State of Iowa
Board of Pharmacy
400 S.W. Eighth Street, Suite E, Des Moines, IA 50309-4688
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Telephone: (515)281-5944 Facsimile: (515)281-4609

**BOARD MEMBERS**
LADONNA GRATIAS
EDWARD McKENNA
EDWARD MAIER

JAMES MILLER
*Board Chair*

ANDREW FUNK
*Executive Director*

**BOARD MEMBERS**
JASON HANSEL
SHARON MEYER
JUDITH TRUMPY

# MINUTES

## August 31 - September 2, 2015

The Iowa Board of Pharmacy met on August 31 - September 2, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

**MONDAY, AUGUST 31, 2015**

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

SPEAKERS
AnthonyPudlo, IPA
Brett Barker, NuCara
Evan Arnold, Centor
Anthony Crofoot, STATdispense
Jordan Esbrook, AAG
Adam Chesler, PTCB
Megan Myers, IPA
Dale Woolery, ODCP
Roby Miller, TelePharm
Ed Dalashmutt, Midwest Respiratory Care Inc.

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

**Call to Order & Announcements**

At 10:00 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order on Monday, August 31, 2015.

**Public Comments**

No public comments.

**Approval of Minutes**

The minutes of the June 23-24, 2015, meeting were reviewed.

Motion by James Miller, seconded by Judith Trumpy, to approve the open session minutes of the June 23-24, 2015, meeting as presented. Motion approved unanimously.

**Election of Officers**

Motion by Jason Hansel, seconded by Edward McKenna, to nominate James Miller for Chair. Motion approved unanimously.

Motion by Judith Trumpy, seconded by Edward McKenna, to nominate Sharon Meyer for Vice-Chair. Motion approved unanimously.

**Reports**

1. Interim Executive Director's Report – August 31, 2015.
   A. Financials

***Board Account*:**

| | |
|---|---|
| Total Revenues FY15: | $ 3,927,802.79 (includes FY14 carry-over $1,504,636.79) |
| Expenditures: | $ 2,380,037.84 |
| Carry-over to FY16: | $ 1,547,764.95 |

***IPRN*:**

| | |
|---|---|
| Expenditures: | $ 107,358.53 |
| Carry-over to FY16: | $ 7,465.47 |
| Transfer from Board CO: | $ 106,034.53 |

***PMP*:**

| | |
|---|---|
| Expenditures: | $ 102,000 |
| No Carry-over to FY16: | --- |
| Transfer from Board CO: | $ 106,800 |

2. Office/Program Updates.

A. Information Technology Specialist Position – The Office of Chief Information Officer (OCIO) did not approve filling this position at this time. OCIO is working to consolidate all IT positions within OCIO. Board staff is currently working with OCIO to assess the needs of the Board.

B. Prescription Monitoring Program (PMP) Interconnect – The Iowa PMP is actively sharing information with neighboring states. Iowa is able to exchange data with Kansas, Illinois, and South Dakota. Iowa users can obtain prescription records from Minnesota and Wisconsin, but these two states are waiting for their software vendor to authorize their PMP users to obtain information from Iowa. Nebraska and Missouri do not currently have a sharable PMP.

C. Website Redesign - Debbie Jorgenson has been converting information from the current Board website to the redesign website and anticipates switching to the new website around October 1, 2015.

3. Meetings.

A. The NABP/AACP District Five Annual Meeting was held in Fargo, North Dakota, on August 6-8, 2015. Edward Maier, Jim Wolfe, Curt Gerhold, Andrew Funk, and Terry Witkowski attended the meeting. Lloyd Jessen will be continuing his District Five duties as secretary, and agreed to work with the Board and both Iowa colleges when Iowa hosts the District Five Meeting in August of 2017.

B. Mark Mather and Andrew Funk will be attending the Council on Licensure, Enforcement, and Regulation (C.L.E.A.R.) investigator training in Boston, Massachusetts, on September 13-16, 2015.

C. Jennifer O'Toole, Jennifer Tiffany, and Terry Witkowski will be providing a presentation at the Iowa Veterinary Medicine Association's annual meeting on September 18, 2015, in Ames. Topics of discussion with include history and overview of Board of Pharmacy functions and responsibilities, Iowa PMP, veterinary compounding, and issues relating to controlled substances, record keeping, and security requirements.

D. Meghan Gavin will be attending the Federal Associations of Regulatory Boards (FARB) Regulatory Law Seminar in Denver, Colorado, on October 1-4, 2015.

E. The Tri-Regulator Symposium is schedule for October 6-7, 2015, in Arlington, Virginia. Representatives of state Medical, Nursing, and Pharmacy Boards have been invited to attend the Symposium.

F. The Annual Meeting of the National Association of State Controlled Substances Authorities (NASCSA) is scheduled for October 19-23, 2015, in Scottsdale, Arizona. Jim Wolfe and Terry Witkowski plan to attend the meeting.

G. The November board meeting is scheduled for November 3-4, 2015, in Des Moines. A committee of the Board will meet with the Iowa Pharmacy Association Board of Trustees for an annual dinner meeting on the evening of November 3, at the Iowa Pharmacy Association's office in Urbandale.

4. Miscellaneous.

The National Association of Boards of Pharmacy (NABP) recently announced the task forces and committees for 2016, and the individuals appointed to those committees. Edward Maier has been appointed to the Task Force on VPP Implementation.

5. Litigation Update Meghan Gavin.

   The Board currently has one judicial review in District Court.

6. Pharmacy Benefit Managers Lawsuit – Jordan Esbrook, Assistant Attorney General.

   In 2014, the Iowa Legislature passed a statue regulating Pharmacy Benefit Managers (PBM), adding to Section 510B of the Iowa Code. It imposed some requirements on PBM that they provide an avenue appeal for pharmacies, and that they use nationally recognized and locally available standards for setting MAC pricing. The Pharmaceutical Care Management (PCM) Association filed suit in September of 2014. PCM originally filed an ERISA Preemption Claim, a Dormant Commerce Clause Claim, and claimed that the statue enacted unconstitutional taking of their property. Ms. Esbrook on behalf of the State moved to dismiss the Takings Claim and the ERISA Claim. Judge Jarvey of the United States District Court for the Southern District of Iowa dismissed the claims last year. The Dormant Commerce Clause Claim still exists, under the United States Constitution states cannot interfere with the flow of goods through Interstate Commerce. PCM is alleging that Section 510B interferes with Interstate Commerce Clause. PCM added another claim that the statue is unconstitutionally vague. In June 2015, Ms. Esbrook moved to dismiss the Dormant Commerce Clause Claim and the Vagueness Claim, that motion is pending, if granted the entire case will be dismissed. PCM has the right to appeal to the Eighth Circuit Court of Appeals. If the motion is not granted, the case will continue to trial in July of 2016.

7. Iowa Pharmacy Recovery Network (IPRN) Report.

   The IPRN Report was provided for review.

8. IPRN Statement of Financial Position.

   The IPRN Statement of Financial Position was provided for review.

9. Iowa TakeAway Medication Disposal Program 2014-2015 Annual Report.

   The Iowa TakeAway Medication Disposal Program 2014-2015 Annual Report was provided for review.

10. Hy-Vee Pharmacy Fulfillment Center – 2nd Quarter 2015 Error Report.

    Hy-Vee Pharmacy Fulfillment Center submitted their 2nd Quarter Error Report for review.

11. Patient Safety & Medication Error Prevention for Pharmacists – Kenneth Wells, Continuing Education Department, Oregon State University, College of Pharmacy.

    The Patient Safety and Medication Error Prevention for Pharmacists is an online continuing education course. The course provides pharmacists with the tools to identify problems, reduce risks, and improve communication, leading to increased patient safety within the pharmacy environment. The course was developed collaboratively by Oregon State University's College of Pharmacy and the Oregon Patient Safety Commission.

12. NuCara Pharmacy, Zearing - 2nd Quarter 2015 Telepharmacy Report.

    NuCara Telepharmacy provided their 2nd Quarter Telepharmacy Report for review.

13. NuCara Pharmacy, State Center - 2nd Quarter 2015 Telepharmacy Report.

    NuCara Telepharmacy provided their 2nd Quarter Telepharmacy Report for review.

14. State Board Position on Protecting Citizens – Evan Arnold, Centor.

    Evan Arnold with Centor provided a presentation. Centor is a supplier of regulatory compliant prescription containers for medication dispensing. Topics of discussion were (1) drug abuse with container/closure prescription solution, (2) labeling the prescription container, and (3) moisture protection for the prescription container.

15. STATdispense – Creative Strategies US.

    Anthony Crofoot provided a presentation via the Internet. STATdispense is a first-dose and emergency medication management software solution providing real-time billing and tracking information and can be used in conjunction with a "tackle-box" system. This item was referred to the Rules Committee.

16. Advancing Patient Safety – Adam Chesler, Pharmacy Technician Certification Board.

    Adam Chesler provided a presentation on Advancing Patient Safety and discussed changes with the Pharmacy Technician Certification Board (PTCB). New PTCB requirements include (1) any continuing education earned after January 1, 2015, must be in pharmacy technician-specific subject matter, and (2) by 2020, PTCB candidates seeking certification will be required to complete an ASHP/ACPE-accredited training program.

