TO NOTIFY OF DISCIPLINE

Respondent is charged with failing to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"k".

#### **COUNT III**

#### FAILURE TO SUBMIT APPLICATION FOR PHARMACY LICENSE CHANGES

Respondent is charged with failing to timely submit an application for a change in ownership or name in violation of 657 IAC 8.35(6), pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

#### D. FACTUAL CIRCUMSTANCES

- 1. Respondent became licensed as an Iowa nonresident pharmacy in October 2011. When initially licensed, Respondent was operated under the name NuVision Pharmacy, Inc. and was owned by JDB Trust.
- 2. From approximately May 1, 2013, until approximately January 15, 2014, Ashley Downing was the sole director for NuVision Pharmacy, Inc.
- 3. On January 15, 2014, Respondent's name changed from NuVision Pharmacy, Inc. to Downing Labs, LLC, and ownership was transferred from JDB Trust to Christopher and Ashley Downing. The Texas State Board of Pharmacy issued Respondent a Texas pharmacy license in the name of Downing Labs on June 25, 2014.
- 4. In September, 2014, the Food and Drug Administration requested that Respondent issue a recall of all sterile drug products based on findings from an inspection conducted from June 3 through July 16, 2014, and based on testing performed on product lots produced between June 2013 and May 2014. Respondent declined to recall its sterile drug products.
- 5. On July 31, 2014, the Michigan Board of Pharmacy issued an Order of Summary Suspension, which immediately suspended Respondent's Michigan pharmacy and controlled substance licenses. The suspension was based on Respondent's refusal to initiate a recall of its compounded products. On June 10, 2015, the Michigan Board of Pharmacy issued a Consent Order that dissolved the summary suspension and indefinitely suspended Respondent until such time as it successfully completes an inspection by the National Association of Boards of Pharmacy. To date, Respondent's Michigan pharmacy license has the status "Lapsed Suspended."
- 6. On October 14, 2014, the Board received a renewal application from Respondent, which also indicated it was an application for a name change from NuVision Pharmacy, Inc. to Downing Labs, LLC, and an ownership change from JDB Trust to Christopher and Ashley Downing. The application did not disclose any discipline.
- 7. On February 2, 2015, the Virginia Board of Pharmacy issued an Order of Mandatory Suspension, which immediately suspended Respondent's Virginia non-resident pharmacy registration. The suspension was based on the Michigan Order. To date, Respondent's Virginia non-resident pharmacy registration is suspended.
  - 8. None of the disciplinary orders issued were timely 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 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 \\	day	of November,	2015,	the	Iowa	Board	of	Pharmacy	found	probable
cause to file this Notice	e of F	Hearing and Sta	tement	t of (	Charge	es.		3		1

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

#### PROOF OF SERVICE

The u	ndersigned certifies that the foregoing instrument was	served	upon Respondent to the above cause by:
1	personal service certified mail, return receipt requested	<del>(1)</del>	first class mail facsimile other
on the	day of November, 2015.		
I decl	are that the statements above are true to the best of my	inform	nation, knowledge and belief.

Debbie S. Jorgenson

# **ADDENDUM J**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

KEYSOURCE MEDICAL INC. WHLESALE DRUG LICENSE NO. 6272 CINCINNATI, OHIO

Re: Wholesale Drug License of	)	CASE NO. 2015-49
KEYSOURCE MEDICAL INC.	)	NOTICE OF HEARING AND STATEMENT OF CHARGES
License No. 6272	)	
Respondent.	)	

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against KeySource Medical Inc. ("Respondent"), 7820 Palace Drive, Cincinnati, Ohio 45249, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa wholesale drug license number 6272 is currently active through December 31, 2015.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications</u>. 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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.17(2), and 657 IAC 17.18 and 36.1(4)"ad".

### COUNT II FAILURE TO NOTIFY OF DISCIPLINE

Respondent is charged with failing to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction, pursuant to Iowa Code section 155A.17(2), and 657 IAC 17.18 and 36.1(4)"k".

## D. FACTUAL CIRCUMSTANCES

- 1. Respondent became licensed as an Iowa drug wholesaler in January 2005.
- 2. In June 2011, the U.S. Drug Enforcement Administration issued an Order to Show Cause and immediate suspension of Respondent's DEA registration. In September 2011, Respondent surrendered its DEA registration. The Board did not receive notice of the surrender from Respondent until November 14, 2011.
- 3. In December 2012, the Indiana Board of Pharmacy placed Respondent's Indiana wholesaler license on indefinite probation. The probation was withdrawn on February 19, 2015. The Board did not receive notice of the Indiana discipline from Respondent.

#### 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 44 day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

#### PROOF OF SERVICE

The undersigned certifies that the foregoing instru	ent was served upon Respondent	to the above cause by:
( ) personal service certified mail, return receipt requested	first class mail facsimile other	
on the 5 th day of November, 2015.		
I declare that the statements above are true to the	st of my information, knowledge	and belief.
	Debbie S. Jorgenson	Lu

## ADDENDUM K

# NOTICE OF HEARING AND STATEMENT OF CHARGES

ADAM D. CASTLE
PHARMACY TECHNICIAN REGISTRATION NO. 19952
CLINTON, IOWA

Re: Certified Technician Registration of	)	CASE NO. 2015-67
ADAM CASTLE Registration No. 19952 Respondent.	)	NOTICE OF HEARING AND STATEMENT OF CHARGES

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Adam Castle ("Respondent"), 236 3<sup>rd</sup> Avenue N, Clinton, IA 52732, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa certified pharmacy technician registration number 19952 is currently active through July 31, 2016.

#### A. TIME, PLACE, AND NATURE OF HEARING

<u>Hearing.</u> A disciplinary contested case hearing shall be held on January <u>17</u>, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings</u>. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference</u>. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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 UNETHICAL CONDUCT

Respondent is charged with unethical conduct in violation of 657 IAC 3.28(4), pursuant to Iowa Code sections 147.55(3), (9), and 155A.6A(5), and 657 IAC 3.30, 36.1(4)"c", and "u".

#### D. FACTUAL CIRCUMSTANCES

While employed as a pharmacy technician, Respondent sent inappropriate text messages regarding controlled substances to an individual.

#### 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 4 day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

#### **PROOF OF SERVICE**

The t	undersigned certifies that the foregoing instrument w	as served	d upon Respondent to the above cause by
4	personal service certified mail, return receipt requested	7)	first class mail facsimile other
on the	e <u>th</u> day of November, 2015.		

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

Debbie S. Jorgenson

# **ADDENDUM L**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

LISA A. GRAY
PHARMACIST LICENSE NO. 18401
URBANDALE, IOWA

Re: ) Pharmacist License of )	Case Nos. 2015-72
LISA A. GRAY  License No. 18401,  Respondent.	STATEMENT OF CHARGES & NOTICE OF HEARING

**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) (2015). Respondent was issued Iowa license 18401. Respondent's license is currently active.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January <u>12</u>, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications</u>. 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**

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

<u>Legal Authority</u>. 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.

<u>Default.</u> 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 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 Iowa Administrative Code rule 657-36.1(4)(c).

## Count II VIOLATION OF A STATUTE OR LAW RELATED TO THE PRACTICE OF PHARMACY

Respondent is charged with violating a statute or law of this state, another state, or the United States which relates to the practice of pharmacy, namely the Health Insurance Portability and Accountability Act, 42 United States Code 1320d *et seq.*, in violation of Iowa Code sections 147.55(9) and 155A.12(8) and Iowa Administrative Code rule 657—36.1(4)(j).

