

State of Iowa
Board of Pharmacy

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

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BOARD MEMBERS

LADONNA GRATIAS
EDWARD McKENNA
EDWARD MAIER

JAMES MILLER

Board Chair

ANDREW FUNK

Executive Director

BOARD MEMBERS

JASON HANSEL
SHARON MEYER
JUDITH TRUMPY

MINUTES

January 12-13, 2016

The Iowa Board of Pharmacy met on January 12-13, 2016, in the conference room at 400 SW Eighth Street, Des Moines, Iowa

TUESDAY, JANUARY 12, 2016

MEMBERS PRESENT

James Miller, Chairperson
Sharon K. Meyer, Vice-Chair
LaDonna Gratiias
Jason Hansel
Edward J. McKenna
Judith M. Trumpy

MEMBERS ABSENT

Edward L. Maier

STAFF PRESENT

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

Call to Order & Announcements

At 9:00 a.m., James Miller, Chairperson called the meeting of the Iowa Board of Pharmacy to order on Tuesday, January 12, 2016.

Motion To Continue Hearing

Minnesota Independent Coop Inc., Wholesale License No. 6764 of Egan, Minnesota.

Motion by Jason Hansel, seconded by Edward McKenna, to approve Motion to Continue Hearing. Motion approved unanimously. A copy of the Motion to Continue Hearing is attached as Addendum A.

Closed Session

At 9:10 a.m., on a 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:

Review of Closed Session Minutes pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required by state or federal law to be kept confidential, specifically to review or discuss information that is confidential under Iowa Code § 21.5(4).

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

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

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

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

At 10:51 a.m., while still in closed session, Edward McKenna moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

2015-37, Wells Pharmacy Network LLC, Nonresident Pharmacy License No. 3385, Ocala, Florida - Motion to Dismiss and Second Motion to Continue

At 11:00 a.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistance Attorney General Meghan Gavin represented the State. Wells Pharmacy Network LLC was represented by Scott Galenbeck and Michael Sellers. The session was conducted in the presence of the Board and open to the public.

At 11:28 a.m., the record was closed.

At 11:30 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 11:55 p.m., while still in closed session, Edward McKenna moved that the Board go into open session, seconded by Judith Trumpy. Motion approved unanimously.

Motion by Jason Hansel, seconded by Edward McKenna to deny Motion to Dismiss and Second Motion to Continue. Motion approved unanimously.

Motion by Judith Trumpy, seconded by Sharon Meyer, to direct Administrative Law Judge LaMarche to draft the Order consistent with the Board's deliberation for case 2015-37, Wells Pharmacy Network LLC, for the Board Chair's signature. Motion approved unanimously. A copy of Board Orders Denying Motion to Dismiss and Second Motion to Continue and Order Granting State Request to Amend Count 1 is attached as Addendum B.

2015-163, Alpine Wellness Inc, Wholesale Drug License No. 7778, Urbandale - Motion to Amend Statement of Charges

At 12:03 p.m., motion by Jason Hansel, seconded by Sharon Meyer, to go into closed session 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).

At 12:06 p.m., while still in closed session, Sharon Meyer moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

Motion by Sharon Meyer, seconded by Jason Hansel, to approve Order Granting Motion to Amend and Amended Notice of Hearing and Statement of Charges. Motion approved unanimously. Copies of the Order Granting Motion to Amend and Amended Notice of Hearing and Statement of Charges are attached as Addendum C.

Closed Session

At 1:04 p.m., motion by Jason Hansel, seconded by Edward McKenna, to go into closed session for the following reason:

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

At 3:06 p.m., while still in closed session. Edward McKenna moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

In open session the following actions were taken:

1. Obudsman's Request.

Motion by Jason Hansel, seconded by Edward McKenna to approve a waiver of the attorney-client privilege as discussed in closed session. Motion approved unanimously.

2. Closed Session Minutes.

Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Closed Session Minutes and Deliberations of the November 3-4, 2015, meeting. Motion approved unanimously.

3. Close With No Action.

Motion by Edward McKenna, seconded by LaDonna Gratias, to close with no further action the following investigative files in complaint numbers: 2015-64, 2015-173, 2015-

174, 2015-175, 2015-176, 2015-178, 2015-179, 2015-180, 2015-183, 2015-190, 2015-194, 2015-200, 2015-204, 2015-210, 2015-211, 2015-218, 2015-219, 2015-220, 2015-177, 2015-155, 2015-159, 2015-151, 2015-154, 2015-193, 2015-209, 2015-152, 2015-105, 2015-187, 2015-207, 2015-208, 2015-130, and 2015-162. Motion approved unanimously.

4. Draft Statement of Charges.

Motion by Edward McKenna, seconded by Jason Hansel, to draft Statement of Charges against the pharmacist in 2015-102, pharmacy in 2014-181, current pharmacist in charge and pharmacy in 2013-81, 2013-129, and 2013-201, technician in 2015-201, pharmacist and pharmacy in 2015-184, technician in 2015-161, and technician in 2015-188. Motion approved unanimously.

5. Combined Statement of Charges and Settlement Agreement.

Motion by LaDonna Gratias, seconded by Edward McKenna, to draft Combined Statement of Charges and Settlement Agreement against the pharmacist in 2015-197. Miller abstains. Motion was approved.

6. Letter of Education.

Motion by LaDonna Gratias, seconded by Sharon Meyer, to issue a Letter of Education to the pharmacist in charge, pharmacy and two technicians in 2015-153, and pharmacist in 2015-164. Motion approved unanimously.

7. Administrative Warning.

Motion by Jason Hansel, seconded by Edward McKenna, to issue an Administrative Warning to the CSA Registrant in 2015-171. Motion approved unanimously.

8. Settlement Agreement and Final Order.

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

- A. Mark Odland, Pharmacist License No 16408 of Dows. A copy of the Settlement Agreement and Final Order is attached as Addendum D.
- B. Downing Labs, LLC f/k/a NuVision Pharmacy, Inc., Nonresident Pharmacy License Nos. 4030 and 4626 of Dallas, Texas. A copy of the Settlement Agreement and Final Order is attached as Addendum E.
- C. Keysource Medical Inc., Wholesale Drug License No. 6272 of Cincinnati, Ohio. A copy of the Settlement Agreement and Final Order is attached as Addendum F.
- D. Adam Castle, Pharmacy Technician Registration No. 19952 of Clinton. A copy of the Settlement Agreement and Final Order is attached as Addendum G.
- E. Dawn Ruehle, Pharmacist License No. 16618 of Cherokee. A copy of the Settlement Agreement and Final Order is attached as Addendum H.
- F. Hy-Vee Pharmacy #1068, Pharmacy License No. 811 of Cherokee. A copy of the Settlement Agreement and Final Order is attached as Addendum I.

- G. Priority Pharmaceuticals, Wholesale License No. 5989 of San Diego, California. A copy of the Settlement Agreement and Final Order is attached as Addendum J.
 - I. Edward Sarazin, Pharmacist License No. 15076 of Iowa City. A copy of the Settlement Agreement and Final Order is attached as Addendum K.
9. Notice of Hearing and Statement of Charges.
- Motion by Judith Trumpy, seconded by Edward McKenna, to approve the Notice of Hearing and Statement of Charges in the following cases. Motion approved unanimously.
- A. Drug Depot, Inc. d/b/a APS Pharmacy, Nonresident Pharmacy License Nos. 4139 and 4375 of Palm Harbor, Florida. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum L.
 - B. Ankeny Pharmacy, Pharmacy License No. 1475 of Ankeny. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum M.
 - C. Rockford Anderson, Pharmacist License No. 20335 of Ankeny. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.
 - D. Justin Adam, Pharmacy Technician Registration No. 12376 of Sioux City. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum O.

Meghan Gavin and Laura Steffensmeier left the room.

Closed Session

At 3:21 p.m., motion by Sharon Meyer, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Findings of Fact, Conclusions of Law, Decision and Order pursuant to Iowa Code § 21.5(5)(f) to discuss the decision to be rendered in the following contested cases: 2015-25, Inie Clement and 2016-104, Kevin J. O'Rourke.

At 3:25 p.m., while still in closed session, Jason Hansel moved that the Board go into open session, seconded by Sharon Meyer. Motion approved unanimously.

In open session, the following action was taken:

Motion by Jason Hansel, seconded by Sharon Meyer to approve the Findings of Fact, Conclusions of Law, Decision and Order in the following cases. Motion approved unanimously.

- A. Inie Clement, Pharmacist License No. 16963 of Des Moines. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum P.
- B. Kevin J. O'Rourke, Pharmacist License No. 15064 of Iowa Falls. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Q.

At 3:27 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, January 13, 2016, at 9:00 a.m.

WEDNESDAY, JANUARY 13, 2016

MEMBERS PRESENT

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

MEMBERS ABSENT

Edward L. Maier

SPEAKERS

Jon Pritchett, PCAB
Pamela Wiltfang, NuCara
Megan Myers, IPA
Anthony Pudlo, IPA
Michael Andreski, Drake
Amanda Latta, IPRN
Robert Fecik, Minneapolis, MN
Carl Olsen, Des Moines
Dave Blaha, North Iowa Pharmacy
Pat Hill, North Iowa Pharmacy
Kate Gainer, IPA
Dale Woolery, ODCP

STAFF PRESENT

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

Call to Order and Announcements

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

Public Comments

No public comments.

Approval of Minutes

The minutes of the November 3-4, 2015, meeting were reviewed.

Motion by Sharon Meyer, seconded by Jason Hansel, to approve the open session minutes of the November 3-4, 2015, meeting as presented. Motion approved unanimously.