17. Rx Return Box Service – Announces Community Anti-Drug Coalitions of America (CADCA) Membership.

    Informational item.

18. New Practice Model Project Phase One and Phase Two Quarter Reports – Megan Myers, Iowa Pharmacy Association.

    Phase One Quarter Five Report and Phase Two Quarter Two Report for the New Practice Model Project were provided for review.

19. Response to Tech Check Tech Memo from Board Compliance Officers – Megan Myers, Iowa Pharmacy Association.

    Board compliance officers visited Phase One and Phase Two Tech Check Tech program sites and provided the Board with their individual observations and concerns. A response to the concerns regarding the pilot project was provided for review.

20. Opioid Overdose Prevention Toolkit – National Association of Boards of Pharmacy.

    Informational item.

**Requests**

1. Request for Internship Credit – Ali Hassan El-Sayad, Pharmacist Intern No. 6369, Mason City.

   Motion by Jason Hansel, seconded by Judith Trumpy, to grant credit for 500 hours of internship in lieu of life experience requiring Mr. El-Sayad to complete an additional 1,000 hours of internship. Motion approved unanimously.

2. Request for Amendment to 2015-2016 Medication Disposal Contract – Iowa Pharmacy Association.

   This item was tabled.

3. Proposals for Renewing Phase One New Practice Model Pilot – Megan Myers, Iowa Pharmacy Association.

   Motion by James Miller, seconded by Judith Trumpy, to approve an 8 month extension for the pilot program. Motion approved unanimously.

4. NuCara Health Solutions Application for Limited Use Pharmacy License.

   Motion by James Miller, seconded by LaDonna Gratias, to approve the Application for Limited Use Iowa Pharmacy License. Motion approved unanimously.

5. Joint Telepharmacy Pilot Project Proposal – Tel-Pharm and NuCara Pharmacies.

   Roby Miller 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.

   Motion by LaDonna Gratias, seconded by Judith Trumpy, to table this request and refer to the Rules Committee. Motion approved unanimously.

**Rules & Legislation**

1. Removal of [123I] Ioflupane from Schedule II of the Controlled Substances Act.

   Informational item.

2. Notice of Intended Action to Amend Various Chapters: Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," and Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes."

   Motion by Judith Trumpy, seconded by Edward McKenna, to approve for Notice of Intended Action. Motion approved unanimously. Copies are attached as Addendum A (Chapter 6), Addendum B (Chapter 8), Addendum C (Chapter 10), and Addendum D (Chapter 22).

3. Proposed for Adoption and Filing - Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice," rescinds Chapter 13, "Sterile Compounding Practices," and rescinds Chapter 20, "Pharmacy Compounding Practices," and adopts new Chapter 20, "Compounding Practices."

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum E.

4. Proposed for Adoption and Filing - Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 15, "Correctional Pharmacy Practice," and Chapter 16, "Nuclear Pharmacy Practice."

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum F.

5. Proposed for Adoption and Filing - Chapter 7, "Hospital Pharmacy Practice," and Chapter 23, "Long-Term Care Pharmacy Practice."

   Motion by Jason Hansel, seconded by Judith Trumpy, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum G.

6. Proposed for Adoption and Filing - Chapter 10, "Controlled Substances."

   Motion by Judith Trumpy, seconded by Jason Hansel, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum H.

**Licensure/Registration**

1. NR & V Drugs, Inc., d/b/a Wyandotte Drugs, Nonresident Pharmacy Application, Wyandotte, Michigan.

   Motion by Judith Trumpy, seconded by James Miller, to approve the Licensure by Consent Agreement. Motion approved unanimously. A copy of the Licensure by Consent Agreement is attached as Addendum I.

2. Han. Sam. Corp., d/b/a River's Edge Pharmacy, Nonresident Pharmacy Application, Palm Desert, California.

   Motion by James Miller, seconded by Judith Trumpy, to approve the Preliminary Notice of Intent to Deny License. Motion approved unanimously. A copy of the Preliminary Notice of Intent To Deny License is attached as Addendum J.

3. Professional Partners, Inc., Nonresident Pharmacy Application, Newport Beach, California

   This item was tabled.

4. Best Care Pharmacy Inc., Nonresident Pharmacy Application, Miami, Florida.

   Motion by Jason Hansel, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

5. Jay Pharmacy of Jay Fla, Inc., Nonresident Pharmacy Application, Jay, Florida.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

6. Perform Specialty, Nonresident Pharmacy Application, Orlando, Florida.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

7. US Specialty Care, Nonresident Pharmacy Application, Lakeland, Florida.

   Motion by Judith Trumpy, seconded by LaDonna Gratias, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

8. OptiMed Pharmacy, Nonresident Pharmacy Application, Kalamazoo, Michigan.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

9. Veterinary Enterprises of Tomorrow, Nonresident Pharmacy Application, Mount View, Oklahoma.

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

10. Dawn Farrell, Pharmacy Support Person Registration Application, Des Moines.

    Motion by James Miller, seconded by Judith Trumpy, to approve the Application for Pharmacy Support Person Registration. Motion approved unanimously.

**Complaints Against Non-Licensees**

1. 2009-146, ANEWrx, Pittsburgh, Pennsylvania.

   Motion by James Miller, seconded by Judith Trumpy, to close with no action. Motion approved unanimously.

2. 2015-139, Midwest Respiratory Care Inc., Iowa Wholesale Drug License Application - Grimes.

   Motion by James Miller, seconded by LaDonna Gratias, to approve the Application for Iowa Wholesale Drug License and close complaint 2015-139. Motion approved unanimously.

**Discussion on Vacant Executive Director Position**

The Board will conduct interviews of the two final candidates for the Executive Director's position on Wednesday, September 2, 2015, at the board office.

**Closed Session Minutes**

Motion by James Miller, seconded by Edward McKenna, to approve the Closed Session Minutes and Deliberations of the June 23-24, 2015, meeting. Motion approved unanimously.

**Closed Session**

At 3:15 p.m., motion by Judith Trumpy, seconded by Jason Hansel, 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.

At 3:52 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by Judith Trumpy. Motion approved unanimously.

In open session, the following actions were taken:

1. Close With No Action.

   Motion by Jason Hansel, seconded by Sharon Meyer, to close with no further action the following investigative files in complaint numbers: 2014-79, 2013-81, 2013-129, 2013-201, 2014-151, and 2015-54. Motion approved unanimously.

2. Close With Referral to Another Agency.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to close 2015-10 and refer to another agency. Motion approved unanimously.

3. Draft Statement of Charges.

   Motion by Judith Trumpy, seconded by Edward McKenna, to draft Statement of Charges against the pharmacy in 2015-6. Motion approved unanimously.

4. Settlement Agreement and Final Order.

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

   A. Thomas B. Dodds, Pharmacist License No. 12951 of Dakota Dunes, South Dakota. A copy of the Settlement Agreement and Final Order is attached as Addendum K.

   B. Rxtra Solutions, Nonresident Pharmacy License No. 4203 of Southfield, Michigan. A copy of the Settlement Agreement and Final Order is attached as Addendum L.

   C. LDI Integrated Pharmacy Services, Nonresident Pharmacy License No. 3816 of Creve Coeur, Missouri. A copy of the Settlement Agreement and Final Order is attached as Addendum M.

5. Notice of Hearing and Statement of Charges.

   Motion by Jason Hansel, seconded by Edward McKenna, to approve the Notice of Hearing and Statement of Charges against Karen Bean, Pharmacy Support Person No. 3456 of Cedar Rapids. Motion approved unanimously. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.

6. Order to Show Cause.

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve the Order to Show Cause for David H. Marcowitz, D.O., Controlled Substance Registration No. 1305770 of Chariton. A copy of the Order to Show Cause is attached as Addendum O.

**Closed Session**

At 3:56 p.m., motion by Judith Trumpy, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Complaints and Investigative 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 4:28 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session, the following actions were taken:

1. Non IBP Disciplinary.

   Motion by Judith Trumpy, seconded by Edward McKenna to take no further action and close pursuant to reason No. 13, regarding out–of-state discipline in cases reference as 13.1, 13.2, 13.3, 13.4, 13.5, 13.7, 13.8, 13.9, 13.10, 13.11 a.k.a. 2015-17, 13.12, and 13.13. Motion approved unanimously.

2. Open a Complaint to Investigate.

   Motion by Jason Hansel, seconded by Sharon Meyer, to open a complaint to investigate 13.6, 2015-05, and 2015-127. Motion approved unanimously.

At 4:32 p.m. the Board recessed.

The meeting reconvened in open session on Tuesday, September 1, 2015, at 9:00 a.m.

## TUESDAY, SEPTEMBER 1, 2015

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

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

### Call to Order and Announcements

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

**Administrative Hearing**

1. Amanda L. Latta, Pharmacist License No. 19669 of Springville.

   At 9:00 a.m., Laura Lockard, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Ms. Latta appeared without counsel. The hearing was conducted in the presence of the Board. The hearing was closed to the public.