#### D. FACTUAL CIRCUMSTANCES

1. Respondent is a licensed pharmacist in the State of Iowa. Her license is currently active, and scheduled to expire on June 30, 2016.

- 2. Between February 14, 2015 and March 29, 2015, while working at Iowa Methodist Medical Center, Respondent accessed her own medical records and the medical records of seven other individuals.
  - 3. There was no professional reason or purpose for Respondent's accessing these files.

## 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 3rd day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

JAMES MILLER, 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 M**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

REMEDIES INC.
PHARMACY LICENSE NO. 611
SIBLEY, IOWA

Re:	)	Case Nos. 2015-81
Pharmacy License of	)	
REMEDIES, INC.	)	STATEMENT OF CHARGES
License No. 611	)	& 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) (2015). Respondent was issued Iowa license 611. Respondent's license is currently active.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January <u>12</u>, 2016, before the Iowa Board of Pharmacy. 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. 8<sup>th</sup> Street, Des Moines, Iowa.

<u>Presiding Officer.</u> 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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**

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

<u>Legal Authority</u>. 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.

<u>Default.</u> 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 ENGAGING IN UNETHICAL CONDUCT

Respondent is charged with engaging in unethical conduct in violation of Iowa Code sections 147.55(3) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 8.3(1) $^{1}$ , 8.11, 19.3, and 36.1(4)(c),(u).

# Count II DISPENSING A SCHEDULE II CONTROLLED SUBSTANCE PURSUANT TO A FACSIMILE

Respondent is charged with dispensing a schedule II controlled substance pursuant to a facsimile in violation of Iowa Code sections 147.55(9) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 8.3(1), 10.27(1), 21.12, and 36.1(4)(u).

#### D. FACTUAL CIRCUMSTANCES

- 1. Respondent is an Iowa-licensed pharmacy with its principle place of business at 936 First St., NE, Sibley, Iowa 51249.
- 2. Between March 17, 2013 and August 11, 2014, Remedies submitted 19 claims to Iowa Medicaid for Dexedrine 10 mg capsules. Dexedrine is a Schedule II, non-narcotic, name brand medication.

<sup>&</sup>lt;sup>1</sup> Effective May 20, 2015, this rule was renumbered to rule 8.3(2).

- 3. An ARCOS (Automation of Reports and Consolidated Orders System) report for Remedies shows that the pharmacy purchased Dexedrine on three occasions during this same time period.
- 4. An ARCOS reports for Remedies shows that the pharmacy purchased the generic version of Dexedrine—d-amphetamine sulfate dibasic 10mg SR—on 13 occasions during this same time period.
- 5. While Iowa Medicaid was billed for Dexedrine on 19 occasions, prescription hard-copy labels show that the generic medication was dispensed on 16 of the 19 occassions.
  - 6. Remedies' processing software, Speedscript, confirms this discrepancy.
- 7. The total payment to Remedies for these 16 claims was \$38,559.97. The payment to Remedies for the product actually dispensed should have been approximately \$16,118.75.
- 8. On one occasion, the Respondent filled one of these Dexedrine prescriptions pursuant to a fax transmission without obtaining the hard-copy prescription.

#### 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 36.6. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

#### F. PROBABLE CAUSE FINDING

On this the 3<sup>rd</sup> day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

JAMES MILLER, 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 N**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

ALAN R. HOPPE PHARMACIST LICENSE NO. 18117 SIBLEY, IOWA

Re: Pharmacist License of	)	Case No. 2015-81
ALAN HOPPE	)	STATEMENT OF CHARGES
License No. 18117, Respondent.	)	& NOTICE OF HEARING

**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 18117. Respondent's license is currently active.

#### A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January <u>12</u>, 2016, before the Iowa Board of Pharmacy. 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. 8<sup>th</sup> Street, Des Moines, Iowa.

<u>Presiding Officer.</u> The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals <u>make</u> 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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**

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

<u>Legal Authority</u>. 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.

<u>Default.</u> 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), 1.11, 10.27(1), 1.12, and 1.11, and 1.11, 1.11, 1.11, 1.11, and 1.11

## Count II ENGAGING IN UNETHICAL CONDUCT

Respondent is charged with engaging in unethical conduct in violation of Iowa Code sections 147.55(3) and 155A.12(2)and 657 Iowa Administrative Code rules 8.11 and 36.1(4)(c),(u).

#### D. FACTUAL CIRCUMSTANCES

- 1. Respondent is the owner and pharmacist-in-charge of Remedies Pharmacy, which operates at 936 First St., NE, Sibley, Iowa 51249.
- 2. Between March 17, 2013 and August 11, 2014, Remedies submitted 19 claims to Iowa Medicaid for Dexedrine 10 mg capsules. Dexedrine is a Schedule II, non-narcotic, name brand medication.

<sup>&</sup>lt;sup>1</sup> Effective May 20, 2015, this rule was renumbered to rule 8.3(2).

- 3. An ARCOS (Automation of Reports and Consolidated Orders System) report for Remedies shows that the pharmacy purchased Dexedrine on three occasions during this same time period.
- 4. An ARCOS reports for Remedies shows that the pharmacy purchased the generic version of Dexedrine—d-amphetamine sulfate dibasic 10mg SR—on 13 occasions during this same time period.
- 5. While Iowa Medicaid was billed for Dexedrine on 19 occasions, prescription hard-copy labels show that the generic medication was dispensed on 16 of the 19 occasions.
  - 6. Remedies' processing software, Speedscript, confirms this discrepancy.
- 7. The total payment to Remedies for these 16 claims was \$38,559.97. The payment to Remedies for the product actually dispensed should have been approximately \$16,118.75.
- 8. On one occasion, the Remedies filled one of these Dexedrine prescriptions pursuant to a fax transmission without obtaining the hard-copy prescription.

#### 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 36.6. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

#### F. PROBABLE CAUSE FINDING

On this the 3rd day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

JAMES MILLER, 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 O**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

MINNESOTA INDEPENDENT COOPERATIVE, INC. WHOLESALE DRUG LICENSE NO. 6464 EAGAN, MINNESOTA

# BEFORE THE IOWA BOARD OF PHARMACY

Re: Wholesale Drug License of	)	CASE NO. 2015-100  NOTICE OF HEARING AND
MINNESOTA INDEPENDENT COOPERATIVE, INC. License No. 6764 Respondent.	) ) )	STATEMENT OF CHARGES

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Minnesota Independent Cooperative, Inc. ("Respondent"), 2980 Commers Drive, Suite 200, Eagan, Minnesota 55121, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa wholesale drug license number 6764 is currently active through December 31, 2015.

# A. TIME, PLACE, AND NATURE OF HEARING

<u>Hearing.</u> A disciplinary contested case hearing shall be held on January <u>/2</u>, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications</u>. 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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.17(2), and 657 IAC 17.18 and 36.1(4)"ad".

# COUNT II FAILURE TO NOTIFY OF CLOSING

Respondent is charged with failing to provide written notification of closing in violation of 657 IAC 17.3(5), pursuant to Iowa Code section 155A.17(2) and 657 IAC 17.18 and 36.1(4)"u".