Reports

1. Executive Director's Report -

Meetings and Travel

- A. Terry Witkowski and Andrew Funk attended Heroin & Opioids: A Community Crisis Seminar at the University of Iowa, College of Public Health on November 12, 2015.
- B. Jennifer O'Toole attended the National Association of Boards of Pharmacy (NABP) Assessment for Remediation Evaluation (PARE) Item Development Workshop on November 12-13, 2015, in Mount Prospect, Illinois.
- C. Sue Mears and Andrew Funk attended the Federal Drug Administration's (FDA) Inter-Governmental Meeting on Pharmacy Compounding and Drug Supply Chain Security on November 16-17, 2015, in Silver Spring, Maryland.
- D. Jennifer Tiffany and Laura Steffensmeier attended the Interactive Compliance Officer and Legal Counsel Forum hosted by NABP on December 1-2, 2015, in Northbrook, Illinois.
- E. Sharon Meyer and Jean Rhodes attended the ASHP Midyear Clinical Meeting on December 6-10, 2015, in New Orleans, Louisiana.
- F. Sharon Meyer, Jim Wolfe, Curt Gerhold, and Andrew Funk attended the Iowa Pharmacy Technician Curriculum Task Force on January 8, 2016, in Des Moines.
- G. The Iowa Pharmacist Recovery Network (IPRN) Planning Committee will meet at the board office on January 14, 2016, in Des Moines.
- H. The Telepharmacy Task Force Committee will meet at the board office on January 15, 2016, in Des Moines.
- I. IPA Legislative Day will be held on January 27, 2016, in Des Moines. Andrew Funk will be presenting the Board's 2016 Legislative Agenda and background of the rule-making process.
- J. The 2016 IPA Midwest Pharmacy Expo will be held in Des Moines on February 12-14, 2016. Andrew Funk plans to attend the Expo.
- K. The APhA Annual Meeting will be held on March 4-7, 2016, in Baltimore, Maryland.
- L. The March board meeting is scheduled for March 8-9, 2016, at the Iowa Memorial Union Building at the University of Iowa in Iowa City.
- M. NABP's 112th Annual Meeting will be held on May 14-17, 2016, in San Diego, California. Andrew Funk plans to attend the meeting.
- N. The Iowa Board of Pharmacy will hold a one-day strategic planning meeting in late May or early June, 2016. The date and location of the meeting to be determined.
- O. The Iowa Board of Pharmacy will be hosting the NABP District 5 Meeting in August of 2017. The location of the meeting is to be determined.

Office/Program Updates

A. Vacant Positions.

- Program Planner - Andrew Funk and Terry Witkowski continue to work on designing and assigning job duties to the position. The primary function of this position will be the Prescription Monitoring Program (PMP) database administration.

- Compliance Officer - position to be based out of the board office.

B. Database Licensing System Options.

- Option 1: eLicense - \$260,000 up-front, with \$3,900 a month for on-going support fees. eLicense is not an approved database option by the Office of the Chief Information Officer (OCIO).
- Option 2: Salesforce – approximately \$700,000 up-front, with \$6,500 a month for on-going support fees. Salesforce and AMANDA are two databases preferred and approved by OCIO.

2. Iowa's Health Improvement Plan 2017-2021; Iowa Board of Pharmacy's Priority Health Issues.

The Department of Public Health (IDPH) is coordinating an assessment that will identify priority health issues and has requested the Board of Pharmacy recommend three priority health issues. Suggested recommendations include: Prescription Monitoring Program, contribute to the control of controlled prescription diversion of Opioid addiction, sterile compounding issues, pharmacy access in rural Iowa, and the TakeAway Program.

3. Iowa Pharmacist Tracking System 2014 Annual Report.

Informational item.

4. Broader Strategies Necessary to Counter Painkiller Over Prescribing, Researchers Say.

Informational item.

5. Pharmacy Compounding Accreditation Board (PCAB) Request for Presentation: "Compounded Drugs – What Tools Can a State Utilize to Preserve Access While at the Same Time Fulfilling the Mission of Protecting Public Safety" – Jon Pritchett.

Jon Pritchett provided a presentation. In 2014, the Accreditation Commission for Health Care (ACHC) launched ACHC Inspection Services (AIS), a division focused on providing inspection services for healthcare organization on behalf of state regulatory bodies and the Pharmacy Compounding Accreditation Board (PCAB) became a service of ACHC. PCAB is an organization that provides an accreditation program for compounding pharmacies nationwide.

6. Legal Update – Addressing the Supreme Court's North Carolina Dental Decision – Options for the States – Meghan Gavin.

Policy and Statutory changes will need to be addressed by the Legislature. Attorney Generals Meghan Gavin and Laura Steffensmeier will continue to advise the Board on a case-by-case basis on issues and concerns regarding this topic.

7. NuCara Pharmacy, Zearing 3rd Quarter 2015 Telepharmacy Report.

NuCara Pharmacy provided their 3rd Quarter Telepharmacy Report for review.

8. NABP Legal/Compliance Forum – Jennifer Tiffany and Laura Steffensmeier.

Laura Steffensmeier and Jennifer Tiffany attended the Interactive Compliance Officer and Legal Counsel Forum hosted by NABP. Sessions attended include: The Drug Supply

Chain Security Act, North Carolina Dental, Diversion and Fraud Prevention, Multistate Pharmacy Inspection Blueprint, and Multi-Topic sessions.

9. 2015 Inter-governmental Working Meeting on Drug Compounding and Drug Supply Chain Security.

Sue Mears and Andrew Funk attended the Federal Drug Administration's (FDA) Inter-Governmental Meeting on Pharmacy Compounding and Drug Supply Chain Security. Sessions attended include: Memorandum of Understanding, Information Sharing and Disclosure, Comparison of cGMP and USP 979, Inspections of Sterile Compounding Facilities and Enforcement and the Drug Supply Chain Security Act.

10. The Drug Enforcement Administration (DEA) Press Release: DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol.

Informational item.

11. New Practice Model Pilot Presentation – Megan Myers and Anthony Pudlo, Iowa Pharmacy Association (IPA).

Megan Myers and Anthony Pudlo provided an update on the New Practice Model Pilot. The New Practice Model Initiative is a Demonstration Project to study the effects of implementing tech-check-tech programs in community practice to engage community pharmacists in clinical pharmacy services. Questions and concerns regarding the Model were addressed.

12. New Practice Model for Community Pharmacy Phase Two Quarter Three Report – Megan Myers, IPA.

Phase Two Quarter Three Report for the New Practice Model Project was provided for review.

13. New Practice Model for Community Pharmacy Phase One Quarter Six Report – Megan Myers, IPA.

Phase One Quarter Six Report for the New Practice Model Project was provided for review.

14. New Practice Model for Community Pharmacy Phase One 18 month Final Report – Megan Myers, IPA and Michael Andreski, Drake.

Phase One 18 Month Final Report for the New Practice Model Project was provided for review. Michael Andreski provided a summary of the report.

15. 50-Year Pharmacist.

A list of Iowa pharmacists receiving their 50-year pharmacist certificates was provided for review.

16. Iowa Pharmacy Recovery Network (IPRN) Report - Amanda Latta.

Amanda Latta provided the IPRN Report.

Requests

1. Reactivation of Pharmacist License – Robert Fecik, Pharmacist License No. 18381 of Minneapolis, Minnesota.

Motion by Edward McKenna, seconded by Jason Hansel, to approve Mr. Fecik's request for reactivation of his Iowa pharmacist license with the conditions he completes 500 hours of internship in a pharmacy approved by the Board, submits an application and reactivation fee of \$630.00, and takes and passes the NAPLEX and MPJE examinations with a deadline of January 13, 2018. Motion approved unanimously.

2. Request for Clarification – Carl Olsen, Des Moines.

Meghan Gavin was asked to provide an update. Mr. Olsen withdrew his Request for Clarification. Ms. Gavin recommended the Board take no action on this agenda item at this time.

3. Mercy Medical Center North Iowa Request for Approval of Tech-Check-Tech Program.

Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the request for Tech-Check-Tech Program. Motion approved unanimously.

4. Request to Modify Contract for Medication Disposal – Iowa Pharmacy Association.

Motion by Judith Trumpy, seconded by Edward McKenna, to approve the request to modify the Contract for Medication Disposal granting additional funding in the amount of \$50,000 to provide for the additional services, equipment, and administration of the pharmaceutical collection and disposal program (TakeAway) as proposed. Motion approved unanimously. Contract Addendum is attached as Addendum R.

Rules and Legislation

1. Fees.

At the November 3-4, 2015, board meeting the Board approved filing Notice of Intended Action to change rules as needed to implement new licensing fees. The proposal was submitted to the Governor's office and was not approved. The Board will continue to review licensing fees at a later date.

2. Proposed for Adoption and Filing – Chapter 4, "Pharmacist-Interns."

Motion by Jason Hansel, seconded by Sharon Meyer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum S.

3. Proposed for Adoption and Filing – Chapter 6, "General Pharmacy Practice," and Chapter 8, "Universal Practice Standards."

Motion by Judith Trumpy, seconded by Edward McKenna, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum T.

4. Proposed for Adoption and Filing – Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses," and Chapter 23, "Long-term Care Pharmacy Practice."

Motion by Edward McKenna, seconded by Judith Trumpy, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum U.

5. Proposed for Adoption and Filing – Chapter 8, “Universal Practice Standards.”

Motion by Jason Hansel, seconded by Edward McKenna, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum V.

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

Motion by Sharon Meyer, seconded by LaDonna Gratias, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum W.

7. Proposed for Adoption and Filing – Chapter 22, “Unit Dose, Alternative Packaging, and Emergency Boxes.”

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

8. Notice of Intended Action to Amend Chapter 20, “Compounding Practices.”

Motion by Jason Hansel, seconded by LaDonna Gratias, to approve for filing Notice of Intended Action. Motion approved unanimously. A copy is attached as Addendum Y.