   The Board heard testimony of a witness and examined exhibits.

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

   At 9:30 a.m., motion by Judith Trumpy, 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 9:40 a.m., while still in closed session, LaDonna Gratias moved that the Board go into open session, seconded by Judith Trumpy. Motion approved unanimously.

   Motion by James Miller, seconded by Judith Trumpy, to direct Administrative Law Judge Lockard to draft the Order consistent with the Board's deliberations in case 2011-43, Amanda L. Latta.

**Closed Session**

At 9:45: a.m., motion by Judith Trumpy, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Complaints and Investigative 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 11:55 p.m., while still in closed session, Judith Trumpy moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session, the following actions were taken:

1. Letter of Education.

   Motion by LaDonna Gratias, seconded by Sharon Meyer, to issue a Letter of Education to the pharmacy and pharmacist in charge in 2015-140. Motion approved unanimously. Jason Hansel recused.

2. Letter of Education.

   Motion by Judith Trumpy, seconded by Edward McKenna, to issue a Letter of Education to the pharmacy in 2015-120, and two CSA registrants in 2015-134. Motion approved unanimously.

3. Close With No Action.

   Motion by LaDonna Gratias, seconded by Jason Hansel, to close with no further action the investigative files in complaint numbers: 2015-128, 2015-114, 2015-126, 2015-131, 2015-68, 2015-77, 2015-78, 2014-202, 2015-62, 2015-76, 2015-82, 2015-129, 2015-113, 2015-133, and 2015-136. Motion approved unanimously.

4. Draft Statement of Charges.

   Motion by Judith Trumpy, seconded by Jason Hansel, to draft Statement of Charges against the pharmacy in 2015-37, pharmacy and pharmacist in 2015-81, and pharmacy and pharmacist in charge in 2015-123. Motion approved unanimously.

5. Draft Statement of Charges.

   Motion by Sharon Meyer, seconded by Jason Hansel, to draft Statement of Charges against the pharmacy and pharmacist in charge in 2015-110. Motion approved unanimously. Edward McKenna recused.

6. Notice of Intent to Rescind License.

   Motion by Judith Trumpy, seconded by Jason Hansel, to issue Notice of Intent to Rescind License to the Wholesaler in 2015-100 and Wholesaler in 2015-115. Motion approved unanimously.

7. Referral to Another Agency.

   Motion by Sharon Meyer, seconded by Edward McKenna, to refer 2015-37 to the Board of Medicine. Motion approved unanimously.

Meghan Gavin and Laura Steffensmeier left the room.

**Presentation on Website Redesign**

Debbie Jorgenson provided an update and visual presentation on the new website redesign.

**Rules Review Planning and Assignment**

Assignments to review chapters of the board rules were issued.

**Discussion on Vacant Executive Director Position**

The Board discussed interview questions, comments, and scoring sheets from the Board's Search Committee Members and board staff. The Board finalized their goals for the position, interviewing process, interview questions, and scoring sheet.

**Closed Session**

At 3:00 p.m., motion by Judith Trumpy, seconded by Jason Hansel, 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(1)(f) to discuss the decision to be rendered in contested case.

At 3:01 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session, the following actions were taken:

A. Settlement Agreement and Final Order.

Motion by Edward McKenna, seconded by Judith Trumpy, to approve the Settlement Agreement and Final Order for Ashley Henson, Pharmacy Technician Registration No. 8907 of Cherokee. A copy of the Settlement Agreement and Final Order is attached as Addendum P.

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

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Findings of Fact, Conclusions of Law, and Decision and Order for Sherri Marshall, Pharmacy Technician Registration No. 18129 of Des Moines. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Q.

At 3:07 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, September 2, 2015, at 8:20 a.m.

**WEDNESDAY, SEPTEMBER 2, 2015**

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

VISITORS
Anthony Pudlo, IPA
Joshua Roehrick, IPA
Erin Beal, IPA

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

**Call to Order and Announcements**

At 8:20 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

**Executive Director Interviews**

The Board conducted in-person interviews with the following candidates:

- Andrew Funk - 8:20 a.m.
- David Sinnwell - 10:00 a.m.

**Executive Director Discussion and Decision**

Members of the Board asked each candidate the same series of questions. Board members independently completed score sheets and comments following the interviews.

Following the interviews, candidate's responses to the questions were discussed and score ratings were accumulated. A list of those questions and scoring sheet are attached as Addendum R.

Motion by Sharon Meyer, seconded by James Miller, to offer Andrew Funk the Executive Director's Position. Motion approved unanimously.

Motion by Edward McKenna, seconded by Judith Trumpy, should Mr. Funk decline the Executive Director's Position David Sinnwell will be offered the position. Motion approved unanimously.

The Board discussed the salary range and having a 6 month performance evaluation for the Executive Director's Position.

Motion by Judith Trumpy, seconded by Jason Hansel, the staring salary for the Executive Director's Position be $92,000 annually. Motion approved unanimously.

The Board offered Andrew Funk the Executive Director's Position and discussion was held regarding salary range, a comprehensive benefits program, and a starting date for the position.

Motion by James Miller, seconded by Sharon Meyer, to amend the previous motion to increase the Executive Director's starting salary from $92,000 to $100,000 annually. Motion approved unanimously.

Motion by Judith Trumpy, seconded by LaDonna Gratias, to adjourn at 1:45 p.m. on September 2, 2015.

Becky Hall
Becky Hall
Recording Secretary

Andrew Funk
Executive Director

James Miller
Board Chair

APPROVED THIS 4th DAY OF November, 2015.

# ADDENDUM A

# NOTICE OF INTENDED ACTION

# CHAPTER 6, "GENERAL PHARMACY PRACTICE," AND CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS"

# AUGUST 31, 2015

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 6, "General Pharmacy Practice," and Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The amendments were approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendments are intended to implement 2015 Iowa Acts, Senate File 462, which authorizes the prescribing of epinephrine auto-injectors in the name of a facility as defined in 135.185(1), a school district, or an accredited nonpublic school. The proposed amendments exclude such a prescription from the requirement for a preexisting patient-prescriber relationship and establish the unique prescription label and recordkeeping requirements for a prescription issued to a facility, school district, or accredited nonpublic school as authorized by Senate File 462.

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 November 17, 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 155A.27 and 2015 Iowa Acts, Senate File 462.

The following amendments are proposed.

Item 1. Amend subrule 6.10(1) as follows:

**6.10(1)** *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

*a.* to *b.* No changes.

*c.* ~~The~~ Except as provided in subrule 657—8.19(7) for epinephrine auto-injectors, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

*d. through h.* No changes.

Item 2. Amend subrule 8.19(1) as follows:

**8.19(1)** *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors.

*a. Written, electronic, or facsimile prescription.* In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) The date issued.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

*b. through d.* No changes.

Item 3. Amend subrule 8.19(5) as follows:

**8.19(5)** *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors.

Item 4. Adopt new subrule 8.19(7) as follows:

**8.19(7)** *Epinephrine auto-injector prescription issued to school or facility.* A physician, advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall

identify the name and address of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

# ADDENDUM B

# NOTICE OF INTENDED ACTION

# CHAPTER 8,
# "UNIVERSAL PRACTICE STANDARDS"

# AUGUST 31, 2015

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 8, "Universal Practice Standards," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment requires that the initial record or report of a continuous quality improvement program event shall be documented no later than three days following the date the error or event was discovered.

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 November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

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

This amendment is intended to implement Iowa Code section 155A.41.

The following amendment is proposed.

Amend subrule 8.26(5) as follows:

**8.26(5)** *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a

written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

*a.* The program event shall initially be documented as soon as practicable but no more than three days following discovery of the event by the staff member who discovers the event or is informed of the event.

*b.* No change.

# ADDENDUM C

# NOTICE OF INTENDED ACTION

# CHAPTER 10, "CONTROLLED SUBSTANCES"

# AUGUST 31, 2015

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 124.201, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current rule 10.38(124) and adopts new rule 10.38(124), temporarily designating certain identified substances as controlled substances, subject to the applicable security and control requirements and penalties provided for in the Iowa Controlled Substances Act (CSA), and removing one substance from the CSA, in conformance with recent scheduling actions of the federal Drug Enforcement Administration (DEA). The substances affected by this action include three synthetic cannabinoids and acetyl fentanyl, all of which are temporarily placed into Schedule 1 of the CSA. Synthetic cannabinoids are chemicals synthesized in laboratories and mimic the biological effects of THC, the main psychoactive ingredient in marijuana. These chemicals are much more potent than marijuana and are often marketed as herbal incense or potpourri. They have no accepted medical use in the United States, and have been reported to produce adverse health effects, including acute and chronic abuse, addiction, and withdrawal. Acetyl fentanyl, a synthetic opioid, has been linked to at least 39 fatalities nationwide in 2013 and 2014 and poses an imminent hazard to public safety. There is currently no approved medical use for acetyl fentanyl and should be appropriately classified as a Schedule 1 controlled substance.