### D. FACTUAL CIRCUMSTANCES

- 1. Respondent became licensed as an Iowa drug wholesaler in 2008.
- 2. In April 2012, the Minnesota Board of Pharmacy disciplined Respondent for purchasing drugs from a company that was not properly licensed. Respondent paid a \$10,000 civil penalty.
- 3. In May 2015, Respondent and its owners were federally indicted in Ohio for allegedly purchasing drugs from illegal sources, providing false pedigree paperwork to purchasers, and deliberately misbranding drugs.
- 4. On or around May 19, 2015, a surveyor with the Minnesota Board of Pharmacy visited Respondent's location and found it to be deserted.
  - 5. Respondent's current license status in its home state of Minnesota is listed as "closed."
  - 6. The Board did not receive any notifications from Respondent regarding closure.

### 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  $4 + \sqrt{1}$  day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

# **ADDENDUM P**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

HY-VEE PHARMACY 1068 PHARMACY LICENSE NO. 811 CHEROKEE, IOWA

# **BEFORE THE IOWA BOARD OF PHARMACY**

Re: Pharmacy License of	)	CASE NO. 2015-110  NOTICE OF HEARING AND
HY-VEE PHARMACY 1068	)	STATEMENT OF CHARGES
License No. 811	)	
Respondent.	)	

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Hy-Vee Pharmacy 1068 ("Respondent"), 800 N Second Street, Cherokee, IA 51012, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacy license number 811 is currently active through December 31, 2015.

# A. TIME, PLACE, AND NATURE OF HEARING

<u>Hearing.</u> A disciplinary contested case hearing shall be held on January <u>/2</u>, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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 ESTABLISH EFFECTIVE CONTROLS AGAINST DIVERSION

Respondent is charged with failing to establish effective controls against diversion of prescription drugs in violation of 657 IAC 6.7 and 10.15, pursuant to Iowa Code section 155A.15(2)"i" and 657 IAC 36.1(4)"u".

# COUNT II FAILURE TO KEEP RECORDS

Respondent is charged with failing to keep records as required by law, specifically supplier invoices, in violation of 657 IAC 8.9(1), pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

# COUNT III FAILURE TO MAINTAIN RECORDS

Respondent is charged with failing to properly maintain records, specifically failing to have a responsible person clearly record the date of receipt of controlled substances on supplier invoices, in violation of 657 IAC 8.9(1), pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

# COUNT IV FAILURE TO MAINTAIN SEPARATE RECORDS

Respondent is charged with failing to maintain records of controlled substances listed in Schedules III, IV, and V separately from all other records or in such a form that the required information is readily retrievable from the ordinary business records, in violation of 657 IAC 10.34(2), pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

# D. FACTUAL CIRCUMSTANCES

- 1. An audit of Respondent's records from September 2013 through April 2015 indicated the following shortages: approximately 5800 tablets of hydrocodone-containing products, approximately 830 tablets of Lorazepam, and approximately 469 tablets of Diazepam.
  - 2. Respondent attributes the losses to employee pilferage.
- 3. For the same audit period, Respondent did not have invoices for the following: approximately 25,000 tablets of hydrocodone-containing products, approximately 30,300 tablets of Lorazepam, and approximately 2,000 tablets of Diazepam.
- 4. A review of Respondent's 2015 invoices for controlled substances revealed the following:
  - a. For multiple months, Respondent's invoices for controlled substances in Schedules III, IV, and V were not maintained separately from other prescription drug invoices.
  - b. In one month, several of Respondent's invoices for controlled substances were not signed or dated by the person responsible for receiving the order.
  - c. Respondent had possession of two original controlled substances invoices for another Hy-Vee pharmacy.

# 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 44 day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor 1305 E. Walnut St. Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

# ADDENDUM Q

# NOTICE OF HEARING AND STATEMENT OF CHARGES

DAWN RUEHLE PHARMACIST LICENSE NO. 16618 CHEROKEE, IOWA

# BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of	)	CASE NO. 2015-110
DAWN RUEHLE License No. 16618 Respondent.	) ) )	NOTICE OF HEARING AND STATEMENT OF CHARGES

**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Dawn Ruehle ("Respondent"), 1828 480<sup>th</sup> Street, Cherokee, Iowa 51012, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacist license number 16618 is currently active through June 30, 2017.

# A. TIME, PLACE, AND NATURE OF HEARING

<u>Hearing.</u> A disciplinary contested case hearing shall be held on January  $\frac{12}{2}$ , 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference</u>. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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 THE DUTIES OF PHARMACIST IN CHARGE

Respondent is charged with violating the duties of the pharmacist in charge, specifically 657 IAC 6.2(12), (13), and (15) (2014), pursuant to Iowa Code sections 147.55(9), 155A.12(1), (4), and 657 IAC 36.1(4)"u" and "ac".

# D. FACTUAL CIRCUMSTANCES

1. Respondent was the pharmacist in charge at Hy-Vee Pharmacy 1068 in Cherokee, Iowa from May 31, 2014 through September 2014.

2. As pharmacist in charge, Respondent is responsible for the violations of Iowa pharmacy laws and regulations identified in the Statement of Charges filed against Hy-Vee Pharmacy 1068 in case number 2015-110, which are incorporated by reference.

# 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 <u>Htn</u> day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor 1305 E. Walnut St. Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

# **ADDENDUM R**

# NOTICE OF HEARING AND STATEMENT OF CHARGES

PRIORITY PHARMACEUTICALS, INC. WHOLESALE DRUG LICENSE NO. 5989 SAN DIEGO, CALIFORNIA

# BEFORE THE IOWA BOARD OF PHARMACY

PRIORITY PHARMACEUTICALS, ) STATEMENT OF CHARGES INC. ) License No. 5989 ) Respondent. )	INC. License No. 5989		CASE NO. 2015-115  NOTICE OF HEARING AND STATEMENT OF CHARGES
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COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Priority Pharmaceuticals Inc. ("Respondent"), 4040 Sorrento Valley Blvd., Suite D, San Diego, California 92121, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa wholesale drug license number 5989 is currently active through December 31, 2015.

# A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, 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 the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

<u>Filing of Pleadings.</u> Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference</u>. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. 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.

<u>Prosecution.</u> 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 2<sup>nd</sup> 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.

<u>Communications.</u> 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

<u>Jurisdiction.</u> The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority.</u> 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 657 IAC 36.

<u>Default.</u> 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.17(2), and 657 IAC 17.18 and 36.1(4)"ad".

### D. FACTUAL CIRCUMSTANCES

1. Respondent became licensed as an Iowa drug wholesaler in 2001.

2. Effective March 13, 2015, Respondent surrendered its California Wholesaler License through a Stipulated Order to resolve a pending disciplinary accusation issued by the California Board of Pharmacy in September 2012.

# 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 4th day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, Chairperson Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier Assistant Attorney General Hoover Building, 2<sup>nd</sup> Floor Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

# **ADDENDUM S**

# ORDER ACCEPTING SURRENDER OF PHARMACIST LICENSE

STEVEN J. JOHNSON PHARMACY LICENSE NO. 18278 CLARINDA, IOWA

# **BEFORE THE BOARD OF PHARMACY**

# OF THE STATE OF IOWA

D	`	ODDED
Re:	)	ORDER
Pharmacist License of	)	ACCEPTING
STEVEN J. JOHNSON	)	SURRENDER OF
License No. 18278	)	PHARMACIST
	)	LICENSE

COMES NOW, James Miller, Chairperson of the Iowa Board of Pharmacy, on the day of November, 2015, and declares that:

- 1. On October 22, 2015, Respondent executed a voluntary surrender of his Iowa Pharmacist License number 18278.
- 2. On November 3, 2015, the Board reviewed Respondent's voluntary surrender of his Pharmacist License and agreed to accept it.