Licensure/Registrations

1. Aeva LLC, d/b/a Aeva Specialty Pharmacy, Las Vegas, Nevada - Application for Nonresident Iowa Pharmacy License.

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

2. Carrollton Prescription, Haleyville, Alabama - Application for Nonresident Iowa Pharmacy License.

This item was tabled.

3. Grove Professional Pharmacy, Inc., Springfield, Missouri - Application for Nonresident Iowa Pharmacy License Application.

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

4. OPS International, d/b/a/ Olympia Pharmacy, Orlando, Florida - Application for Nonresident Iowa Pharmacy License.

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

5. Pharmatek Pharmacy, Peoria, Arizona – Application for Nonresident Iowa Pharmacy License.

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

6. Sentriz Pharmacy and Discounts, Pompano Beach, Florida – Application for Nonresident Iowa Pharmacy License.

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

7. Trigen Laboratories, Sayerville, New Jersey – Iowa Wholesale Drug License Application.

Motion by Edward McKenna, seconded by Judith Trumpy, to approve the Iowa Wholesale Drug License Application. Motion approved unanimously.

Complaints Against Non-Licensees

1. 2015-143 John Stidham, McClland.

Motion by Judith Trumpy, seconded by Jason Hansel to close. Motion approved unanimously.

Motion by Judith Trumpy, seconded by Edward McKenna to adjourn at 1:48 p.m. on January 13, 2016.

Becky Hall
Recording Secretary

Andrew Funk
Executive Director

James Miller
Board Chair

APPROVED THIS _____ DAY OF _____, 20____.

ADDENDUM A

MOTION TO CONTINUE HEARING

**MINNESOTA INDEPENDENT COOP INC.
WHOLESALE LICENSE NO. 6764
EGAN, MINNESOTA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-100
Wholesale Drug License of)	
)	MOTION TO CONTINUE HEARING
MINNESOTA INDEPENDENT)	
COOPERATIVE, INC.)	
License No. 6764)	
Respondent.)	

COMES NOW the State of Iowa, by and through the undersigned, and pursuant to 657 IAC 35.16, requests that the contested case hearing in the above-captioned matter, currently scheduled for January 12, 2016, be continued, based on the following:

1. The Iowa Board of Pharmacy filed a Notice of Hearing and Statement of Charges in the above-captioned matter on November 4, 2015.
2. The Notice of Hearing and Statement of Charges was sent via certified mail return-receipt requested to Respondent's address of record in Minnesota.
3. The certified mail was signed for by an unknown individual. The signature is illegible.
4. The Factual Circumstances contained in the Notice of Hearing and Statement of Charges allege that Respondent ceased operations and closed its location in Minnesota.
5. The State does not believe that service is sufficient under Iowa Code section 17A.12 given these circumstances.
6. The State requests that the hearing be continued to allow for proper service.

WHEREFORE, the State of Iowa respectfully requests that the hearing in this matter be continued pending further order of the Board.

Respectfully submitted,

THOMAS J. MILLER
Attorney General of Iowa

/s/ Laura Steffensmeier
LAURA STEFFENSMEIER
Assistant Attorney General
Iowa Department of Justice
Hoover State Office Bldg., 2nd Floor
Des Moines, Iowa 50319-0108
Tele: (515) 281-6690
FAX: (515) 281-4209
E-mail: laura.steffensmeier@iowa.gov
ATTORNEY FOR THE STATE

ORIGINAL FILED

Copy to:

Minnesota Independent Cooperative
2980 Commers Drive, Ste. 200
Eagan, MN 55121

Proof of Service	
The undersigned certifies that the foregoing instrument was served upon each of the persons identified as receiving a copy by delivery in the following manner on the 7 th day of January, 2016.	
<input checked="" type="checkbox"/> U.S. Mail	<input type="checkbox"/> FAX
<input type="checkbox"/> Hand Delivery	<input type="checkbox"/> Overnight Courier
<input type="checkbox"/> Federal Express	<input type="checkbox"/> Other
<input type="checkbox"/> Electronically	
Signature: <u>R. Dales</u>	

ADDENDUM B

**BOARD ORDERS DENYING MOTION TO DISMISS AND
2ND MOTION TO CONTINUE**

**ORDER GRANTING STATE REQUEST TO AMEND
COUNT 1**

**WELLS PHARMACY NETWORK, LLC
NONRESIDENT PHARMACY LICNESE NO. 3385
OCALA, FLORIDA**

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF :

CASE NO. 2015-37

WELLS PHARMACY NETWORK, LLC
License No. 3385

BOARD ORDERS DENYING
MOTION TO DISMISS AND
2ND MOTION TO CONTINUE

RESPONDENT

ORDER GRANTING STATE
REQUEST TO AMEND COUNT I

Procedural History: On November 4, 2015, the Iowa Board of Pharmacy (Board) found probable cause to issue a Notice of Hearing and Statement of Charges to Wells Pharmacy Network, LLC (Respondent). Respondent is charged with six (6) legal counts, and the Statement of Charges includes eight (8) paragraphs of Factual Circumstances in support of those counts. On November 30, 2015, the hearing in this matter was continued to March 8, 2016. The continuance was issued in response to Respondent's 1st Motion to Continue.

On December 9, 2015, Respondent's attorney filed a Combined Motion to Dismiss and Memorandum. Respondent asked the Board to dismiss the first four (4) counts in the Statement of Charges. On December 21, 2015, Respondent's attorney filed a Second Motion for Continuance asserting that the Motion to Dismiss must be separately and preliminarily considered by the Board due to the necessity of having out-of-state witnesses for any evidentiary hearing. On December 22, 2015, the state's attorney filed a Resistance to Combined Motion to Dismiss and Second Motion to Continue. Respondent filed a Reply to the state's resistance on December 30, 2015.

On January 12, 2016, the Board convened to consider the pending Motion to Dismiss and the 2nd Motion to Continue. The attorneys were each allowed 10 minutes of oral argument before the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate their decision.

Notice Requirements Under the Iowa Administrative Procedures Act and Legal Standard for Motions to Dismiss: Parties to an administrative hearing are entitled to notice and an opportunity to defend. Iowa Code section 17A.12(1). *See also Alfredo v. Iowa Racing and Gaming Comm'n*, 555 N.W.2d 827, 833(Iowa 1966). The Iowa

Administrative Procedures Act (Iowa Code chapter 17A) requires that notice of a contested case hearing contain a “short and plain statement of the matters asserted.” Iowa Code section 17A.12(d)(2). Similarly, the Board’s administrative rule governing notices of hearing (657 IAC 35.5) requires the notice of hearing to include, in relevant part:

...

b. A statement of the legal authority and jurisdiction under which the hearing is to be held;

c. A reference to the particular sections of the statutes and rules involved;

d. A short and plain statement of the matters asserted. If the board or other party is unable to state the matters in detail at the time the notice is served, the initial notice may be limited to a statement of the issues involved. Thereafter upon application, a more definite and detailed statement shall be furnished;

...

A motion to dismiss tests the legal sufficiency of a challenged pleading. *Southard v. Visa U.S.A. Inc.*, 734 N.W.2d 192, 194. (Iowa 2007). In determining whether to grant a motion to dismiss for failure to state a claim upon which relief may be granted, a court view the well-pled facts of the petition in the light most favorable to the plaintiff, resolving any doubts in the plaintiff’s favor. *Turner v. Iowa State Bank & Trust Co. of Fairfield*, 743 N.W. 2d 1, 3 (Iowa 2007). When considering a motion to dismiss for failure to state a claim upon which any relief may be granted, a court cannot consider factual allegations contained in the motion or the documents attached to the motion; the court must ignore these facts, except those of which the court may take judicial notice. *Id.*

Count I: Count I charged Respondent with dispensing a prescription without verifying a valid patient-practitioner relationship, in violation of Iowa Code sections 147.55(9), 155A.13A(3) and 657 IAC 8.3(1), 8.19(4), 19.3, and 36.1(4)(u). The factual circumstances related to this charge are found in paragraph 4 and state:

4. Wells Pharmacy dispensed numerous prescriptions from Randall L. Sisam, whose Iowa medical license is inactive, to Iowa patients. The prescription indicates that Dr. Sisam resides in Maine, while Mr. Sisam’s LinkedIn profile states that he resides in South Carolina and consults for Kingsberg Medical. Wells Pharmacy took

no action to ensure that a valid, preexisting patient-prescriber relationship existed.

Respondent asserts that: (1) the Statement of Charges fails to cite legal authority for the stated charge; (2) the Iowa Code and Iowa Administrative Code sections cited in Count I do not require a pharmacist to verify the validity of a patient-practitioner relationship prior to dispensing each prescription; and (3) no other provision of the Iowa Code or Iowa Administrative Code require a pharmacist to verify the existence of a valid patient-practitioner relationship prior to dispensing each prescription. Respondent notes that 657 IAC 8.19(1) states that a valid prescription drug order shall be based on a valid patient-prescriber relationship. Respondent asserts that the elements of a valid patient-prescriber relationship are not defined and is a task most appropriately left to the provider's licensing boards.

The state responded by pointing out that the citation to rule 8.19(4) in Count I appears to be a scrivener's error and that the correct citation is 8.19(5). The state moved to amend Count I to correct this error. Upon review of 8.19(4) and 8.19(5), it is clear to the Board that there was a scrivener's error in Count I. 657 IAC 8.19(4) pertains solely to identifying the authorized receiving agents for a new prescription and for a refill or renewal order. That administrative code provision bears no logical relationship to the legal charge described in Count I or in the factual circumstances. 657 IAC 8.19(5) provides:

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.