Also affected by this temporary action is naloxegol, a new molecular entity and derivative of naloxone. The Food and Drug Administration (FDA) recently approved naloxegol for marketing for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. Based on the

FDA's approval of naloxegol for marketing for an identified medical purpose, and the lack of evidence of a high potential for abuse of this product, the Board concurs with the DEA's decision to remove naloxegol from control under the CSA.

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 November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

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

This amendment is intended to implement Iowa Code section 124.201.

The following amendment is proposed.

Rescind current rule 10.38(124) and adopt the following new rule in lieu thereof:

**657—10.38 (124) Temporary designation of controlled substances.**

**10.38(1)** Amend Iowa Code subsection 124.204(9) by adding the following new paragraphs "g," "h," "i," and "j":

g. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Oher names: AB-CHMINACA.

h. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-PINACA.

i. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: THJ-2201.

j. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: acetyl fentanyl.

**10.38(2)** Amend Iowa Code subsection 124.206(2), paragraph "a," as follows

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

# ADDENDUM D

# NOTICE OF INTENDED ACTION

# CHAPTER 22,
# "UNIT DOSE, ALTERNATIVE PACKAGING, AND EMERGENCY BOXES"

# AUGUST 31, 2015

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 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment eliminates the requirement for a record, on the prescription, identifying the patient med pak in which the prescription drug is packaged. The patient med pak record requires identification of each prescription included in the patient med pak. Requiring the complimentary record on the prescription is duplicative and unnecessary. The amendment further clarifies that the unique identification number of the current prescription drug order must be included in the patient med pak record. The removal of paragraph "b" results in the organization and renumbering of the components of the subrule.

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 November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

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

This amendment is intended to implement Iowa Code sections 126.10, 126.11, and 155A.28.

The following amendment is proposed.

Amend subrule 22.5(8) as follows:

**22.5(8)** *Record keeping.*

~~*a.*~~ The record of each patient med pak shall contain, at a minimum:

~~(1)~~ a. The name and address of the patient;

~~(2)~~ b. ~~A~~ The unique identification number for each of the current prescription drug orders for each of the drug products contained therein;

~~(3)~~ c. A unique identification number for the patient med pak;

~~(4)~~ d. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

~~(5)~~ e. The date of preparation of the patient med pak and the beyond-use date that was assigned;

~~(6)~~ f. Any special labeling instructions; and

~~(7)~~ g. The name, unique identification, or initials of the responsible pharmacist.

~~*b. The record of the individual prescription drug orders for each of the drug products packaged in a patient med pak shall include the unique identification number for the patient med pak wherein the prescription drug is dispensed.*~~

# ADDENDUM E

# ADOPTED AND FILED

# CHAPTER 3, "PHARMACY TECHNICIANS," CHAPTER 6, "GENERAL PHARMACY PRACTICE," CHAPTER 7, "HOSPITAL PHARMACY PRATICE"; RESCINDS CHAPTER 13, "STERILE COMPOUNDING PRACTICES"; AND RESCINDS CHAPTER 20, "PHARMACY COMPOUNDING PRACTICES" AND ADOPTS NEW CHAPTER 20, "COMPOUNDING PRACTICES"

# AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice"; rescinds Chapter 13, "Sterile Compounding Practices"; and rescinds Chapter 20, "Pharmacy Compounding Practices," and adopts new Chapter 20, "Compounding Practices," Iowa Administrative Code.

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

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

Notice of Intended Action was published in the April 29, 2015, Iowa Administrative Bulletin as ARC 1979C. The Board received numerous written comments regarding the proposed amendments. Comments from one national pharmacy chain questioned the need to include all identified information on the label of a compounded drug product prepared for general pharmacy or outpatient dispensing. In response to those comments, the Board determined that there is no need to include the FDA contact information on the prescription label as such information can be provided in or on auxiliary information provided to the patient with the prescription. The Board did not agree that other required information, such as the identification of the product as a compounded product, was

unnecessary.

Other comments suggested realigning and adding verbiage in the definition of "compounding" to ensure understanding of the exceptions identified in the definition. The Board determined that the definition, as proposed, accurately defines the term and identifies the exceptions to the definition. The Board also received comments from practitioners objecting to the stated restrictions regarding the compounded of nonpatient-specific products for practitioner administration to patients (office use). The Board is unable to authorize Iowa pharmacies to compound and distribute nonpatient-specific products for office use unless the Iowa pharmacy is registered with the FDA as a 503B outsourcing facility. The federal Compounding Quality Act specifically addresses this issue and the Board may not adopt less stringent requirements.

The adopted amendments differ from those published under Notice. In response to comments identified above, paragraph "e" in subrule 20.19(1) is removed and subsequent paragraphs are appropriately renumbered. The removed paragraph would have required pharmacies to include, on the prescription label of a compounded drug product packaged for general pharmacy or outpatient dispensing, FDA contact information including the FDA website address or toll-free telephone number.

The amendments were approved during the August 31, 2015, meeting of the Board of Pharmacy.

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

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

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

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

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

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

*a.* to *h.* No change.

*i.* Perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*j.* Perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

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

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

*a.* to *g.* No change.

*h.* Under the supervision of a pharmacist who provides training and evaluates and monitors trainee competence in the compounding processes, perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*i.* Under the supervision of a pharmacist who provides training and evaluates and monitors trainees, and contingent on successful completion of appropriate media fill testing processes, perform~~

~~drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

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

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

ITEM 3. Amend paragraph **7.8(1)"b"** as follows:

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

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

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

CHAPTER 20

COMPOUNDING PRACTICES

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

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

*"Anticipatory compounding"* means the compounding of preparations in advance of the pharmacy's receipt of patient-specific prescriptions.

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

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

*"Bulk drug substance"* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

*"Compounding"* means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

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

*"Flavoring agent"* means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

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

Food, Drug, and Cosmetic Act.

*"USP"* means United States Pharmacopeia.

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

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

**657—20.5(126,155A) Delayed compliance.** A pharmacy that is unable to meet the requirements for full compliance with these rules and with USP Chapter 795 or USP Chapter 797 by May 18, 2016, shall, prior to that date, request and obtain from the board a waiver of the specific requirement or requirements that the pharmacy is unable to meet. A pharmacy that cannot meet the requirements for full compliance with these rules, including applicable USP chapters, and that has not obtained from the board a waiver of the specific requirement or requirements shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved a waiver of the specific requirement or requirements.

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

**657—20.7** and **20.8** Reserved.

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

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

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

**20.10(2)** *Pharmacies.* Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.

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

**657—20.12(126,155A) Compounding copies of an approved drug.** A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on

the FDA Web site, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

**657—20.13(124,126,155A) Use of flavoring agents.** A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

**657—20.14** Reserved.

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

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

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

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

distributed for office use pursuant to this rule shall not be further distributed to other practitioners or to patients for administration outside of the office.

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

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

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

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

**657—20.17** and **20.18** Reserved.

**657—20.19(124,126,155A) Labeling.** The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

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

*a.* The name and concentration of each active ingredient.

*b.* The date that the preparation was compounded.

*c.* The beyond-use date of the compounded preparation.

*d.* Special storage and handling instructions, if applicable.

*e.* The statement "COMPOUNDED PREPARATION" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

*f.* If the compounded preparation is sterile, the word "STERILE."

*g.* If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

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

*a.* The name and concentration of each active ingredient.

*b.* The date that the preparation was compounded.

*c.* The beyond-use date of the compounded preparation.

*d.* If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

*e.* Special storage and handling instructions, if applicable.

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

*a.* The statement "THIS IS A COMPOUNDED DRUG" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

*b.* The name, address, and telephone number of the outsourcing facility that compounded the preparation.

*c.* The established name of the preparation.

*d.* The dosage form and strength.

*e.* The quantity of the preparation.

*f.* The date that the preparation was compounded.

*g.* The beyond-use date of the compounded preparation.

*h.* Storage and handling instructions.

*i.* The lot or batch identification or control number.

*j.* The national drug code number, if available.

*k.* The statement "Not for resale" and, if the preparation is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "OFFICE USE ONLY."

*l.* The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

(1) Directions for use including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor Web site or telephone number) to facilitate adverse event reporting.

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

*n.* If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

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

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

**657—20.21** and **20.22** Reserved.

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

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308,

124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

# ADDENDUM F

# ADOPTED AND FILED

# CHAPTER 6, "GENERAL PHARMACY PRACTICE," CHAPTER 7, "HOSPITAL PHARMACY PRATICE," CHAPTER 15, "CORRECTIONAL PHARMACY PRACTICE," AND CHAPTER 16, "NUCLEAR PHARMACY PRACTICE"

# AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 15, "Correctional Pharmacy Practice," and Chapter 16, "Nuclear Pharmacy Practice," Iowa Administrative Code.

The amendments eliminate the requirements that pharmacies maintain the *Iowa Pharmacy Law and Information Manual* and authorize pharmacies to utilize other sources, including electronic or Internet-based sources, for Iowa pharmacy laws, rules, and regulations.

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

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2065C. The Board received numerous written comments regarding the proposed amendments. Comments were split between support of the amendments and opposition or suggestions for alternatives to the amendments. The adopted amendments differ from those published under Notice. In response to suggestions from commenters, the Board has clarified that an acceptable law reference will include all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

The amendments were approved during the August 31, 2014, meeting of the Board of Pharmacy.