This surrender, pursuant to 657 Iowa Administrative Code § 36.15, shall be considered a revoked license with respect to any future request for reinstatement. Any request for reinstatement will be handled under terms established by 657 Iowa Administrative Code § 36.13.

*WHEREFORE*, it is hereby ordered that Respondent's voluntary surrender of his Iowa Pharmacist License number 18278 is hereby accepted.

AMES MILLER, Chairperson

# **VOLUNTARY SURRENDER OF PHARMACIST LICENSE**

I, Steven J. Johnson, a resident of Clarinda, of my own free will and without any mental reservation and not as a result of any inducement, promise or threat on the part of anyone, do hereby voluntarily surrender my pharmacist license in the State of Iowa, number 18278, to the Iowa Board of Pharmacy, for an indefinite period of time. This surrender of license shall become effective upon the signature of the licensee, Steven J. Johnson, being affixed to this voluntary surrender document.

I, Steven J. Johnson, of my own free will and without any mental reservation and not as a result of any inducement, promise or threat given or made by any representative, officer, or employee of the Iowa Board of Pharmacy, or of any other state official, do hereby further acknowledge that by voluntarily signing this surrender statement that I am knowingly and willingly giving up the exercise of the following legal rights:

- (1) My right to a formal hearing before the Iowa Board of Pharmacy on the matter of my continued licensure as a pharmacist pursuant to Chapter 155A, Code of Iowa (2015).
- (2) My right to be represented by an attorney in preparation for and during such formal hearing before the Iowa Board of Pharmacy.
- (3) My right to submit evidence and to have witnesses called on my own behalf at such formal hearing.
- (4) My right to be represented by an attorney in this matter at this time.

I, Steven J. Johnson, do hereby acknowledge that pursuant to 657 Iowa Administrative Code section 36.15, a pharmacist license which has been voluntarily surrendered shall be considered a revocation of license with respect to a request for reinstatement, which will be handled under the terms established by 657 Iowa Administrative Code section 36.13, which provides as follows:

**657—36.13 (17A,124B,147,155A,272C) Reinstatement.** Any person whose license to practice pharmacy or to operate a pharmacy or whose wholesale drug license or permit to handle precursor substances or whose pharmacist-intern registration, pharmacy technician registration, or pharmacy support person registration has been revoked or suspended shall meet the following eligibility requirements for reinstatement:

**36.13(1)** *Prerequisites.* The individual shall satisfy all terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license, registration, or permit was voluntarily surrendered, an initial application for reinstatement may not be made

until one year has elapsed from the date of the board's order or the date of voluntary surrender.

**36.13(2)** Pharmacist license revoked or surrenderedexaminations required. A person whose license to practice pharmacy was revoked or voluntarily surrendered must successfully pass the North American Pharmacist Licensure Examination (NAPLEX) or an equivalent examination as determined by NABP and the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition.

36.13(3) Proceedings. The respondent shall initiate all proceedings for reinstatement by filing with the board an application for reinstatement of the license, registration, or permit. The application shall be docketed in the original case in which the license, registration, or permit was revoked, suspended, or surrendered. All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board. The board and the respondent may informally settle the issue of reinstatement. The respondent may choose to have an informal reinstatement conference before the board, as provided in rule 657—36.14(17A,124B,147,155A,272C).

36.13(4) Burden of proof. An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension no longer exists and that it will be in the public interest for the license, registration, or permit to be reinstated. The burden of proof to establish such facts shall be on the respondent.

36.13(5) Order. An order for reinstatement shall be based upon a decision that incorporates findings of facts and conclusions of law and shall be based upon the affirmative vote of a quorum of the board. This order shall be available to the public as provided in 657—Chapter 14.

I, Steven J. Johnson, hereby further acknowledge that I shall not engage in any of the practices or aspects of a pharmacist in the State of Iowa for which a license is required.

 $\frac{10 / 22 / 15}{\text{Date of signature}}$ 

# **ADDENDUM T**

# FINDINGS OF FACT, CONCLUSIONS OF LAW, DECISION AND ORDER

AMANDA LATTA
PHARMACIST LICENSE NO. 19669
SPRINGVILLE, IOWA

### BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:	)	
	)	Docket No. 2011-43
Request for Reinstatement of	)	DIA No. 15PHB019
Pharmacist License	)	
AMANDA LATTA	)	
License No. 19669,	)	FINDINGS OF FACT,
~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	)	CONCLUSIONS OF LAW,
Respondent.	)	DECISION, AND ORDER
1	ĺ	,
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### STATEMENT OF THE CASE

On September 1, 2015, a hearing was held before the Iowa Board of Pharmacy (Board) on the application for reinstatement filed by Respondent Amanda Latta. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratias; Jason Hansel; Judith Trumpy; Sharon Meyer; and Edward McKenna. Respondent appeared and was self-represented. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of Respondent, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

### THE RECORD

The record includes Respondent's July 19, 2015 e-mail correspondence requesting reinstatement; the Notice of Hearing; the March 7, 2012 Notice of Hearing and Statement of Charges; the April 27, 2012 Stipulation and Consent Order; and State's Exhibits 1 through 19.

# FINDINGS OF FACT

In 2002, Respondent Amanda Latta was issued pharmacist license number 19669. On March 7, 2012, the Board issued a Statement of Charges alleging that Latta had admitted to a history of alcohol and prescription medication abuse, along with diversion of hydrocodone. The Statement of Charges further alleged that Respondent had entered into a contract with the Iowa Pharmacist Recovery Network (IPRN), but did not follow through with her contractual responsibilities. Additionally, the Board alleged that Respondent's health care providers do not recommend that she be employed where she would handle controlled substances. (Exh. 5).

On April 27, 2012, the Board entered a Stipulation and Consent Order resolving the then-pending disciplinary proceeding. The order resulted in the indefinite suspension

of Latta's pharmacist license and set forth terms upon which the suspension could be terminated. Specifically, the order provides that in order to terminate the suspension, Latta must: 1) obtain a complete physical and mental health evaluation, including a substance abuse evaluation, from a physician/treatment provider pre-approved by the Board; 2) deliver to the Board a written, fully documented, and current physical and mental health evaluation, including a substance abuse evaluation, which concludes that Latta is mentally and physically fit to practice pharmacy, including an assessment of Latta's ability to cope with the presence of controlled substances in the pharmacy setting; and 3) permit the Board complete access to her medical records, including records of substance abuse evaluation and treatment. The order goes on to indicate that at such time that Latta can satisfy the conditions for termination of the suspension, a five-year period of probation with specified terms shall commence. (Exh. 6).

On July 19, 2015, Latta submitted an e-mail to the Board requesting an appearance for the Board to consider termination of her indefinite suspension. (Exh. 1).

From March through May 2011, Latta completed inpatient treatment at Hazelden Addiction Treatment Center. During that time period, she self-reported substance abuse to the Board and to IPRN. Latta attended Alcoholic Anonymous (AA) after release from Hazelden and relapsed with alcohol in August 2012 and August 2013. Latta's last use of alcohol was on August 26, 2013 and her last misuse of prescription drugs was on October 17, 2013. (Latta testimony; Exh. 18).