The state's request to amend Count I to change the administrative code citation from 657 IAC 8.19(4) to 8.19(5) should be granted. The wording of Count I and the factual circumstances alleged in paragraph 4 provided adequate legal notice and a short and plain statement as to the nature of the charge embodied by this count. The Respondent has more than adequate time to prepare prior to the hearing

scheduled for March 8, 2016, and the correction of the scrivener's error in the rule citation does not justify a further delay in the hearing.

Count II: Count II charged Respondent with regularly compounding commercially available products and/or compounding inordinate amounts of drugs which are essentially copies of commercially available product, in violation of Iowa Code sections 147.55(9), 155A.13A(3) and 657 IAC 8.3(1), 19.3, 20.3(1), 20.3(5)(b), and 36.1(4)(u). At the time relevant to these charges, 657 IAC 20.3(1) provided:

20.3(1) *Compounding commercially available product.* Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace, if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if the use of the compounded product is in the best interest of the patient. "Significant difference" would include the removal of a dye for a medical reason such as an allergic reaction. When a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

In addition, at the time relevant to the Statement of Charges, 657 IAC 20.3(5)"b" provided that pharmacists shall not compound..."[r]egularly or in inordinate amounts drugs that are essentially copies of a commercially available drug product except as provided in subrule 20.3(1).

The factual circumstances related to Count II are found in paragraphs 5 and 6 as follows:

5. Wells Pharmacy compounded large quantities of testosterone in grape seed oil. Testosterone is commercially available in sesame seed oil. Individual patients would receive small portions of the compounded medication.
6. Wells Pharmacy compounded large quantities of testosterone cypionate in sesame seed oil. This product is commercially available

in cottonseed oil. Individual patients would receive small portions of the compounded medication.

Respondent asserts that there is no legal or factual basis for the charge because Respondent used different oils for the compounded products. The Board has reviewed the charge and is satisfied that the Statement of Charges provides an adequate legal and factual basis for Count II. Respondent has been provided a short and plain statement of the matters asserted with respect to this count. The issue of whether the compounded products described in paragraphs 5 and 6 met the legal requirements of subrules 20.3(1) and 20.3(5)"b," requires factual determinations, which must be made through an evidentiary hearing.

Count III: Count III charged Respondent with failing to provide records in a timely manner, in violation of Iowa Code sections 147.55(9), 155A.13A(3) and 657 IAC 6.16(2), 8.3(1), 8.9, 19.3, and 36.1(4)(u), (ag). The factual circumstances in support of Count III are found at paragraph 8:

8. On May 8, 2015, the Board requested copies of 32 prescriptions that were dispensed into Iowa from April 1, 2014 to April 1, 2015. Respondent was given until May 15, 2015 to provide the Board copies of the requests (sic) prescriptions. Respondent did not provide the requested records until May 27, 2015.

657 IAC 6.16(2) requires pharmacies to maintain the original prescription drug order for a period of two years from the date of the last activity on the prescription. 657 IAC 8.9 provides that every inventory or other record required to be maintained by a pharmacy pursuant to Board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified. 657 IAC 36.1(4)(ag) authorizes the Board to impose license discipline for "failure to timely provide the board or a representative of the board prescription fill data or other required pharmacy or controlled substance records."

Respondent asserts that the rules do not authorize discipline for failure to comply with a *non-emergency* seven day deadline to produce records and that the rules do not define "timely." Respondent asserts that Count III should be dismissed because the prescription records were produced in 19 days. The Board disagrees. The Statement of Charges includes both a legal and factual basis for Count III. The

Board's rules do not have a different standard for emergency or non-emergency requests for records; all requests must be responded to in a timely manner. As asserted in the Statement of Charges, the Board's representative requested Respondent to produce, within 7 days, prescription records that Respondent is required by Board rule to maintain and keep available for inspection and copying. Respondent did not respond until 19 days after the request was made.

Count IV: Count IV charged Respondent with failing to perform a prospective drug review, in violation of Iowa Code sections 147.55(9), 155A.13A(3) and 657 IAC 8.3(1), 8.21, 19.3, and 36.1(4)(u). 657 IAC 8.21 states, in relevant part, that:

For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication to identify:.. 1. Overutilization or underutilization; 2. therapeutic duplication...

The factual circumstance in support of Count IV is found at paragraph 7 and state: "Wells Pharmacy did not perform a drug use review on prescriptions dispensed in Iowa, resulting in duplicative therapy." The Statement of Charges includes a legal basis for Count IV and a short and plain statement of the factual basis or matters asserted. As pointed out by the state, if Respondent requires additional articulation of the facts that allegedly support Count IV, Respondent may file a request for a more definite and detailed statement as provided by 657 IAC 35.5(2)"d." Respondent may also use discovery procedures to obtain additional information or details concerning the factual basis for the charges. 657 IAC 35.12. Dismissal of the charge is not warranted.

2nd Motion to Continue: The hearing has already been continued at Respondent's request and is now scheduled for March 8, 2015. The Board does not believe that the issues raised in Respondent's Motion to Dismiss warrant a further continuance of the hearing. Respondent has been provided sufficient time to prepare a defense to the charges.

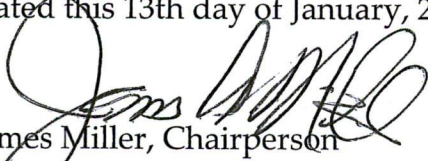
ORDERS

IT IS THEREFORE ORDERED that Respondent's Combined Motion to Dismiss is hereby DENIED in its entirety.

IT IS FURTHER ORDERED that Respondent's 2nd Motion to Continue is DENIED.

IT IS FURTHER ORDERED that the state's request to amend Count I to correct a scrivener's error is GRANTED. The reference in Count I to 657 IAC 8.19(4) is hereby CORRECTED and AMENDED to read "657 IAC 8.19(5)."

Dated this 13th day of January, 2016.


James Miller, Chairperson
Iowa Board of Pharmacy

cc: Michael Sellers, Attorney for Respondent
Meghan Gavin, Attorney for State

ADDENDUM C

**ORDER GRANTING MOTION TO AMEND
AND
AMENDED NOTICE OF HEARING AND STATEMENT OF
CHARGES**

**ALPINE WELLNESS INC.
WHOLESALE DRUG LICENSE NO. 7778
URBANDALE, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case No. 15-163
Wholesale Drug License of:)
ALPINE WELLNESS, INC.) **ORDER GRANTING**
License no. 7778) **MOTION TO AMEND**
Respondent)

On October 23, 2015, the Iowa Board of Pharmacy (Board) issued a Notice of Hearing and Statement of Charges to Alpine Wellness, Inc. (Respondent), which alleged two legal counts and seven (7) numbered paragraphs in the Factual Circumstances. On that same date, the Board also issued an Emergency Adjudicative Order, which indefinitely suspended Respondent's license to operate as a drug wholesaler, effective immediately upon issuance of the order. The hearing has now been continued to March 8, 2016 at Respondent's request.

On November 3, 2015, the state filed a Motion to Amend Statement of Charges and an Amended Statement of Charges, which seeks to add a third legal count (for engaging in misrepresentation or fraud in the distribution of a drug or device) and one additional Factual Circumstance (paragraph 8) to the Statement of Charges. The motion states that after the charges were filed, the state obtained evidence indicating that Respondent had included a falsified transaction history with a shipment of drugs to a customer in Arizona. The state asserts that in the interest of judicial economy, the new charge and circumstance should be considered in conjunction with the original charges. Respondent has not filed any objection to the Motion to Amend Statement of Charges.

On January 12, 2016, the Board considered the Motion to Amend and voted in open session to grant the State's Motion to Amend Statement of Charges and to approve the Amended Statement of Charges that was attached to the motion.

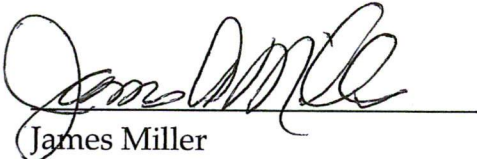
ORDER

IT IS THEREFORE ORDERED that the State's Motion to Amend Statement of Charges in case no. 15-163, as reflected in the Amended Notice of Hearing and Statement of Charges, is hereby GRANTED.

Case No. 15-163

Page 2

Dated this 12th day of January, 2016.

A handwritten signature in black ink, appearing to read "James Miller", written over a horizontal line.

James Miller

Chairperson, Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General
Gregory G.T. Ervanian, Attorney for Respondent

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 15-163
Wholesale Drug License of)	
)	
ALPINE WELLNESS, INC.)	AMENDED NOTICE OF HEARING
License No. 7778)	AND STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Amended Notice of Hearing and Statement of Charges against Alpine Wellness, Inc. ("Respondent"), 3650 68th Street, Suite B, Urbandale, IA 50322, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa wholesale drug license number 7778 is currently active through December 31, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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

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

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.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

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

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

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

C. CHARGES

COUNT I

FAILURE TO MAINTAIN RECORDS

Respondent is charged with failing to maintain records of all transactions regarding the receipt and distribution of prescription drugs in violation of 657 IAC 17.16, pursuant to Iowa Code section 155A.17(2), and 657 IAC 17.18, 36.1(4)"u", and "ac".

COUNT II

SUBVERTING A BOARD INVESTIGATION

Respondent is charged with engaging in any conduct that subverts or attempts to subvert a board investigation pursuant to Iowa Code section 155A.17(2), and 657 IAC 17.18 and 36.1(4)"z".

**COUNT III
MISREPRESENTATION OR FRAUD**

Respondent is charged with engaging in misrepresentation or fraud in the distribution of a drug or device in violation of 155A.23(1)"p" and 657 IAC 17.6(1), pursuant to Iowa Code section 155A.17(2) and 657 IAC 17.18, 36.1(4)"c", and "u".