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

These amendments are intended to implement Iowa Code section 155A.31.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend rule 657—6.3(155A) as follows:

**657—6.3(155A) Reference library.** References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 8. No change.

ITEM 2. Amend rule 657—7.3(155A) as follows:

**657—7.3(155A) Reference library.** References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 9. No change.

ITEM 3. Amend rule 657—15.4(155A) as follows:

**657—15.4(155A) Reference library.** References may be printed or computer-accessed. Each correctional pharmacy shall have on site, at a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 8. No change.

ITEM 4. Amend rule 657—16.5(155A) as follows:

**657—16.5(155A) Library.** Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. No change.

2. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice;

3. and 4. No change.

# ADDENDUM F

# ADOPTED AND FILED

# CHAPTER 6, "GENERAL PHARMACY PRACTICE," CHAPTER 7, "HOSPITAL PHARMACY PRACTICE," CHAPTER 15, "CORRECTIONAL PHARMACY PRACTICE," AND CHAPTER 16, "NUCLEAR PHARMACY PRACTICE"

# AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 7, "Hospital Pharmacy Practice," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments permit, as authorized by federal law, the administration of any influenza or pneumococcal vaccine to a hospital or long-term care facility patient pursuant to physician-approved hospital or facility policy after the patient has been assessed for contraindications. Current subrules limit this authority to the administration of influenza and pneumococcal polysaccharide vaccines only.

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

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2063C. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the August 31, 2015, meeting of the Board of Pharmacy.

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

These amendments are intended to implement Iowa Code sections 155A.13, 155A.15, 155A.23, and 155A.35.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend subrule 7.8(14) as follows:

**7.8(14)** *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal

patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal ~~polysaccharide~~ vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

ITEM 2. Amend subrule 23.9(4) as follows:

**23.9(4)** *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal ~~polysaccharide~~ vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's record. The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

# ADDENDUM H

# ADOPTED AND FILED

# CHAPTER 10, "CONTROLLED SUBSTANCES"

# AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.2, the Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendment rescinds rule 657—10.41(124A) in which certain substances are identified and classified as imitation controlled substances. Those substances have been identified and classified by legislative action as controlled substances subject to Iowa Code chapter 124. Rescinding the designation of those substances as imitation controlled substances eliminates the confusion created by their dual classification as imitation controlled substances, subject to the penalties for unlawful possession of imitation controlled substances, and their classification as controlled substances, subject to different penalties for unlawful possession of controlled substances.

Requests for waiver or variance are not addressed because there are no provisions from which to request a waiver or variance.

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2064C. The Board received no written comments regarding the proposed amendments. The adopted amendment is identical to that published under Notice.

The amendment was approved during the August 31, 2015, meeting of the Board of Pharmacy.

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

This amendment is intended to implement Iowa Code section 124A.2.

This amendment will become effective on November 18, 2015.

The following amendment is adopted.

Rescind and reserve rule **657—10.41(124A)**.

# ADDENDUM I

# LICENSURE BY CONSENT AGREEMENT

## NR & V DRUGS, INC.,
## d/b/a WYANDOTTE DRUGS
## WYANDOTTE, MICHIGAN

## BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---|---|---|
| Re: Application for Nonresident Pharmacy Licensure of | ) | **LICENSURE BY CONSENT AGREEMENT** |
| **NR & V DRUGS, INC., d/b/a WYANDOTTE DRUGS,** Applicant. | ) | |

**COMES NOW** the Iowa Board of Pharmacy ("Board") and N R & V Drugs, Inc., doing business as Wyandotte Drugs ("Applicant"), 364 Eureka Road, Wyandotte, Michigan 48192, and enter into this Licensure by Consent Agreement ("Agreement") pursuant to Iowa Code section 17A.10 (2015).

1. Applicant has applied for a nonresident pharmacy license.

2. Applicant provided pharmacy services to Iowa patients prior to licensure.

3. The Board has authority to deny an application for nonresident pharmacy licensure for violations of Iowa Code section 155A.13A and rules of the Board. *See* Iowa Code section 155A.13A(3) and 657 IAC 19.10.

4. It is a violation of Iowa Code section 155A.13A(1) and 657 IAC 19.2 and 36.1(4)"v" to provide pharmacy services to Iowa patients prior to obtaining a nonresident pharmacy license from the Board.

5. THEREFORE, **IT IS HEREBY ORDERED** that the Applicant shall be issued an Iowa nonresident pharmacy license with the following conditions:

   a. Applicant's license shall be placed on **PROBATION** for a period of two (2) years.

   b. Applicant shall pay a civil penalty in the amount of one-thousand dollars ($1000). This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the Executive Director of the Board within thirty (30) days of the Board's approval of this Agreement. All civil penalty payments shall be deposited into the State of Iowa general fund.

6. Applicant shall fully and promptly comply with this Agreement. Should Applicant violate the terms of this Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

7. By entering into this Agreement, the Applicant voluntarily waives any right to a contested case hearing regarding this matter. Once entered, this Agreement shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Applicant acknowledges that it has read this Agreement in its entirety, that it understands its content, and that it executed this Agreement freely and voluntarily.

9. The State's legal counsel may present this Agreement to the Board *ex parte*.

10. Applicant acknowledges that it has a right to be represented by counsel on this matter.

11. This Agreement is subject to approval by a majority of the full Board. If the Board fails to approve this Agreement, it shall be of no force or effect to either the Board or Applicant. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

12. Applicant understands that this Agreement is a public record available for inspection and copying in accordance with Iowa Code chapter 22.

13. Applicant acknowledges and understands that this Agreement will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse.

This Licensure by Consent Agreement is voluntarily submitted by Applicant to the Board for its consideration on the ___ day of _____, 2015.

N R & V Drugs, Inc., d/b/a Wyandotte Drugs
Applicant

By this signature, Nehal R. Patel acknowledges s/he is the President for N R & V Drugs, Inc., and is authorized to sign this Agreement on behalf of N R & V Drugs, Inc.

This Licensure by Consent Agreement is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

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

Copy to:

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

# ADDENDUM J

# PRELIMINARY NOTICE OF INTENT TO DENY LICENSE

## HAN. SAM. CORP.,
## d/b/a RIVER'S EDGE PHARMACY
## PALM DESERT, CALIFORNIA

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re:<br>The Application for Nonresident Pharmacy License of<br><br>**HAN. SAM. CORP.,**<br>**d/b/a RIVER'S EDGE PHARMACY**<br>Applicant. | ) | **PRELIMINARY NOTICE OF INTENT TO DENY LICENSE** |

**TO:** Han. Sam. Corp.
d/b/a River's Edge Pharmacy
36919 Cook Street, Suite 102
Palm Desert, CA 92211

**YOU ARE HEREBY NOTIFIED** that on the 31st day of August, 2015, the Iowa Board of Pharmacy ("Board") voted to deny your application for an Iowa nonresident pharmacy license. The intent to deny licensure is based upon the following:

## FACTUAL CIRCUMSTANCES

1. On April 3, 2015, the Board received an Iowa nonresident pharmacy license application from Han. Sam. Corp., d/b/a River's Edge Pharmacy.

2. On the license application, Applicant answered "No" to the question "Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?"

3. On the license application, Applicant answered "No" to the question "Does the pharmacy engage in compounding?"

4. On January 23, 2015, the California Board of Pharmacy issued an Accusation against Applicant's California retail pharmacy permit. The Accusation is currently pending.

5. Applicant's California inspection reports indicate that Applicant engages in sterile compounding.

## LEGAL GROUNDS

6. Applicants for an Iowa nonresident pharmacy license must apply in accordance with Iowa Code section 155A.13A and 657 IAC 19.2.

7. The Board has the authority to deny an Iowa nonresident pharmacy application for licensure for violations of rules of the Board. *See* Iowa Code section 155A.13A(3).

8. It is a violation of 657 IAC 36.1(4)"a" to engage in fraud in procuring a license.

## NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of 657 IAC 36.16, you may appeal the Board's preliminary notice of denial of licensure by serving a written notice of appeal and request for hearing upon the Board not more than thirty (30) days following the date of service of this notice. Applicant's written notice of appeal and request for a hearing should be directed to Terry Witkowski, Acting Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The written notice of appeal and request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be a contested case conducted pursuant to the procedures outlined at 657 IAC 35.

**If a written notice of appeal and request for hearing is not timely filed, this preliminary notice of intent to deny licensure will become final, and the Iowa nonresident pharmacy license application for Han. San. Corp. d/b/a River's Edge Pharmacy will be DENIED.**

**DATED** this 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

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

# ADDENDUM K

# SETTLEMENT AGREEMENT AND FINAL ORDER

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

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re: | ) | CASE NO. 2014-86 |
| Pharmacist License of | ) | |
| | ) | **SETTLEMENT AGREEMENT** |
| **THOMAS B. DODDS** | ) | **AND FINAL ORDER** |
| License No. 12951 | ) | |
| Respondent. | ) | |

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Thomas B. Dodds ("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 #12951 is currently active, but on probation until January 12, 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 duties of a pharmacist-in-charge 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 agrees not to serve as a pharmacist-in-charge (PIC) without the express, written consent of the Board.