After her last relapse with alcohol, Latta attended St. Luke's relapse prevention program from July through September 2013. Latta has been regularly attending AA meetings since September 2013 and has been working with her current sponsor since April 2014. In March 2015, Latta became an AA sponsor. Additionally, Latta is the general service representative for her home AA group. She attends at least three AA meetings per week. (Latta testimony; Exh. 18).

Additionally, Latta re-signed a contract with IPRN in August 2014 and attends monthly meetings. In June 2015, Latta attended the APhA Institute on Alcoholism and Drug Dependencies with a scholarship from the Iowa Pharmacy Association. Latta currently has a job offer to be a monitor for IPRN. In addition, Latta has attended meetings every other week of the University of Iowa Professionals Program Aftercare Group since November 2014. (Latta testimony; Exh. 18).

Latta submitted an August 14, 2015 physical evaluation from her primary health care provider, physician assistant Tod Walker. Walker notes that he provides primary care for Walker, but she receives mental health care from Dr. Mungala and Cher Stephenson, LISW. With regard to Latta's chronic back pain, Walker indicates that this condition has been clinically stable and occasional exacerbations are manageable without the use of narcotics. Latta is working with a pain clinic to manage her chronic pain and, as part of that pain management, is receiving steroid injections, physical therapy, and massage therapy. (Exh. 7, pp. 52-53; Latta testimony).

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Latta also submitted an August 6, 2015 Visit Summary from Dr. Jill Liesveld with University of Iowa Hospitals & Clinics Behavioral Health Services. Dr. Liesveld noted that Latta has been sober since October 27, 2013. Dr. Liesveld opined that Latta can safely return to working as a pharmacist with monitoring through IPRN. (Exh. 14, pp. 73-80).

An August 7, 2015 letter from Cher Stephenson, LMHC, states that Latta self-initiated counseling with Stephenson in July 2014 as part of her treatment program to manage symptoms of mental health issues and to augment her substance abuse recovery. Stephenson states that over the past year Latta has significantly improved symptom recognition and developed a variety of skills to address the symptoms she is experiencing at any particular time. Stephenson also notes that Latta is open to asking for and accepting help from those in her support team, including Stephenson and primary physician, psychiatrist, AA sponsor and other members, spouse, family members, and church community. (Exh. 16, p. 87).

# **CONCLUSIONS OF LAW**

The Board's regulations regarding reinstatement provide, in relevant part:

**657-36.13 Reinstatement.** Any person whose license to practice pharmacy . . . has been revoked or suspended shall meet the following eligibility requirements for reinstatement:

**36.13(1)** Prerequisites. The individual shall satisfy all terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license, registration, or permit was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the board's order or the date of voluntary surrender.

**36.13(4)** *Burden of proof.* An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension no longer exists and that it will be in the public interest for the license, registration, or permit to be reinstated. The burden of proof to establish such facts shall be on the respondent.

The Board's rules place a heavy burden on persons seeking reinstatement of a revoked or surrendered license. In this instance, the Board concludes that Latta has met this burden. Latta was candid in acknowledging and taking responsibility for the actions that resulted in her suspension. Her own testimony and the documents submitted by her health care providers and her mental health counselor demonstrate that she has committed herself fully to the recovery process and continues to actively participate in a

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significant way in AA and other structured activities related to recovery, including monitoring through the IPRN.

Latta has fully satisfied the terms the Board laid out in the April 2012 settlement agreement. The evaluations Latta submitted demonstrate that she is mentally and physically fit to practice pharmacy, taking into account her prior substance abuse issues. Latta has demonstrated, by a preponderance of the evidence, that the basis for the suspension no longer exists and that it is in the public interest for her license to be reinstated, subject to the probationary terms outlined in this order.

# **DECISION AND ORDER**

IT IS THEREFORE ORDERED that upon submission of verification of the required continuing education and payment of the applicable fee, Respondent's pharmacist license number 19669 shall be REINSTATED. Respondent's license shall immediately be placed on PROBATION for a term of five years.

IT IS FURTHER ORDERED that Respondent's probation shall be subject to the following terms and conditions:

- A. Respondent shall inform the Board, in writing, of any change of home address, place of employment, home telephone number, or work telephone number, within ten days of such a change.
- B. Respondent shall report to the Board quarterly, in writing. The report shall include Respondent's place of employment, current address, Respondent's most recent efforts to comply with the terms of probation, and any further information deemed necessary by the Board from time to time. The reports shall be filed no later than March 5, June 5, September 5, and December 5 of each year of Respondent's probation.
- C. Respondent shall notify all employers and prospective employers (no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by this reinstatement order.
- D. Within 15 days of undertaking new employment as a pharmacist, Respondent shall cause her pharmacy employer, and any pharmacist-in-charge she works under, to report to the Board in writing acknowledging that the employer and the pharmacist-in-charge have read this document and understand it.
- E. Upon her return to active pharmacy practice and during the time period of her probation, Respondent's PIC shall submit quarterly reports to the Board. The reports shall be filed no later than March 5, June 5, September 5, and December 5 of each year of Respondent's active pharmacy practice while her probation is still in effect.

- F. Respondent is prohibited from serving as a pharmacist-in-charge and from ownership of a pharmacy.
- G. During the first six months of employment during probation, Respondent shall not work more than 24 hours per week. Following successful completion of six months of employment, Respondent may request permission from the Board to work additional hours per week.
- H. Respondent shall appear informally before the Board, upon the request of the Board, for the purpose of reviewing her performance as a pharmacist during Respondent's probationary period. Respondent shall be given reasonable notice of the date, time, and place for the appearances.
- I. Respondent shall obey all federal and state laws, rules, and regulations related to the practice of pharmacy.
- J. Respondent shall not possess or use alcohol or any controlled substance or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for Respondent by a licensed, treating physician or other qualified treating health care provider. Respondent shall inform any treating physician or treating health care provider of her medical history, including any history of chemical dependency.
- K. Respondent shall provide witnessed blood, hair or urine specimens on demand by the Board or its agents. The specimens shall be used for alcohol and drug screening, and to verify Respondent's compliance with this order and any drug therapy ordered by Respondent's physician or treatment provider. All costs related to the analysis of such specimens shall be paid by Respondent.
- L. To facilitate performance of the preceding paragraph, Respondent shall report to and provide a specimen to any health care provider specified by the Board said health care provider to be located in reasonable proximity to Respondent on the same day that the Board provides notice that a specimen is required. Respondent agrees to cooperate with the Board in establishing a specimen testing program through National Toxicology Services. Respondent shall sign all necessary releases to allow National Toxicology Services or any other testing facility to disclose to the Board her medical information, including test results, generated by Respondent's contact with the facility.
- M. Respondent shall promptly provide, upon request of an agent of the Board, copies of or access to all her medical records.
- N. Respondent shall ensure that the health care provider managing her chronic pain submits quarterly reports to the Board regarding her pain management. The reports shall be filed no later than March 5, June 5, September 5, and December 5 of each year of Respondent's active pharmacy practice while her probation is still in effect.

- O. Respondent shall attend and participate in Alcoholics Anonymous (AA), Narcotics Anonymous (NA), or a similarly structured support group on a regular weekly basis and shall maintain documentation of her attendance, which shall be included with her quarterly reports. Respondent shall maintain her relationship with her AA sponsor.
- P. Respondent shall not supervise any registered pharmacist-intern and shall not perform any of the duties of a pharmacy preceptor.
- Q. Respondent shall participate in the Iowa Pharmacy Recovery Network (IPRN) program, under the direct support of a pharmacist advocate.
- R. Should Respondent violate or fail to comply with any of the terms and conditions of probation, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacist license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.