D. FACTUAL CIRCUMSTANCES

1. The Board received a complaint alleging that Respondent was providing false information on transaction records.

2. On October 21, 2015, Board compliance officers performed an inspection of Respondent's location at 3650 68th Street, Suite B, Urbandale, Iowa.

3. During the inspection, Board compliance officers found approximately six cardboard boxes containing what appeared to be brand-name, high-dollar prescriptions drugs.

4. Respondent was unable to produce any records demonstrating the source of the prescription drugs.

5. Respondent was unable to produce adequate documentation demonstrating where it was shipping the prescription drugs.

6. Respondent was instructed by Board compliance officers to keep the prescription drugs at Respondent's location until further notice.

7. When Board compliance officers executed an administrative search warrant at Respondent's location on October 22, 2015, all of the cardboard boxes containing the drugs had been removed from the facility.

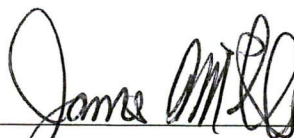
8. The cardboard boxes were subsequently located in Arizona. The documentation accompanying the boxes indicated that Respondent had purchased the drugs from Cardinal Health. Cardinal Health confirmed that it has not shipped any products to Respondent.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Amended Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copies to:

Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Gregory G.T. Ervanian
Graham, Ervanian and Cacciatore, L.L.P.
317 6th Avenue, Suite 900
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

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

ADDENDUM D

SETTLEMENT AGREEMENT AND FINAL ORDER

**MARK ODLAND
PHARMACIST LICENSE NO. 16408
DOWS, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NOS. 2011-183 and 2012-27
Pharmacist License of)	
)	SETTLEMENT AGREEMENT
MARK ODLAND)	AND FINAL ORDER
License No. 16408)	
Respondent.)	

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 Mark Odland ("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 Statement of Charges and Notice of Hearing and an Emergency Adjudicative Order on January 8, 2013. Respondent's license has been suspended pursuant to the Emergency Adjudicative Order since January 8, 2013.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that he has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

9. 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.

10. 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.

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

IT IS THEREFORE ORDERED:

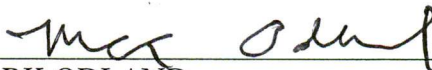
12. Respondent agrees to **VOLUNTARY SURRENDER** his pharmacist license to resolve this matter.

13. This voluntary surrender is considered discipline and, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15. Respondent may not request reinstatement for at least one year from the date of this Order. Respondent may request reinstatement of his Iowa pharmacist license by filing an application for reinstatement under 657 IAC 36.13. Respondent's license shall not be reinstated except upon a showing by Respondent that the basis for revocation of his license no longer exists, and that it is in the public interest for the license to be reinstated.

14. Respondent agrees not to work in a pharmacy in any capacity in Iowa unless his pharmacist license is reinstated.

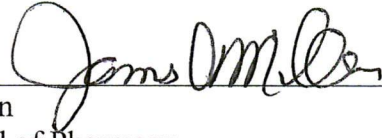
15. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 29 day of DECEMBER, 2015



MARK ODLAND
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12 day of January, 2016.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

ADDENDUM E

SETTLEMENT AGREEMENT AND FINAL ORDER

**DOWNING LABS, LLC
f/k/a NUVISION PHARMACY, INC.
NONRESIDENT PHARMACY LICENSE NOS.
4030 AND 4626
DALLAS, TEXAS**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-48
Nonresident Pharmacy License of)	
)	SETTLEMENT AGREEMENT
DOWNING LABS, LLC)	AND FINAL ORDER
f/k/a NUVISION PHARMACY, INC.)	
License Nos. 4030 & 4626)	
Respondent.)	

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 Downing Labs, LLC, formerly known as NuVision Pharmacy, Inc. ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
9. This Order shall not be binding as to any new complaints received by the Board.

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

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

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

IT IS THEREFORE ORDERED:

13. NuVision Pharmacy agrees to pay a **CIVIL PENALTY** in the amount of five-thousand dollars (\$5000) no later than March 11, 2016. This civil penalty shall be made payable to the Treasurer of Iowa. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309. All civil penalty payments shall be deposited into the State of Iowa general fund. This civil penalty is considered discipline against NuVision Pharmacy only and resolves Counts I and II in the Statement of Charges in case 2015-48. Downing Labs is responsible for ensuring that the civil penalty is paid on behalf of NuVision Pharmacy.

14. Effective immediately, nonresident pharmacy license #4030 is hereby cancelled.

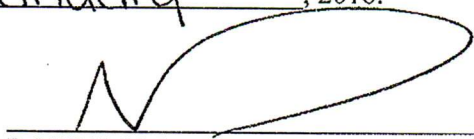
15. Effective immediately, Downing Labs shall be issued a new nonresident pharmacy license number. Downing Labs is issued nonresident pharmacy license #4626.

16. Downing Labs, nonresident pharmacy license #4626, is hereby **CITED** for failing to timely submit a new application for pharmacy license changes and **WARNED** that failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline. This citation and warning is considered discipline against Downing Labs only and resolves Count III in the Statement of Charges in case 2015-48.

17. Respondent agrees to follow all federal and state laws and regulations governing the practice of pharmacy and compounding. Respondent agrees to abide by the terms of any agreements with the FDA.

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 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 11 day of January, 2016.



DOWNING LABS, LLC
f/k/a NUVISION PHARMACY, INC.
Respondent

By this signature, Ashley Downing acknowledges s/he is the owner for Downing Labs, LLC f/k/a NuVision Pharmacy, Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Downing Labs, LLC f/k/a NuVision Pharmacy, Inc.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 2016.

James Miller
Chairperson
Iowa Board of Pharmacy

Copy to:

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

ADDENDUM F

SETTLEMENT AGREEMENT AND FINAL ORDER

**KEYSOURCE MEDICAL INC.
WHOLESALE LICENSE NO. 6272
CINCINNATI, OHIO**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-49
Wholesale Drug License of)	
)	SETTLEMENT AGREEMENT
KEYSOURCE MEDICAL INC.)	AND FINAL ORDER
License No. 6272)	
Respondent.)	

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 Keysource Medical Inc. ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent neither admits nor denies the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
9. This Order shall not be binding as to any new complaints received by the Board.

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

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

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

IT IS THEREFORE ORDERED:

13. Respondent is hereby **CITED** for violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state and for failing to timely notify the Board of discipline, and is **WARNED** that Respondent's failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline.

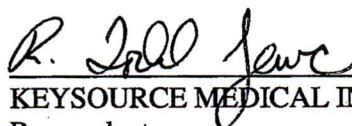
14. Respondent shall pay a **CIVIL PENALTY** in the amount of one thousand dollars (\$1,000) within thirty (30) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

15. Respondent hereby acknowledges and agrees that until such time as Respondent's DEA registration is reinstated, Respondent is prohibited from shipping controlled substances into Iowa. Upon the reinstatement of Respondent's DEA registration, Respondent shall provide proof of such registration to the Board within thirty (30) days.

16. Respondent shall comply with all laws and rules governing drug wholesalers in Iowa.

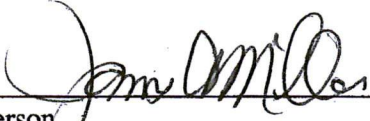
17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 31 day of December, 2015.


KEYSOURCE MEDICAL INC.
Respondent

By this signature, R. TODD SZWEC acknowledges s/he is the CFO / VP, Administration for Keysource Medical Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Keysource Medical Inc.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the
12th day of January, 2016.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

ADDENDUM G

SETTLEMENT AGREEMENT AND FINAL ORDER

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

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-67
Certified Technician Registration of)	
)	SETTLEMENT AGREEMENT
ADAM CASTLE)	AND FINAL ORDER
Registration No. 19952)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36, the Iowa Board of Pharmacy ("Board") and Adam Castle ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that he has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

9. 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.

10. 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.

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

IT IS THEREFORE ORDERED:

12. Respondent agrees to **VOLUNTARILY SURRENDER** his pharmacy technician registration to resolve this matter.

13. This voluntary surrender is considered discipline and, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15. Respondent may not request reinstatement for at least one year from the date of this Order.

14. Respondent may request reinstatement of his Iowa pharmacy technician registration by filing an application for reinstatement under 657 IAC 36.13. Respondent's registration shall not be reinstated except upon a showing by Respondent that the basis for revocation of his registration no longer exists, and that it is in the public interest for the registration to be reinstated.

15. Respondent agrees not to work in a pharmacy in any capacity in Iowa unless his technician registration is reinstated.

16. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 28 day of December, 2015.



ADAM CASTLE
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 2016.



Chairperson
Iowa Board of Pharmacy

Copy to:

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 H
SETTLEMENT AGREEMENT AND FINAL ORDER

DAWN RUEHLE
PHARMACIST LICENSE NO. 16618
CHEROKEE, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-110
Pharmacist License of)	
)	
DAWN RUEHLE)	SETTLEMENT AGREEMENT
License No. 16618)	AND FINAL ORDER
Respondent.)	

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 Dawn Ruehle ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent denies the allegations in the Statement of Charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that she has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
9. This Order shall not be binding as to any new complaints received by the Board.

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

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

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

IT IS THEREFORE ORDERED:

13. Respondent is hereby **CITED** for violating the duties of a pharmacist in charge and **WARNED** that Respondent's failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline.

14. Respondent shall complete 1.0 CEU/10 contact hours of continuing education in the area of pharmacy laws and rules; recordkeeping, DEA regulations, and/or managing a pharmacy within six (6) months of Board approval of this Order. These CEUs are in addition to the CEUs required for license renewal and cannot be counted towards the CEUs required for license renewal under 657 IAC 2.12. Respondent shall submit certificates to the Board as proof of completion of this requirement. The certifications can be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309. Respondent is responsible for all costs associated with obtaining the required continuing education.