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 272C and 155A and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 11 day of August, 2015.

THOMAS B. HODDS
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

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

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

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 L

# SETTLEMENT AGREEMENT AND FINAL ORDER

# RXTRA SOLUTIONS
# NONRESIDENT PHARMACY LICENSE NO. 4203
# SOUTHFIELD, MICHIGAN

## BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---|---|---|
| Re:<br>Nonresident Pharmacy License of<br><br>**RXTRA SOLUTIONS**<br>License No. 4203<br>Respondent. | )<br>)<br>)<br>)<br>)<br>) | CASE NO. 2015-34<br><br>**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 Rxtra Solutions ("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 April 29, 2015.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. Respondent now does business under the name "Creams 'N Caps". A hearing regarding the Notice of Intent to Deny Licensure to Creams 'N Caps is currently scheduled for September 1, 2015.

4. Respondent does not admit the allegations in the Statement of Charges. Respondent does, however, acknowledge 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 Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

6. Respondent acknowledges that it has the right to be represented by counsel on this matter.

7. 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.

8. 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.

9. 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.

10. This Order shall not be binding as to any new complaints received by the Board.

11. 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.

12. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

13. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

**IT IS THEREFORE ORDERED:**

14. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license and to withdraw its request for hearing regarding the Notice of Intent to Deny Licensure to Creams 'N Caps, which will result in the denial of such application, to resolve this matter.

15. This voluntary surrender, when accepted by the Board, 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.

16. Respondent shall return its Iowa nonresident pharmacy license to the Board on or before October 1, 2015, but in any event within thirty (30) days of this Order.

17. 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 voluntarily submitted by Respondent to the Board for its consideration on the 28th day of August, 2015.

RXTRA SOLUTIONS, now d/b/a
CREAMS 'N CAPS
Respondent

By this signature, Wisam Arawish acknowledges s/he is the Principal for Rxtra Solutions, now d/b/a Creams 'N Caps, and is authorized to sign this Settlement Agreement and Final Order on behalf of Rxtra Solutions, now d/b/a Creams 'N Caps.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

Copy to:

Nicholas Nahorski and Kim J. Sveska
Foley, Baron, Metzger & Juip, PLLC
38777 Six Mile Rd., Suite 300
Livonia, MI 48152
ATTORNEYS FOR RESPONDENT

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

# ADDENDUM M

# SETTLEMENT AGREEMENT AND FINAL ORDER

# LDI INTEGRATED PHARMACY SERVICES
# NONRESIDENT PHARMACY LICENSE NO. 3816
# CREVE COEUR, MISSOURI

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re:<br>Pharmacy License of<br><br>**LDI INTEGRATED PHARMACY SERVICES**<br>License No. 3816<br>Respondent. | )<br>)<br>)<br>)<br>)<br>)<br>) | CASE NO. 2015-44<br><br>**SETTLEMENT AGREEMENT AND FINAL ORDER** |

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), the Iowa Board of Pharmacy ("Board") and LDI Integrated Pharmacy Services ("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 #3816 is currently active.

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 June 23, 2015.

4. Respondent has chosen not to contest the allegation 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. The allegations in this case centered on out-of-state discipline which occurred in 2014. This Order thus constitutes reciprocal discipline based on events already reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and National Practitioner Data Bank.

6. 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.

7. Respondent is freely and voluntarily entering into this Order.

8. Respondent acknowledges that it has the right to be represented by counsel on this matter.

9. 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.

10. 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.

11. 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.

12. Respondent acknowledges and understands that this Order will be reported to the National Practitioners Data Bank and National Association of Boards of Pharmacy's Disciplinary Clearinghouse, as applicable.

13. 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.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

**IT IS THEREFORE ORDERED:**

15. Respondent is hereby **CITED** for violating the pharmacy laws of another state and failing to timely notify the Board of the violation and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

16. Respondent agrees to pay a civil penalty in the amount of one-thousand dollars ($1000.00). 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. The civil penalty though payable to the general fund shall be submitted to the Board by mailed—Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

18. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of May, 2015.

LDI Integrated Pharmacy Services
Respondent

By his signature Leonard S. Dino, Jr. acknowledges he is authorized to this Settlement Agreement and Final Order on behalf of LDI Integrated Pharmacy Services.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

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

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

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 N

# NOTICE OF HEARING
# AND
# STATEMENT OF CHARGES

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

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re: | ) | CASE NO. 2015-43 |
| Pharmacy Support Person Registration of | ) | |
| | ) | **NOTICE OF HEARING &** |
| **KAREN BEAN** | ) | **STATEMENT OF CHARGES** |
| Registration No. 3456 | ) | |
| 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 17 A.18(3) (2015). Respondent was issued Iowa pharmacy support person registration number 3456. Respondent's license is currently active.

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

Hearing. A disciplinary contested case hearing shall be held on November 3, 2015, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S. W. 8'h Street, Des Moines, Iowa.

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

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

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

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

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

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

## B. LEGAL AUTHORITY AND JURISDICTION

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

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, I4 7, 148C, and 272C and 657 Iowa Administrative Code chapter 36.

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

## C. CHARGES

### Count I
### UNETHICAL CONDUCT OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical conduct or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(3) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.25(4), 5.26(1) and 36.1(4)(*c*).

### Count II
### OBTAINING OR POSSESSING PRESCRIPTION DRUGS WITHOUT LAWFUL AUTHORITY

Respondent is charged with obtaining, possessing, or attempting to obtain or possess prescription drugs without lawful authority in violation of Iowa Code sections 147.55(9) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.26(1) and 36.1(4)(*aj*).

### Count III
### DIVERSION OF PRESCRIPTION DRUGS

Respondent is charged with diverting a prescription drug from a pharmacy for personal use or distribution in violation of Iowa Code sections 147.55(9) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.26(1) and 36.1(4)(*ak*).

## D. FACTUAL CIRCUMSTANCES

1. Respondent worked as a full-time assistant manager and pharmacy support person for HyVee.

2. The pharmacy received reports from customers that tablets were missing from hydrocodone prescriptions.

3. Closed circuit TV footage revealed that Respondent accessed some bags of filled prescriptions.

4. Respondent admitted to taking hydrocodone tablets from filled prescription bags on 10-15 occasions.

## 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 1st day of September 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

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 50319

Karen H. Bean
575 Ashton Place NE #7
Cedar Rapids, IA 52402

PROOF OF SERVICE

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

| | | | |
|---|---|---|---|
| ( ) | personal service | (X) | first class mail |
| (X) | certified mail, return receipt requested | ( ) | facsimile |
| | Article Number 9171999991703106714900 | ( ) | other _____ |

on the 21st day of September, 2015.

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

Debbie S. Jorgenson

Debbie S. Jorgenson

# ADDENDUM O

# ORDER TO SHOW CAUSE

# DAVID MARCOWITZ, D.O.
# CONTROLLED SUBSTANCE REGISTRATION NO. 1305770
# CHARITON, IA 50049

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re:<br>Controlled Substance Registration of<br><br>**DAVID MARCOWITZ, D.O.**<br>Registration No. 1305770<br>Respondent. | )<br>)<br>)<br>)<br>)<br>) | CASE NO. 2014-171<br><br>**ORDER TO SHOW CAUSE** |

TO: David Marcowitz, D.O.
1200 N Seventh Street
Chariton, IA 50049

**NOTICE:**

**Pursuant to the provisions of Iowa Code sections 124.304 and 124.305 (2015) and 657 IAC 10.12, you are hereby ordered to show cause why controlled substance registration number 1305770 should not be suspended.**

**To request a full hearing regarding the suspension of your controlled substance registration, you must file a request for a hearing in writing with the Board within thirty (30) days of service of this Order.**

**If you do not request a hearing in this matter within thirty (30) days of service of this order, your controlled substance registration will be SUSPENDED.**

## I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2015) and 657 IAC 10, the Iowa Board of Pharmacy ("Board") has jurisdiction over those who prescribe controlled substances in Iowa. The Board issued David Marcowitz ("Respondent") controlled substance registration number 1305770, subject to the laws of the State of Iowa and the rules of the Board. Controlled substance registration number 1305770 is currently active and expires after January 31, 2016.

## II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent is a licensed physician with the Iowa Board of Medicine.

2. On January 31, 2014, the Department of Financial and Professional Regulation of the State of Illinois approved a Consent Order that suspended his Illinois license to practice medicine and his Illinois controlled substance license for thirty days. The Consent Order provided that Respondent's licenses would be placed on permanent Inactive Status after the period of suspension. Respondent signed the Consent Order on January 2, 2014.

3. On January 22, 2014, Respondent submitted a controlled substance registration renewal to the Board. Respondent answered "no" to the question "has the applicant ever been convicted

of a felony in connection with controlled substances under any State or Federal law or ever surrendered (in lieu of disciplinary action) or had a CSA registration revoked, suspended, or denied?" Respondent did not report the Illinois Consent Agreement to the Board after it was approved on January 31, 2014.