Dated this 4th day of November, 2015

James Miller

Chairperson, Iowa Board of Pharmacy

cc:

Meghan Gavin, Assistant Attorney General

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

# **ADDENDUM U**

# NOTICE OF INTENDED ACTION

CHAPTER 6, "GENERAL PHARMACY PRACTICE,"
CHAPTER 7, "HOSPITAL PHARMACY PRACTICE,"
CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"
CHAPTER 10, "CONTROLLED SUBSTANCES,"
CHAPTER 17, "WHOLESALE DRUG LICENSES,"
AND
CHAPTER 23, "LONG-TERM CARE PHARMACY
PRACTICE"

# 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 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses," and Chapter 23, "Long-term Care Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the November 4, 2015, regular meeting of the Board of Pharmacy. The proposed amendments incorporate into Board rules updated federal regulations, finalized in October 2014, authorizing certain registrants to voluntarily administer an authorized collection program to collect unwanted controlled substances from patients for the purpose of disposal. The amendments also rescind rules that are in conflict with federal regulations and that would otherwise prohibit such collection activities.

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 December 29, 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.

These amendments are intended to implement Iowa Code section 124.301.

The following amendments are proposed.

ITEM 1. Amend rule 657—6.7(124,155A), introductory paragraph, as follows:

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—Chapter Chapters 10 and 21 and federal regulations for authorized controlled substance collection programs, which can be found at <a href="http://deadiversion.usdoj.gov/drug\_disposal/">http://deadiversion.usdoj.gov/drug\_disposal/</a>.

ITEM 2. Amend rule 657—7.6(124,155A) as follows:

**657—7.6(124,155A)** Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in <u>and under the control of</u> the pharmacy:

7.6(1) to 7.6(5) No change.

7.6(6) Authorized collection program. Receptacles that are located in the hospital for the authorized collection of controlled substances shall be secured pursuant to 657—Chapter 10 and federal regulations for disposal of controlled substances. Federal regulations regarding disposal of controlled substances can be found at http://deadiversion.usdoj.gov/drug disposal/.

- ITEM 3. Adopt the following **new** subrule 8.5(9):
- **8.5(9)** Authorized collection program. A pharmacy that is registered with the United States Department of Justice, Drug Enforcement Administration, to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at <a href="http://deadiversion.usdoj.gov/drug\_disposal/">http://deadiversion.usdoj.gov/drug\_disposal/</a>.
  - ITEM 4. Amend rule 657—10.1(124) as follows:
- 657—10.1(124) Who shall register Purpose and definitions. Any person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.
- 10.1(1) Who shall register. Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.
  - **10.1(2)** Definitions. For the purpose of this chapter, the following definitions shall apply:
- "Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug disposal/. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.
  - "DEA" means the United States Department of Justice, Drug Enforcement Administration.
  - ITEM 5. Amend rule 657—10.6(124) as follows:
- 657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3), or this rule, or federal regulations.
  - 10.6(1) to 10.6(5) No change.
  - ITEM 6. Amend subrule 10.15(1) as follows:
- **10.15(1)** Physical security. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.
  - a. and b. No change.
- c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at <a href="http://deadiversion.usdoj.gov/drug">http://deadiversion.usdoj.gov/drug</a> disposal/.
  - ITEM 7. Amend rule 657—10.18(124) as follows:
- 657—10.18(124) Disposal of registrant stock. Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of

such drugs pursuant to the procedures and requirements of this rule. Disposal records shall be maintained in the files of by the registrant.

10.18(1) and 10.18(2) No change.

- 10.18(3) Previously dispensed controlled substances. Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:
- a. The source of the controlled substance (patient identifier or administering practitioner, if applicable, prescription number or other unique identification number, and date of return);
  - b. The name, strength, and dosage form of the substance;
  - c. The quantity returned and destroyed or otherwise disposed of:
  - d. The date the substance is destroyed or otherwise disposed of;
  - e. The signatures or other unique identification of the pharmacist and the witness;
- f. The name and address of the dispensing pharmacy or practitioner if the controlled substance was not dispensed by the pharmacy completing the destruction.
  - ITEM 8. Rescind rule 657—10.19(124) and adopt the following **new** rule in lieu thereof:
- **657—10.19(124) Disposal of previously dispensed controlled substances.** A registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.
  - ITEM 9. Amend subrule 10.34(3) as follows:
- 10.34(3) Date of record. The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, or distribution, exportation, disposal, or transfer.
  - ITEM 10. Amend subrule 10.35(1) as follows:
- 10.35(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.
  - a. and b. No change.
- c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.
  - d. and e. No change.
- f. The inventory record, unless otherwise provided under federal law, shall include the following information:
  - (1) The name of the substance;
  - (2) The strength and dosage form of the substance; and

- (3) The quantity of the substance-; and
- (4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

g. and h. No change.

ITEM 11. Adopt the following new definitions in rule 657—17.1(155A):

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at <a href="http://deadiversion.usdoj.gov/drug\_disposal/">http://deadiversion.usdoj.gov/drug\_disposal/</a>. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

ITEM 12. Amend rule 657—17.3(155A), introductory paragraph, as follows:

**657—17.3(155A)** Wholesale drug license. Every wholesaler as defined in rule 657—17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of or collection via an authorized collection program of controlled substances shall also register pursuant to 657—Chapter 10.

ITEM 13. Adopt the following **new** subrule 17.10(4):

17.10(4) Authorized collection program. Licensees that are authorized to administer a controlled substances collection program shall provide security pursuant to 657—Chapter 10 and federal regulations.

ITEM 14. Adopt the following **new** subrule 17.14(4):

**17.14(4)** Authorized collection program. Substances, including controlled substances, collected through an authorized collection program shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

ITEM 15. Adopt the following **new** subrule 17.16(5):

17.16(5) Authorized collection program. A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.

ITEM 16. Adopt the following new definitions in rule 657—23.1(155A):

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at <a href="http://deadiversion.usdoj.gov/drug\_disposal/">http://deadiversion.usdoj.gov/drug\_disposal/</a>.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

ITEM 17. Amend subrule 23.11(4) as follows:

23.11(4) Floor stock. Prescription drugs, as defined by Iowa Code section 155A.3(30) 155A.3(37), shall not be floor-stocked in a long-term care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. and b. No change.

- 657—23.21(124,155A) Destruction Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring destruction disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating destruction disposal shall be destroyed disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.
- 23.21(1) <u>Destruction Disposal</u> in the facility. In facilities staffed by one or more persons licensed to administer drugs, a licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may <u>destroy</u> <u>dispose of</u> controlled substances in witness of one other responsible adult. The professional <u>destroying or otherwise</u> disposing of the drug shall prepare and maintain a readily retrievable record of the <u>destruction or other</u> disposition which shall be clearly marked to indicate the <u>destruction or other</u> disposition of resident drugs. The record shall include, at a minimum, the following:
- a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;
  - b. The name, strength, and dosage form of the substance;
  - c. The quantity destroyed or otherwise disposed of;
  - d. The date the substance is destroyed or otherwise disposed of;
- e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;
  - f. The name and address of the dispensing pharmacy or the dispensing practitioner.
- 23.21(2) Destruction or other disposition in the long term care pharmacy Authorized collection program within a facility. Controlled substances returned to the pharmacy for destruction or other disposition may be destroyed or otherwise disposed of pursuant to the requirements of 657—subrule 10.18(3). Registrants registered with DEA to administer an authorized collection program may install and maintain a collection receptacle in a long-term care facility for the purpose of disposal of prescription drugs, including controlled substances, pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug\_disposal/.