15. Prior to accepting any position as pharmacist in charge, Respondent must provide a copy of the Notice of Hearing and Statement of Charges and this Order to the potential pharmacy employer.

16. Immediately upon beginning her next position as pharmacist in charge, Respondent shall contact the Board to schedule an inspection of the pharmacy by a compliance officer. Follow-up inspections by a Board compliance officer shall occur at six (6) months and twelve (12) months. Respondent shall work with the Board compliance officers to ensure any deficiencies uncovered during any of these inspections are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion shall be considered a violation 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.

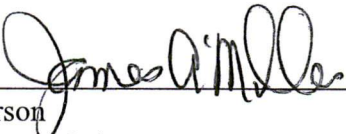
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 24th day of November, 2015



DAWN RUEHLE

Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 2016.



Chairperson
Iowa Board of Pharmacy

Copies to:

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

Richard Cook
The Cook Law Firm
209 West Willow Street
P.O. Box 209
Cherokee, IA 51012-0209
ATTORNEY FOR RESPONDENT

ADDENDUM I

SETTLEMENT AGREEMENT AND FINAL ORDER

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

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-110
Pharmacy License of)	
)	SETTLEMENT AGREEMENT
HY-VEE PHARMACY 1068)	AND FINAL ORDER
License No. 811)	
Respondent.)	

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 Hy-Vee Pharmacy 1068 ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent denies the allegations contained in the Statement of Charges, but in the interest of settlement has chosen not to contest the allegations. Respondent acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

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

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

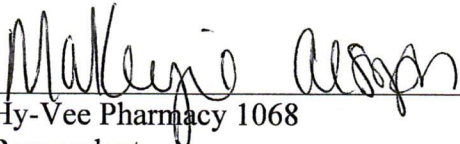
IT IS THEREFORE ORDERED:

13. Respondent's license is hereby placed on **PROBATION** for a period of three (3) years subject to the following terms:

- a. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars (\$5,000) within thirty (30) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.
- b. Respondent shall perform monthly audits of its controlled substances. All audits should be documented and available to the Board upon request.
- c. Respondent shall undergo quarterly inspections by a Board compliance officer. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during the inspections are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion shall be considered a violation of this Order.
- d. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- e. The Board may, in its discretion, decrease the frequency of the required audits or inspections during the probationary period based on satisfactory performance by Respondent.

14. 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.

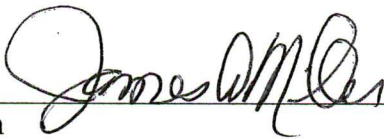
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 10 day of December, 2015.



Hy-Vee Pharmacy 1068
Respondent

By this signature, Makenzie Aesoph acknowledges s/he is the Pharmacy Manager for Hy-Vee Pharmacy 1068 and is authorized to sign this Settlement Agreement and Final Order on behalf of Hy-Vee Pharmacy 1068.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 2016.



Chairperson
Iowa Board of Pharmacy

Copies to:

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

Edwin McIntosh
Dorsey & Whitney LLP
801 Grand, Suite 4100
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

ADDENDUM J

SETTLEMENT AGREEMENT AND FINAL ORDER

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

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-115
Wholesale Drug License of)	
)	SETTLEMENT AGREEMENT
PRIORITY PHARMACEUTICALS,)	AND FINAL ORDER
INC.)	
License No. 5989)	
Respondent.)	

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 Priority Pharmaceuticals, Inc. ("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 November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

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

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

IT IS THEREFORE ORDERED:

13. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa wholesale drug license to resolve this matter. Respondent has already ceased operations.

14. 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.

15. 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.

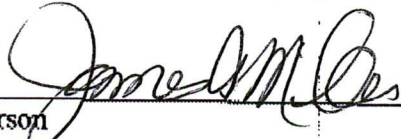
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 10 day of November, 2015



PRIORITY PHARMACEUTICALS, INC.
Respondent

By this signature, DAVID C ZEIGER acknowledges s/he is the Pres/CEO for Priority Pharmaceuticals, Inc., and is authorized to sign this Settlement Agreement and Final Order on behalf of Priority Pharmaceuticals, Inc..

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the
12th day of January, 2014.



Chairperson
Iowa Board of Pharmacy

Copy to:

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 K

SETTLEMENT AGREEMENT AND FINAL ORDER

**EDWARD SARRAZIN
PHARMACIST LICENSE NO. 15076
IOWA CITY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2013-214
Pharmacist License of)	
ED SARRAZIN)	SETTLEMENT AGREEMENT AND
License No. 15076)	FINAL ORDER
Respondent.)	

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), the Iowa Board of Pharmacy ("Board") and Ed Sarrazin ("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. Respondent holds Iowa pharmacist license number 15076, which is currently active and expires on June 30, 2017.
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 March 12, 2014. Prior to the issuance of the Statement of Charges, Respondent voluntarily ceased practice. Respondent has not practiced pharmacy during the pendency of the Statement of Charges. Additionally, Respondent has voluntarily undergo addiction treatment, including active participation in Iowa Pharmacist Recovery Network, and submitted quarterly reports to the Board detailing his progress.
4. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order. As a point of clarification, however, the parties acknowledge (1) that Respondent distributed controlled substances solely to himself— Respondent did not distribute to others, and (2) at no time was Respondent represented by attorney Tom Whorley. Mr. Whorley was inadvertently copied on the Statement of Charges.
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 and the National Practitioner Data Bank, 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.

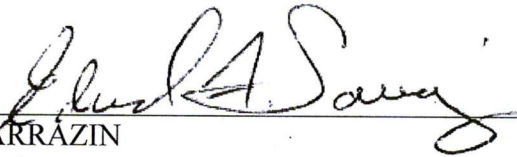
IT IS THEREFORE ORDERED:

14. Due to the unique facts and circumstances of this case, namely Respondent's voluntary secession of practice and extensive and ongoing treatment efforts, the Respondent's license shall be placed on **PROBATION**, subject to the following terms and conditions:
 - a. The period of probation shall be five (5) years. Only those time periods during which Respondent is employed as a pharmacist shall count toward exhaustion of the probationary term. "Employed as a pharmacist" means working at least twenty hours per month as a pharmacist.
 - b. Respondent shall not possess or use any controlled substance or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for Respondent by a licensed, treating physician or other qualified treating health care provider. Respondent shall inform any treating physician or other treating health care provider of his medical history, including any history of chemical dependence.
 - c. Respondent shall provide witnessed blood, hair, or urine specimens on demand by the Board or its agents. The specimens shall be used for alcohol and drug screening, and to verify Respondent's continued compliance with this Settlement Agreement and Final Order and any drug therapy ordered by Respondent's physician or treatment provider. All costs related to the analysis of such specimens shall be paid by Respondent.
 - d. To facilitate performance of the preceding paragraph, Respondent shall report daily to and provide a specimen when requested to any healthcare provider/testing facility specified by the Board—said healthcare provider to be located in reasonable proximity to Respondent—on the same day that the Board provides notice that a specimen is

- required. Respondent agrees to cooperate with the Board in establishing a specimen testing program through the Board's chosen testing program, and hereby consents to disclosure to the Board, by the testing facility, of all medical information, including test results, generated by Respondent's contact with the facility.
- e. Respondent shall inform the Board, in writing, of any change of home address, place of employment, home telephone number, or work telephone number, within ten (10) days of such a change.
 - f. Respondent shall report to the Board quarterly, in writing. The report shall include Respondent's place of employment, current address, *Respondent's most recent efforts to implement the provisions of this Settlement Agreement and Final Order*, by date, and any further information deemed necessary by the Board from time to time.
 - g. Respondent shall notify all employers and prospective employers (no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by this Settlement Agreement and Final Order.
 - h. Within thirty (30) days after approval of this Settlement Agreement and Final Order by the Board, or within fifteen (15) days of undertaking new employment as a pharmacist, Respondent shall cause his pharmacy employer, and any pharmacist-in-charge he works under, to report to the Board in writing acknowledging that the employer and the pharmacist-in-charge have read this document and understand it.
 - i. Respondent shall appear informally before the Board, upon the request of the Board, for the purpose of reviewing his performance as a pharmacist during Respondent's probationary period. Respondent shall be given reasonable notice of the date, time, and place for appearances.
 - j. Respondent shall obey all federal and state law, rules, and regulations related to the practice of pharmacy as well as any lawfully issued Board orders, including this Settlement Agreement and Final Order.
 - k. Respondent shall promptly provide, upon request of an agent of the Board, copies of or access to all his medical records.
 - l. Respondent shall comply with treatment recommendations by his physician or treatment provider. In the event Respondent is participating in a substance abuse treatment program, Respondent's physician/treatment provider shall submit quarterly reports to the Board documenting Respondent's compliance with the treatment program.
 - m. Respondent shall not supervise any registered pharmacist-intern and shall not perform any of the duties of a pharmacy preceptor.
 - n. Respondent shall not serve as a pharmacist-in-charge.

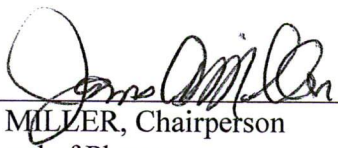
- o. Respondent shall continue to participate in IPRN.
- p. Should Respondent violate or fail to comply with any of the terms and conditions of probation, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacist license or impose other licensee discipline as authorized by Iowa Code chapter 155A and 272C 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 January, 2016.



ED SARRAZIN
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 12th day of January, 2016.