4. On February 6, 2015, the Iowa Board of Medicine filed a Statement of Charges against Respondent, charging him with having a license to practice osteopathic medicine and surgery revoked or suspended, or having other disciplinary action taken by a licensing authority of another state.

5. On June 25, 2015, the Iowa Board of Medicine issued its Findings of Fact, Conclusions of Law, Decision and Order, in Respondent's contested case. The Board indefinitely suspended Respondent's medical license, but stayed the suspension pending successful completion of a mental health evaluation within 60 days, a comprehensive clinical competency evaluation within 90 days, and a professional ethics program within 120 days. The Board issued Respondent a Citation and Warning and ordered him to pay a $3,000 civil penalty. The Board also prohibited him from prescribing, administering, or dispensing controlled substances for the treatment of chronic pain and placed him on probation for five years subject to monitoring.

6. Iowa Code section 124.304(1)"e" and 657 IAC 10.12(1)"e" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has been disciplined by the registrant's professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances.

7. Iowa Code section 124.304(1)"d" and 657 IAC 10.12(1)"d" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest as determined under that section. Under 657 IAC 36.1(4)"k", the Board has the authority to impose discipline on registrants for failing to notify the Board within 30 days after a final decision entered by the licensing authority of another state which decision resulted in a license or registration revocation, suspension, or other disciplinary action.

## III. ORDER

Respondent is hereby ordered to show cause why controlled substance registration number 1305770 should not be suspended.

Respondent may request a hearing before the Board in response to this Order by filing a written request with the Board within thirty (30) days of service of this Order. Respondent's written request for a hearing should be directed to Terry Witkowski, Interim Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. If Respondent submits a timely request for a hearing on the matter, a hearing will be scheduled for the Board's next available hearing date. A separate notice of hearing will be sent to Respondent detailing the date, time, and location of the hearing.

**If Respondent does not request a hearing in this matter within thirty (30) days of service of this Order, controlled substance registration number 1305770 will be SUSPENDED.**

**IT IS SO ORDERED** on this 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

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

# ADDENDUM P

# SETTLEMENT AGREEMENT
# AND
# FINAL ORDER

# ASHLEY HENSON
# PHARMACY TECHNICIAN REGISTRATION NO. 8907
# CHEROKEE, IOWA

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re:<br>Certified Technician Registration | ) | CASE NO. 2015-74 |
| | ) | **SETTLEMENT AGREEMENT AND FINAL ORDER** |
| **ASHLEY HENSON,**<br>Registration No. 8907,<br>Respondent. | ) | |

**COME NOW** the Iowa Board of Pharmacy ("Board") and Ashley Henson ("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 certified technician registration number 8907, which expired on June 30, 2015.

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 June 23, 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

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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 certified technician 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 certified technician 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 28 day of August, 2015.

Ashley Henson

ASHLEY HENSON
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the 1st day of September, 2015.

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

Copies to:

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

# ADDENDUM Q

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

# SHERRI MARSHALL
# PHARMACY TECHNICIAN REGISTRATION NO. 18129
# DES MOINES, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

---

| | |
|---|---|
| IN THE MATTER OF THE<br>STATEMENT OF CHARGES AGAINST: | CASE NO. 2014-189<br>DIA NO. 15PHB008 |
| SHERRI MARSHALL<br>Registration No. 18129 | FINDINGS OF FACT,<br>CONCLUSIONS OF LAW,<br>DECISION AND ORDER |
| RESPONDENT | |

---

On March 10, 2015, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing and Statement of Charges against Sherri Marshall (Respondent), which charged her with three counts:

Count I: Obtaining or attempting to obtain a prescription drug by forging a prescription, in violation of Iowa Code section 155A.23 and pursuant to Iowa Code sections 147.55(8), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"j."

Count II: Making a statement tending to deceive, misrepresent, or mislead anyone, or being a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy, in violation of 657 IAC 3.28(1), and pursuant to Iowa Code sections 147.55(3) and (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."

Count III: Engaging in unethical behavior, in violation of 657 IAC 3.28(4), and pursuant to Iowa Code sections 147.55(3) and (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."

The hearing was held on June 23, 2015 at 9:10 a.m. The following members of the Board presided at the hearing: Edward Meier, Chairperson; Edward McKenna; James Miller; Sharon Meyer; Jason Hansel; and LaDonna Gratias. Assistant Attorney General Laura Steffensmeier represented the state. Respondent failed to appear for hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1)(2015), and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate their decision. The administrative law judge

was instructed to prepare the Findings of Fact, Conclusions of Law, Decision and Order, in conformance with the Board's deliberations.

## THE RECORD

The record includes the testimony of Jennifer Tiffany, R.Ph. and State Exhibits 1-17. Protective orders were issued for Exhibits 2, 6, 7, 8, 10, 11, and 13 because they include information that is confidential under Iowa Code section 22.7(2).

## FINDINGS OF FACT

1. The Board has issued pharmacy technician registration number 18129 to Respondent, which authorizes her to serve as a pharmacy technician, subject to the laws of the state of Iowa and the rules of the Board. Respondent's pharmacy technician registration is active and will expire on March 31, 2016. (State Exhibits 1, 5)

2. In October and November 2014, Respondent was employed as a pharmacy technician by the Wal-Mart Pharmacy located at SE 14th Street in Des Moines. On November 7, 2014, Wal-Mart notified the Board that Respondent's employment had been terminated based on her involvement with forged prescriptions for hydrocodone/acetaminophen 10/325 mg. Board Compliance Officer Jennifer Tiffany, R.Ph. was assigned to investigate this complaint. (State Exhibits 2, 3, 4; Tiffany testimony).

3. On November 20, 2014, Jennifer Tiffany met with a member of Wal-Mart's Security/Loss Prevention team, who provided documentation from Wal-Mart's investigation and security video footage from the pharmacy. Wal-Mart's investigation was initiated after an individual (JH) contacted the pharmacy on October 9, 2014. JH is subject to a pain management contract that requires him to fill all of his prescriptions at Walgreens. Upon checking the Prescription Monitoring Program (PMP) data base, JH's pain management physician discovered that a prescription in JH's name had been filled at the SE 14th Street Wal-Mart Pharmacy. The prescription was for 240 tablets of hydrocodone/apap 10/325, and it was filled under JH's name on September 25, 2014. (Tiffany testimony; State Exhibits 6, 7)

After JH notified Wal-Mart that he was not aware of this prescription and did not pick it up, a Wal-Mart pharmacist contacted the nurse practitioner who was listed on the prescription as the prescriber. The nurse practitioner confirmed that she did not

authorize the prescription and that it was a forgery. The nurse practitioner signed a statement attesting to that fact. (State Exhibits 6, 7; Tiffany testimony)

JH filed a criminal complaint with the Des Moines Police Department, and Des Moines Police Officer Rahn Bjornson was assigned to investigate the criminal matter. JH told Officer Bjornson that the nurse practitioner whose name was on the prescription worked at the same clinic as his pain management physician, but she did not provide treatment for him. He also told Officer Bjornson that he does not have a prescription for hydrocodone. (State Exhibit 13)

4. Wal-Mart had security video footage from September 25, 2014, which is the date that the forged prescription was transcribed and filled. The video footage shows Respondent transcribing the prescription for JH between 7:30 and 7:50 p.m. and then stapling shut the bag containing the hydrocodone/apap prescription. Respondent should have left the bag open and unsecured to allow counseling by the pharmacist because JH would have been a new customer at the Wal-Mart. Prescription bags are normally hung from a rack behind the register, but the video footage shows Respondent placing the bag with JH's prescription under the counter at the checkout register. The video footage later shows Respondent selling the bag with JH's prescription to a young male, later identified as Respondent's nephew, KL. During the transaction, Respondent reached over the counter and signed the electronic signature capture device for JH's prescription. Additional video footage showed KL leaving the pharmacy and getting into a white SUV that was registered to Adam Patrick, who was reported to be Respondent's boyfriend. (Tiffany testimony; State Exhibits 2, 8, 9)

5. Wal-Mart's security staff showed the video footage from the September 25th transaction to JH and his wife. JH's wife identified the young male who picked up the prescription as KL, who she used to babysit for. JH's wife reported that she knew KL through Respondent, who was a former friend of hers. Officer Bjornson then met with KL, who was then 15 years old, and his mother. KL told Officer Bjornson that he was paid $50 by Adam Patrick to pick up a prescription for "J" on September 25, 2014. KL further stated that Patrick told him that Respondent (his aunt) would be working. KL told Bjornson that Respondent did not ask him any questions when he picked up the prescription and that Respondent signed for the prescription. KL further reported that he repeated the procedure about one week later, but he could not remember the name on the second prescription that he picked up. When KL's mother mentioned the name of JM, KL replied that he thought that was the name on the second prescription. KL's mother reported that JM is a friend of Adam Patrick's who is currently incarcerated. (State Exhibits 2, 13; Tiffany testimony)

6. Two additional hydrocodone prescriptions that were transcribed by Respondent and filled at the SE 14th Street Wal-Mart pharmacy were also identified as fraudulent.