# ADDENDUM V NOTICE OF INTENDED ACTION CHAPTER 7, "HOSPITAL PHARMACY PRACTICE,"

# 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 7, "Hospital Pharmacy Practice," Iowa Administrative Code.

The amendment was approved at the November 4, 2015, regular meeting of the Board of Pharmacy. The proposed amendment eliminates restrictions regarding the dispensing of prescription drugs to patients seen in a hospital emergency department when 24-hour pharmacy services are available within 15 miles of the hospital. The amendment specifically authorizes the dispensing, to hospital emergency department patients, of appropriately packaged and labeled prescription drugs in quantities not exceeding a 72-hour supply except as specifically identified in subrule 7.12(3). The amendment eliminates the requirement that drugs dispensed through the emergency department only be dispensed in prepackaged quantities, clarifies that the prescriber is responsible for ensuring the drug is appropriately packaged and labeled but not that the prescriber must complete the labeling, and adds that the quantity of the drug dispensed must be included on the dispensing label.

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 December 29, 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 <a href="mailto:terry.witkowski@iowa.gov">terry.witkowski@iowa.gov</a>.

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

This amendment is intended to implement Iowa Code sections 124.301, 155A.13, and 155A.28.

The following amendment is proposed.

Amend subrule 7.12(3) as follows:

- 7.12(3) Drug dispensing. In those facilities with 24-hour pharmacy services, only 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, pursuant to the provisions of this rule shall apply.
- a. Responsibility. 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 shall be maintained.
- (1) Prepackaging. Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers, except that a seven-day supply of doxycycline provided through the department of public health pursuant to the crime victim compensation program of the Iowa department of justice may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).
- (2) Labeling. Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3)"*b*," including necessary auxiliary labels.

- b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph.
- (1) Labeling. Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall appropriately complete the label such be responsible for ensuring that the dispensing container bears a label with at least the following information:
  - 1. Name and address of the hospital;
  - 2. Date dispensed;
  - 3. Name of prescriber;
  - 4. Name of patient;
  - 5. Directions for use;
  - 6. Name, quantity, and strength of drug.
- (2) Delivery of drug to patient. Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, prepackaged packaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.

## ADDENDUM W NOTICE OF INTENDED ACTION CHAPTER 4, "PHARMACIST-INTERNS,"

### 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 sections 147.76 and 155A.6, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 4, "Pharmacist-Interns," Iowa Administrative Code.

The amendment was approved at the November 4, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment changes the elements required for registration as a pharmacist-intern to indicate that the Board will accept either a social security number or an individual tax identification number (ITIN). The ITIN enables a foreign student and the student's dependents to be identified and to file tax returns when the student or dependents are not eligible for a social security number. The individuals identified using an ITIN may be employed or be in receipt of scholarship or fellowship funding. The Board's proposed amendment recognizes the ITIN as a valid element of identification when a social security number is not obtainable.

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 December 29, 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 substantial impact on jobs has been found. Changing the identification requirements for registration as a pharmacist-intern to accept either social security number or individual tax identification number (ITIN) enables a foreign student and the student's dependents to be identified and file tax returns when the student or dependents are not eligible for a social security number. The individuals identified using an ITIN may be employed or be in receipt of scholarship or fellowship funding. The Board's acceptance of the ITIN in lieu of a social security number does not create or eliminate the job; the Board's action recognizes the ITIN as a valid means of identification.

This amendment is intended to implement Iowa Code section 155A.6.

The following amendment is proposed.

Amend subrule 4.6(1) as follows:

**4.6(1)** Application for registration—required information. Application for registration as a pharmacist-intern shall be on forms provided by the board, and all requested information shall be provided on or with such application. The application shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number or individual tax identification number (ITIN); and name and location of college of pharmacy and anticipated month and year of graduation. The college of pharmacy shall certify the applicant's eligibility to practice as a pharmacist-intern.

### **ADDENDUM X**

### NOTICE OF INTENDED ACTION

CHAPTER 2, "PHARMACIST LICENSES,"
CHAPTER 4, "PHARMACIST-INTERNS,"
CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"
CHAPTER 10, "CONTROLLED SUBSTANCES,"
CHAPTER 17, "WHOLESALE DRUG LICENSES,"
AND
CHAPTER 24, "PHARMACY INTERNET SITES"

### PHARMACY BOARD [657]

### Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 2, "Pharmacist Licenses," Chapter 4, "Pharmacist-Interns," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses,", and Chapter 24, "Pharmacy Internet Sites," Iowa Administrative Code.

The amendments were approved at the November 4, 2015, regular meeting of the Board of Pharmacy.

The proposed amendments increase fees for the licensure and registration of pharmacists, pharmacist-interns, pharmacies, drug wholesalers, pharmacy Internet sites, and persons involved in the distribution of controlled substances in Iowa. Late payment penalty fees and examination and license transfer fees are also increased. Pursuant to Iowa Code section 147.80, the Board reviewed current fee schedules and projected revenues and expenditures and determined that fees should be increased to align revenues with anticipated expenses relating to support Board programs and activities.

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 December 29, 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.

These amendments are intended to implement Iowa Code sections 124.301, 124.302, 147.10, 147.11, 147.34, 147.44, 147.53, 147.80, 155A.6, 155A.11, 155A.13, 155A.13A, 155A.13B, 155A.14, and 155A.17.

The following amendments are proposed.

Item 1. Amend subrule 2.3(1) as follows:

**2.3(1)** Fees to the board. The biennial license fee shall be the fee established by rule 657—2.11(147,155A), including surcharge. The processing fee shall be \$72 \$100. No refunds of the processing fee shall be made for cancellation or withdrawal of applications. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, cashier's check, or certified check. No refund of fees shall be made for failure to complete all licensure requirements within the period specified in subrule 2.1(2).

Item 2. Amend rule 657—2.6(147) as follows:

once shall be allowed to schedule a time to retake the examination no less than 91 days following administration of the failed examination. A candidate who fails to pass the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination no less than 30 days following administration of the failed examination. A candidate who fails to pass either examination following administration of the failed examination. A candidate who fails to pass either examination following a second or subsequent examination may petition the board for permission to take the examination again. Determination of a candidate's eligibility to take an examination more than two times shall be at the discretion of the board.

Each applicant for reexamination shall file an application on forms provided by the board. Processing fees of \$36 \$40 each will be charged to take NAPLEX or MPJE, Iowa Edition, and shall be paid to the board as provided in subrule 2.3(1). In addition, candidates will be required to

complete the appropriate examination registration application as provided in rule 657—2.2(155A) and to pay to NABP the registration and administration fees for each examination as provided in subrule 2.3(2). All applications, registration forms, and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

Item 3. Amend subrule 2.9(4) as follows:

**2.9(4)** Fees. The fee for license transfer shall consist of the biennial license fee established by rule 657—2.11(147,155A) including surcharge and a processing fee of \$90 \$100. No refunds of the processing fee shall be made for cancellation or withdrawal of an application. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, cashier's check, or certified check.