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

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

ADDENDUM L

NOTICE OF HEARING AND STATEMENT OF CHARGES

**DRUG DEPOT, INC.
d/b/a APS PHARMACY
NONRESIDENT PHARMACY LICENSE NOS.
4139 AND 4375
PALM HARBOR, FLORIDA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2013-4139
Nonresident Pharmacy License of)	
)	NOTICE OF HEARING AND
DRUG DEPOT, INC.)	STATEMENT OF CHARGES
d/b/a APS PHARMACY)	
License Nos. 4139 & 4375)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Drug Depot, Inc., doing business as APS Pharmacy ("Respondent"), 34911 US Highway 19 N, Ste 600, Palm Harbor, FL 34684, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license #4139 is currently delinquent, effective January 1, 2014. Respondent's Iowa nonresident pharmacy license #4375 is currently active through December 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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

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

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.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need

to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

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

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

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

C. CHARGES

Count I

PROVIDING PHARMACY SERVICES WITHOUT A LICENSE

Respondent is charged with providing pharmacy services to Iowa residents without an active Iowa pharmacy license in violation of Iowa Code section 155A.13A(1) and 657 IAC 19.2, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"v".

D. FACTUAL CIRCUMSTANCES

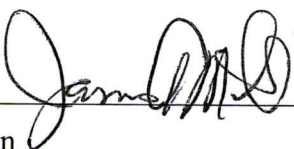
1. Respondent was issued Iowa nonresident pharmacy license #4139 in April 2013. Iowa nonresident pharmacy license #4139 became delinquent on January 1, 2014.
2. In August 2014, Respondent submitted a new application for an Iowa nonresident pharmacy license. On September 8, 2014, Respondent was issued Iowa nonresident pharmacy license #4375.
3. From January 1, 2014, through September 7, 2014, Respondent shipped approximately 100 prescriptions into Iowa without an active pharmacy license.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

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

ADDENDUM M

NOTICE OF HEARING AND STATEMENT OF CHARGES

**ANKENY PHARMACY
PHARMACY LICENSE NO. 1475
ANKENY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-123
Pharmacy License of)	
ANKENY PHARMACY)	NOTICE OF HEARING AND
License No. 1475)	STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Ankeny Pharmacy ("Respondent"), 1325 SW Oralabor Road, Suite 200, Ankeny, IA 50023, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacy license number 1475 is currently active through December 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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

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

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.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

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

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

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

C. CHARGES

COUNT I

IMPROPER DELEGATION TO PHARMACY TECHNICIANS

Respondent is charged with permitting pharmacy technicians to perform final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order in violation of Iowa Code section 155A.33, and 657 IAC 3.21(1) and 3.23(1), pursuant to Iowa Code section 155A.15(2)"c", and 657 IAC 36.1(4)"l" and "u".

COUNT II

FAILURE TO PROPERLY VERIFY AND DOCUMENT

Respondent is charged with failing to provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the

patient's representative in violation of 657 IAC 8.3(7), pursuant to Iowa Code section 155A.15(2)"c" and 657 IAC 36.1(4)"u".

COUNT III

MISUSE OF RETURNED PATIENT MED PAKS

Respondent is charged with returning drugs dispensed in patient med paks to pharmacy stock in violation of 657 IAC 22.5(2)"c", pursuant to Iowa Code section 155A.15(2)"c" and 657 IAC 36.1(4)"u".

COUNT IV

FAILURE TO MAINTAIN ACCURATE PERPETUAL INVENTORY

Respondent is charged with failing to maintain an accurate perpetual inventory of Schedule II controlled substances in violation of 657 IAC 10.33, pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

COUNT V

FAILURE TO KEEP AND MAINTAIN RECORDS

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

COUNT VI

FAILURE TO MAINTAIN ANNUAL INVENTORY OF CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain an annual inventory of controlled substances in violation of 657 IAC 10.35, pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

D. FACTUAL CIRCUMSTANCES

1. Respondent utilized pharmacy technicians to perform final verification of strips of med paks for long-term care facilities.
2. When pharmacists were utilized to perform final verification of strips of med paks, the med paks were not verified individually.
3. Respondent did not retain documentation of pharmacist final verification for the strips of med paks.
4. Respondent disassembled returned med paks in order to re-use the previously dispensed medication.
5. An audit of Respondent's inventory of controlled substances from January 2014 through September 2015 revealed shortages or overages for a majority of the drugs audited.
6. An audit of Respondent's records of controlled substances from January 2014 through September 2015 revealed the following:

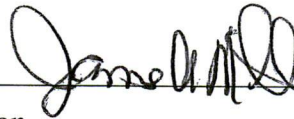
- a. Respondent did not maintain proper records for transfers of controlled substances to and from other pharmacies.
 - b. Respondent's perpetual inventory of Schedule II controlled substances did not match billing or dispensing records.
 - c. Respondent did not have invoices for approximately 6,000 tablets of Lorazepam.
 - d. Several of Respondent's invoices for controlled substances were not signed or dated by the person responsible for receiving the order.
7. Respondent could not produce its most recent annual inventory of controlled substances.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

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

ADDENDUM N

NOTICE OF HEARING AND STATEMENT OF CHARGES

**ROCKFORD ANDERSON
PHARMACIST LICENSE NO. 20335
ANKENY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-123
Pharmacist License of)	
)	NOTICE OF HEARING AND
ROCKFORD ANDERSON)	STATEMENT OF CHARGES
License No. 20335)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Rockford Anderson ("Respondent"), 1865 NW 86th Way, Ankeny, IA 50023, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacist license number 20335 is currently active through June 30, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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

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

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.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

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

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

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

C. CHARGES

COUNT I

IMPROPER DELEGATION TO PHARMACY TECHNICIANS

Respondent is charged with permitting pharmacy technicians to perform final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order in violation of Iowa Code section 155A.33 and 657 IAC 3.21(1) and 3.23(1), pursuant to Iowa Code sections 147.55(9), 155A.12(1), and (3), and 657 IAC 36.1(4)"l" and "u".

COUNT II

FAILURE TO PROPERLY VERIFY AND DOCUMENT

Respondent is charged with failing to provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the

patient's representative in violation of 657 IAC 8.3(7), pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), and (4), and 657 IAC 36.1(4)"u".

COUNT III

MISUSE OF RETURNED PATIENT MED PAKS

Respondent is charged with returning drugs dispensed in patient med paks to pharmacy stock in violation of 657 IAC 22.5(2)"c", pursuant to Iowa Code sections 147.55(9), 155A.12(1), and (3), and 657 IAC 36.1(4)"u".

COUNT IV

FAILURE TO MAINTAIN ACCURATE PERPETUAL INVENTORY

Respondent is charged with failing to maintain an accurate perpetual inventory of Schedule II controlled substances in violation of 657 IAC 10.33, pursuant to Iowa Code sections 147.55(9), 155A.12(3), (4), and (5), and 657 IAC 36.1(4)"u" and "ac".

COUNT V

FAILURE TO KEEP AND MAINTAIN RECORDS

Respondent is charged with failing to keep and maintain records as required by law, specifically for failing to keep supplier invoices and for failing to have a responsible person clearly record the date of receipt of controlled substances on supplier invoices in violation of 657 IAC 8.9(1), pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), and (4), and 657 IAC 36.1(4)"u" and "ac".

COUNT VI

FAILURE TO MAINTAIN ANNUAL INVENTORY OF CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain an annual inventory of controlled substances in violation of 657 IAC 10.35, pursuant to Iowa Code sections 147.55(9), 155A.12(3), (4), and (5), and 657 IAC 36.1(4)"u" and "ac".

COUNT VII

VIOLATING THE DUTIES OF PHARMACIST IN CHARGE

Respondent is violating the duties of the pharmacist in charge, specifically 657 IAC 8.3(1), 8.3(4)"f", "h", "i", and "j", pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), (4), and (5), and 657 IAC 36.1(4)"u".

COUNT VIII

MISREPRESENTATIVE DEEDS

Respondent is charged with making a statement intended 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 8.11(1), pursuant to Iowa Code sections 147.55(3), (9), 155A.12(1), and (3), and 657 IAC 36.1(4)"c" and "u".

D. FACTUAL CIRCUMSTANCES

1. Respondent is the owner and pharmacist in charge at Ankeny Pharmacy and has been in these roles since the pharmacy was initially licensed in December 2013.

2. Respondent utilized pharmacy technicians to perform final verification of strips of med paks for long-term care facilities.

3. When Respondent performed final verification of strips of med paks, the med paks were not verified individually.

4. Respondent did not retain documentation of pharmacist final verification for the strips of med paks.

5. Respondent instructed pharmacy staff to disassemble returned med paks in order to re-use the previously dispensed medication.

6. An audit of Ankeny Pharmacy's inventory of controlled substances from January 2014 through September 2015 revealed shortages or overages for a majority of the drugs audited.

7. An audit of Ankeny Pharmacy's records of controlled substances from January 2014 through September 2015 revealed the following:

- a. Ankeny Pharmacy did not maintain proper records for transfers of controlled substances to and from other pharmacies.
- b. Ankeny Pharmacy's perpetual inventory of Schedule II controlled substances did not match billing or dispensing records.
- c. Ankeny Pharmacy did not have invoices for approximately 6,000 tablets of Lorazepam.
- d. Several of Ankeny Pharmacy's invoices for controlled substances were not signed or dated by the person responsible for receiving the order.