- One prescription, dated September 26, 2014, had purportedly been phoned in by the same nurse practitioner as the September 25th prescription for JH. This prescription was also for 240 tablets of hydrocodone/apap 10/325 and was written for patient EM. The same nurse practitioner was again contacted, and she signed a statement attesting that this prescription was not authorized by her and that it was forged or altered. (Tiffany testimony; State Exhibits 2, 10);
- The other prescription was dated October 1, 2014, was for 300 tablets of hydrocodone/apap 10/325, and was written for patient JM, who was the same person previously identified as a friend of Adam Patrick. Officer Bjornson called the practitioner listed as the authorizing prescriber on this prescription, and the clinic told Bjornson that JM was not one of their patients. Security video footage from October 2, 2014 shows KL picking up the fraudulent prescription for JM from Respondent while she was working. (State Exhibits 2, 11, 12)

7. On October 23, 2014, Officer Bjornson spoke to Respondent by phone and recorded their conversation. Respondent admitted having her nephew KL pick up the prescription for JH. Respondent told Bjornson that she paid KL $20 or $30 and that she planned to kill herself with the pills. Respondent admitted that she knew JM but did not admit involvement with that prescription. (State Exhibits 2, 13)

8. On December 8, 2014, Compliance Officer Jennifer Tiffany sent Respondent a certified letter informing her of the allegations against her related to forgery of prescriptions and theft of controlled substances from the Wal-Mart Pharmacy. Respondent replied by email on December 18, 2014. Respondent wrote that the allegations that she was stealing hydrocodone and forging prescriptions were false. Criminal charges were filed against Respondent and were still pending as of the date of the hearing. (Tiffany testimony; State Exhibits 2, 14, 15)

9. Respondent was personally served with the Notice of Hearing and Statement of Charges by Jennifer Tiffany on May 12, 2015. Respondent failed to appear for hearing. (State Exhibit 17; Tiffany testimony)

## CONCLUSIONS OF LAW

Iowa Code section 147.55(2013) provides, in relevant part, that the Board may revoke, suspend, or otherwise discipline a license for any of the following offenses:

> ...
>
> 3. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.
>
> ...
>
> 8. Willful or repeated violations of the provisions of this chapter, chapter 272C, or a board's enabling statute.
>
> 9. Other acts or offenses as specified by board rule.

*See also* 657 IAC 36.1(4)"c" and "u."

Iowa Code section 155A.6A(5)(2013) and 657 IAC 3.30 authorize the board to suspend or revoke the registration of a registered pharmacy technician for any violation of the laws of this state, ... relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, 124B, 126, 147, 205, or 272C or any rule of the board.

### *Count I-Forging Prescriptions*

Iowa Code section 155A.23(1)(a)(2013) provides, in relevant part, that a person shall not obtain or attempt to obtain a prescription drug or device by: (1) engaging in fraud, deceit, misrepresentation, or subterfuge; (2) Forging or altering a written, electronic or facsimile prescription or any written, electronic or facsimile order.

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

> **36.1(4)** *Grounds for discipline.* The board may impose any of the disciplinary sanctions set out in rule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts or offenses:
>
> ...
>
> *j.* Violating a statute or law of this state,...without regard to its designation as either a felony or misdemeanor, which statute or law

> relates to the practice of pharmacy or the distribution of controlled substances, prescription drugs, or nonprescription drugs.
> ...

The preponderance of the evidence in this record established that Respondent forged prescriptions for hydrocodone, a controlled substance, and engaged in additional acts of deception and misrepresentation that facilitated the prescriptions to be filled and picked up by persons for whom they were not legitimately prescribed. Respondent engaged in these acts while employed as a pharmacy technician. The evidence collected in the investigations, including but not limited to the security video footage, the statements made by KL and his mother, and Respondent's admissions to the Board's investigator, constitute overwhelming evidence of Respondent's active participation in creating and filling fraudulent prescriptions at the pharmacy where she was employed. Respondent has violated Iowa Code sections147.55(8), 155A.6A(5), 155A.23 and 657 IAC 3.30 and 36.1(4)(j).

*Count II-Misrepresentative Deeds*

657 IAC 3.28(1) provides that it is unethical conduct for a pharmacy technician to make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

The preponderance of the evidence in this record established that Respondent engaged in unethical conduct through misrepresentative deeds when she participated in forging and filling forged hydrocodone prescriptions. Respondent has violated Iowa Code sections 147.55(3), (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."

*Count III-Engaging in Unethical Behavior*

657 IAC 3.28(4) prohibits pharmacy technicians from exhibiting unethical behavior in connection with the technician's pharmacy employment. Unethical behavior includes but is not limited to theft. The preponderance of the evidence in this record established that Respondent engaged in unethical conduct, i.e. theft, when she participated in forging and filling forged hydrocodone prescriptions at the pharmacy where she was employed. Respondent has violated Iowa Code sections 147.55(3), (9), 155A.6A(5) and 657 IAC 3.28(4), 3.30 and 36.1(4)"c" and "u."

DECISION AND ORDER

The very serious nature of Respondent's violations and her failure to appear for hearing justifies the revocation of her registration as a pharmacy technician. IT IS THEREFORE ORDERED that pharmacy technician registration number 18129, issued to Sherri Marshall, is hereby REVOKED. If Respondent seeks reinstatement of her pharmacy technician registration in the future, the burden will be placed on her to show that the basis for the revocation no longer exists and that is in the public interest for her registration to be reinstated. 657 IAC 36.13(4).

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondent shall pay $75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 1st day of September, 2015.

Edward Maier, Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General
Hoover State Office Building (LOCAL)

A default decision or decision rendered on the merits after a party has failed to appear or participate in a contested case hearing shall become final board action unless within 15 days after the date of notification or mailing of the decision a motion to vacate is filed and served on all parties or unless an appeal of a decision is timely initiated within the time provided by rule 35.26. A motion to vacate must state all facts relied upon by the moving party which establish good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated shall be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) shall be attached to the motion. 657 IAC 35.21. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate. 657 IAC 35.21(4).

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 R

# IOWA BOARD OF PHARMACY
# EXECUTIVE DIRECTOR INTERVIEW QUESTIONS
# AND
# SCORING SHEET

# Iowa Board of Pharmacy
## Executive Director Interview Questions

Candidate: _____ Date: **September 2, 2015**

Board Member: _____

I. Working with a Board and staff of diverse personalities with different interests and priorities can be a challenge. In addition, the Board of Pharmacy has numerous constituencies including the people of Iowa; pharmacists, pharmacy owners, and pharmacy staff; legislators and the Governor; other regulatory boards, state, and federal agencies; the Attorney General's office; professional organizations, associations, and societies including IPA, IMS, NABP, and ODCP; consumer groups; and Board staff, to name a few. What basic principles would you use in dealing with these diverse groups? How have you handled similar situations?

_____

II. How would you handle discipline with your staff and peers working for the Board of Pharmacy?

_____

III. What excites you most about this position? What challenges are you looking for in this position? Why should we hire you for this position?

_____

IV. What one word would your co-workers and peers use to best describe you?

_____

V. Provide an example of how you worked with one or more employees or colleagues to improve their skills and abilities.

_____

VI. What do you see as the biggest challenges facing pharmacy in the next five years? How do you see the role of the Board of Pharmacy in addressing these challenges?

_____

VII. How would you deal with someone you knew was 100% wrong about something? How would you handle it?

_____

VIII. What resources do you anticipate being able to draw upon as executive director if circumstances present or issues develop in which you have no experience or procedural knowledge? Where do you turn for assistance or direction?

---

IX. Many duties or projects can be competently handled by staff members. If you delegate to a member of your staff, how do you determine if the staff member has gone too far with the task or if the task has been satisfactorily completed?

---

X. Have you contacted the past executive director to discuss this position and the duties and responsibilities of the position? If yes, what were his two best pieces of information or advice to you?

---

XI. Tell us about a time when you had to cope with strict time demands. How did you cope? What was the result?

---

XII. What are the active listening techniques you have found to be most effective? Provide a specific example from your past experience to illustrate. Describe the situation, what you did, and how you know you were effective.

---

XIII. What is the one thing you want to do, investigate, or get clarified on your first day of working for the Board of Pharmacy?

---

XIV. What do you expect from the Board in this position?

---

XV. What questions would you ask of Board members if you were interviewing us?

---

# Iowa Board of Pharmacy
# Executive Director Interview Questions

Candidate: _____ Date: **September 2, 2015**

Board Member: _____

**Total Score:_____ (***Maximum 105***)**

| | | |
|---|---|---|
| Managerial Experience<br>• Budgeting, revenue and expenses<br>• Human resources, recruiting, hiring, monitoring, disciplinary<br>• People skills | (20 points maximum) | |
| Leadership/Team Building Experience | (10 points maximum) | |
| Pharmacy/ Public Safety Vision | (15 points maximum) | |
| Organizational Skills | (20 points maximum) | |
| State Political Process Experience | (10 points maximum) | |
| Communication Skills | (15 points maximum) | |
| State Board of Pharmacy Experience | (15 points maximum) | |

Additional Comments or Observations:

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