Item 4. Amend rule 657—2.11(147,155A) as follows:

657—2.11(147,155A) License expiration and renewal. A license to practice pharmacy shall expire on the second thirtieth day of June following the date of issuance of the license, with the exception that a new pharmacist license issued between April 1 and June 29 shall expire on the third thirtieth day of June following the date of issuance. The license renewal certificate shall be issued upon completion of the renewal application and timely payment of a \$180 \$200 fee plus applicable surcharge pursuant to 657—30.8(155A).

**2.11(1)** Late payment penalty. Failure to renew the license before July 1 following expiration shall require payment of the renewal fee, a penalty fee of \$180 \$200, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before August 1 following expiration shall require payment of the renewal fee, a penalty fee of \$270 \$300, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before September 1 following expiration shall require payment of the renewal fee, a penalty fee of \$360 \$400, and applicable surcharge pursuant to 657—

30.8(155A). Failure to renew the license before October 1 following expiration may require an appearance before the board and shall require payment of the renewal fee, a penalty fee of \$450 \$500, and applicable surcharge pursuant to 657—30.8(155A). In no event shall the combined fee and penalty fee for late renewal of the license exceed \$630 \$700 plus applicable surcharge pursuant to 657—30.8(155A). The provisions of Iowa Code section 147.11 shall apply to a license that is not renewed within five months of the expiration date.

2.11(2) No change.

Item 5. Amend rule 657—4.8(155A) as follows:

**657—4.8(155A) Fees.** The fee for registration as a pharmacist-intern is \$30 \$50, plus applicable surcharge pursuant to 657—30.8(155A), which shall be payable with the application.

Item 6. Amend subrule 8.35(4) as follows:

**8.35(4)** *License expiration and renewal.* General pharmacy licenses, hospital pharmacy licenses, special or limited use pharmacy licenses, and nonresident pharmacy licenses shall be renewed before January 1 of each year. The fee for a new or renewal license shall be \$135 \$185.

a. Late payment penalty. Failure to renew the pharmacy license before January 1 following expiration shall require payment of the renewal fee and a penalty fee of \$135 \$185. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of \$225 \$300. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of \$315 \$400. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of \$405 \$500 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a pharmacy license exceed \$540 \$685.

b. No change.

Item 7. Amend rule 657—10.3(124) as follows:

657—10.3(124) Registration and renewal. For each registration or timely renewal of a registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities, or conduct chemical analysis with controlled substances listed in Schedules I through V of Iowa Code chapter 124, registrants shall pay a biennial fee of \$90 \$100.

**10.3(1)** *Time and method of payment.* Registration and renewal fees shall be paid at the time the application for registration or renewal is submitted. Payment should be made in the form of a personal, certified, or cashier's check or a money order made payable to the Iowa Board of Pharmacy. Payments made in the form of foreign currency or third-party endorsed checks will not be accepted.

10.3(2) Late renewal. Any registered person or business may apply, on forms provided by the board office, for registration renewal not more than 60 days prior to the expiration of the registration. Failure to renew a registration prior to the first day of the month following expiration shall require payment of the renewal fee and a penalty fee of \$90 \$100. Payment shall be made as specified in subrule 10.3(1).

Item 8. Amend subrule 17.3(2) as follows:

**17.3(2)** *License expiration and renewal.* A wholesale drug license shall be renewed before January 1 of each year. The fee for a new or renewal license shall be \$270 \\$325.

a. Late payment penalty. Failure to renew the license before January 1 shall require payment of the renewal fee and a penalty fee of \$270 \$325. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of \$360 \$450. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of \$450 \$575. Failure to renew the license before April 1 following expiration shall

require payment of the renewal fee and a penalty fee of \$540 \$675 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a wholesale drug license exceed \$810 \$1000.

b. No change.

Item 9. Amend subrule 24.7(2) as follows:

- **24.7(2)** *Timeliness of application.* An application for pharmacy Internet site registration or registration renewal shall be timely submitted to the board.
- a. Existing Internet site. If the application is for registration of a pharmacy Internet site that is operational on or before February 1, 2012, the application and registration fee shall be due no later than May 1, 2012.
- b. New Internet site. If the application is for registration of a new pharmacy Internet site that was not operational on or before February 1, 2012, the application and registration fee shall be due no less than 30 days prior to implementation of the Internet site.
- *e.* <u>b.</u> *Renewal.* If the application is for renewal of an existing pharmacy Internet site registration, the application and registration fee shall be due prior to expiration of the current registration.

Item 10. Amend subrule 24.7(4) as follows:

- **24.7(4)** *Fees and term of registration.* The following fees, as applicable, shall accompany an application for pharmacy Internet site registration or registration renewal:
- a. Initial registration. The fee for initial registration of a pharmacy Internet site shall be \$135
   \$185. All registrations shall expire annually on December 31.
- b. Registration renewal. The fee for renewal of a pharmacy Internet site registration shall be \$135 \$185. Failure to renew a registration prior to expiration shall require payment of a late payment fee in the amount of \$135 \$185 in addition to the renewal fee. Failure to renew a registration within

30 days following expiration shall require payment of a late payment fee in the amount of \$225 \$300 in addition to the renewal fee. Failure to renew a registration within 60 days following expiration shall require payment of a late payment fee in the amount of \$315 \$400 in addition to the renewal fee. Failure to renew a registration within 90 days following expiration shall require payment of a late payment fee in the amount of \$405 \$500 in addition to the renewal fee. The total renewal and late payment fee shall not exceed \$540 \$685. Failure to timely renew a registration may subject the registrant to disciplinary action.

### ADDENDUM Y ADOPTED PROPOSAL FOR FEE INCREASES

# ADOPTED PROPOSAL FOR FEE INCREASES

Effective June 2016

\$ 346,990	evenues:	Increase to Average Revenues: \$ 346,990	Increase to											
100.00%	0.01%	34.81%	20.34%	0.02%	6.87%	7.24%	0.98%	0.78%	3.68%	0.59%	1.06%	2.11%	21.51%	% of Total Revenues
\$2,556,665	360	890,000	555 520,000	555	175,750	185,000	25,000 185,000 175,750	20,000	94,000	15,000	27,000 15,000	54,000	550,000 54,000	Revenues
	\$ 180	\$ 100 \$	\$ 325 \$	185 \$ 185 \$	\$ 185	\$ 185	\$ 25	\$ 20	\$ 40	300 \$ 50	\$ 300	200 \$ 300	\$ 200	Proposed
	0%	11.1%	20.4%	37.0% 37.0%	37.0%	37.0%	0%	0%	0%	66.7%	11.1%	19.0%	11.1%	% Increase
100.00%	0.02%	36.25%	19.55%	5.80% 0.02%	5.80%	6.11%	1.13%	0.91%	4.25%	0.41%	1.10%	2.05%	22.40%	Revenues
360 <b>\$2,209,675</b>	360	801,000	432,000	405	128,250	135,000	25,000	20,000	94,000	9,000	24,300	45,360	495,000	Current Revenues
	180	90	270	135	135	135	25	20	40	30	270	252	180	Current Fee
	2	8,900	1,600	ω	950	1,000	1,000	1,000	2,350	300	90	180	2,750	Avg. No. /Year
Revenue Totals	Precursor Permit	Substances Precursor Reg. Permit	Drug License	Site Reg.	Pharmacy License	Pharmacy License	Support Pharmacy Pharmacy Person License License	Technician Trainee	Certified Technician	Intern Reg.	License License by by Exam Reciprocity	License by Exam	Pharmacist License License by License by Exam Reciprocity	
		Controlled	Internet Wholesale Controlled	Internet	Z	lowa	Pharmacy							
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