8. Respondent could not produce Ankeny Pharmacy's most recent annual inventory of controlled substances.

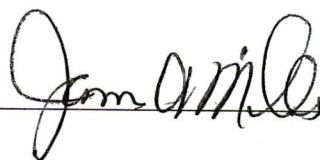
9. Respondent instructed a pharmacy technician to forge approximately four months of refrigerator logs to provide to agent of the Board who was conducting an inspection of the pharmacy the following day.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

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

ADDENDUM O

NOTICE OF HEARING AND STATEMENT OF CHARGES

**JUSTIN ADAM
PHARMACY TECHNICIAN REGISTRATION NO. 12376
SIOUX CITY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-150
Certified Technician Registration of)	
)	NOTICE OF HEARING AND
JUSTIN ADAM)	STATEMENT OF CHARGES
Registration No. 12376)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Adam Castle ("Respondent"), 2811 Myrtle Street, Sioux City, IA 51103, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa certified pharmacy technician registration number 12376 is currently active through July 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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

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

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.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

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

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

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

C. CHARGES

COUNT I UNETHICAL CONDUCT

Respondent is charged with unethical conduct in violation of 657 IAC 3.28(1) and (2), pursuant to Iowa Code sections 147.55(3), (9), and 155A.6A(5), and 657 IAC 3.30, 36.1(4)"c", and "u".

D. FACTUAL CIRCUMSTANCES

1. While employed as a pharmacy technician, Respondent enrolled patients into a discount prescription plan without their knowledge or permission.

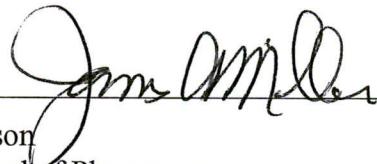
2. Respondent received a commission from the discount prescription plan based on the number of prescriptions filled using the plan.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

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

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

ADDENDUM P

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

**INIE CLEMENT
PHARMACIST LICENSE NO. 16963
DES MOINES, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF THE
STATEMENT OF CHARGES AGAINST:

CASE NO. 2015-25
DIA NO. 15PHB016

INIE CLEMENT
License No. 16963

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
DECISION AND ORDER

RESPONDENT

On June 23, 2015, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing and Statement of Charges against Inie Clement (Respondent), which alleged a violation of Iowa Code sections 147.55(9), 155A.12(1), (3) and 657 IAC 2.15 and 36.1(4)(u) by failing to notify the Board within ten days of a change of address. The hearing was held on November 3, 2015. The following members of the Board presided at the hearing: James Miller, Chairperson; Edward Maier; Edward McKenna; Sharon Meyer; Jason Hansel; and LaDonna Gratias. Assistant Attorney General Meghan Gavin represented the state. Respondent failed to appear for hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1), and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with its deliberations.

THE RECORD

The record includes the testimony of Jennifer O'Toole, R.Ph., Debbie Jorgenson, two Notices of Hearing and Statement of Charges, and State Exhibits 1-7 (See Exhibit List for description).

FINDINGS OF FACT

1. The Board has issued Inie Clement (Respondent) license number 16963 to engage in the practice of pharmacy in the state of Iowa, subject to the statutes and rules of the Board. Respondent's license is current and will expire on June 30, 2017. Respondent has provided the Board with the following address of record for her license: 1168 22nd Street, Des Moines, Iowa 50311. Respondent's last known employment as a pharmacist was through RPh on the Go in 2012. (State Exhibits 1, 3, 4)

2. Respondent is the owner of multiple rental properties in Des Moines. The Iowa Department of Revenue has contacted the Board on four occasions to serve Respondent with license sanction certificates of non-compliance. The first two license sanctions were both issued in 2011 and were later withdrawn after Respondent paid the debt.

In 2012, the Board was unable to serve Respondent with the Department of Revenue's license sanction. The notice of license sanction was sent to Respondent by certified mail at her address of record at 1168 22nd Street, but the notice was returned to the Board marked "unclaimed." One of the Board's compliance officers, Jennifer O'Toole, then attempted to personally serve Respondent. Respondent's daughter answered the door at 1168 22nd Street and told Ms. O'Toole that her mother had moved out of state months earlier, and she did not know where she was. Respondent's daughter stated, however, that Respondent continued to receive her mail at 1168 22nd Street. Ms. O'Toole left a message asking Respondent to contact her, but Respondent never did. The Department of Revenue later withdrew the notice of sanction. (O'Toole testimony; State Exhibit 3)

3. In early 2015, the Board received the fourth Notice of Intention to Suspend License from the Iowa Department of Revenue. This notice stated that Respondent's license would be suspended effective 60 days following service of the notice. The notice of license sanction was sent to Respondent at 1168 22nd Street in Des Moines by certified mail, restricted delivery. On February 2, 2015, the notice of license sanction was returned to the Board by the United States Postal Service marked "Return to Sender, Vacant, Unable to Forward." (O'Toole testimony; State Exhibits 3, 7)

After the notice was returned, Jennifer O'Toole conducted an internet search (via Accurint) in an attempt to identify another address for Respondent. Ms. O'Toole also reviewed the Polk County Assessor's page in an attempt to identify properties that were owned by Respondent. Ms. O'Toole identified several possible addresses but none of them could be verified. Ms. O'Toole sent letters to all of the possible addresses for Respondent, none of which were returned to the Board by the postal service. Ms. O'Toole also followed up on information she obtained indicating that Respondent might be a Zumba instructor, but she was unable to identify any location where Respondent was listed as a Zumba instructor (O'Toole testimony; State Exhibits 3, 5)

4. On June 23, 2015, the Board issued a Notice of Hearing and Statement of Charges charging Respondent with failure to notify the Board of her change of address. The hearing was scheduled for September 1, 2015. The Notice of Hearing and Statement of Charges was initially sent to Respondent by restricted certified mail and by first-class

mail 1168 22nd Street, but the notice that was sent by certified mail was returned to the Board by the postal service. (O'Toole, Jorgenson testimony; State Exhibits 1, 4)

5. In late June or early July 2015, Respondent renewed her pharmacist license. She once again listed the mailing address of 1168 22nd Street in Des Moines on her renewal application. (State Exhibit 4)

6. The Board unsuccessfully attempted to personally serve Respondent with the Notice of Hearing and Statement of Charges for the September 1, 2015 hearing. The Board planned to reschedule the hearing and serve Respondent by publication. On September 1, 2015, however, Respondent appeared at the Board's office for her hearing. The state was not prepared to go forward with the hearing at that time. The Board's Administrative Assistant, Debbie Jorgenson, met with Respondent at that time and served Respondent with notice of the rescheduled hearing. Respondent signed an Acceptance of Service for this new notice, which scheduled the hearing for November 3, 2015 at 9:00 a.m. Respondent failed to appear for the hearing on November 3, 2015. (Jorgenson testimony; Notice of Hearing issued September 1, 2015; State Exhibit 2)

CONCLUSIONS OF LAW

I. Failure to Appear

657 IAC 35.5(1) allows a Notice of Hearing and Statement of Charges to be served on a licensee by personal service, certified mail return receipt requested, or publication, as provided in the Iowa Rules of Civil Procedure. In this case, Respondent was personally served with the Notice of Hearing and Statement of Charges on September 1, 2015 but failed to appear for hearing.

657 IAC 35.21 allows the Board to proceed with the hearing and render a decision in the absence of the licensee if the licensee fails to appear after proper service of notice. The Board was authorized to proceed with the hearing when Respondent failed to appear.

II. Failure to Report Change of Address to the Board

Pursuant to Iowa Code section 147.55(9), 155A.12(1), (3)(2015) and 657 IAC 36.1(4)"u," the Board is authorized to discipline a licensee for any violation of the Board's rules. 657 IAC 2.15 requires a pharmacist to report to the Board a change of the pharmacist's name, address, or pharmacy employment within ten days.

The preponderance of the evidence established that Respondent violated Iowa Code sections 147.55(9), 155A.12(1), (3), and 657 IAC 36.1(4)"u" when she failed to timely notify the Board of an address change, as required by 657 IAC 2.15. When licensees fail to notify the Board of an address change, it becomes more difficult or even impossible for the Board to carry out its regulatory functions, such as contacting a licensee when a complaint is received and serving essential notices on the licensee. In this case, Respondent's failure to keep the Board informed of her current address prevented Board staff from timely serving her with a Department of Revenue notice of license sanction and with the Board's Notice of Hearing and Statement of Charges. As a result of Respondent's violation, the Board's staff was required to expend extraordinary time and resources locating and serving Respondent. Moreover, Respondent failed to appear for the hearing before the Board, even though she had been personally served with the Notice of Hearing and Statement of Charges. The Board believes that the circumstances of the violation warrants suspending Respondent's license to practice pharmacy until she has paid a civil penalty, has provided the Board with a verified current address, and has appeared before the Board for reinstatement.

DECISION AND ORDER

IT IS THEREFORE ORDERED that license number 16963, issued to Respondent Inie Clement, is hereby suspended effective immediately upon service of this Decision and Order.

IT IS FURTHER ORDERED that Respondent shall pay a civil penalty of one thousand dollars (\$1000), within thirty (30) days of service of this Decision and Order.

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, within thirty (30) days of service of this Decision and Order.

IT IS FURTHER ORDERED that the suspension of Respondent's license shall continue until:

- 1) Respondent has paid the \$1000 civil penalty and hearing fee in full;
- 2) Respondent has provided the Board with a verified current address; and
- 3) Respondent appears before the Board for a reinstatement hearing. *See* 657 Iowa Administrative Code (IAC) 36.13.

Dated this ^{12th} day of January, 2016.



James Miller, Chairperson
Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General

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 Q

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

**KEVIN J. O'ROURKE
PHARMACIST LICENSE NO. 15064
IOWA FALLS, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

RE:)	CASE NO: 2006-104
Pharmacist License of)	DIA NO: 15PHB021
)	
KEVIN J. O'ROURKE)	FINDINGS OF FACT,
License No. 15064)	CONCLUSIONS OF LAW,
Respondent)	DECISION AND ORDER

On November 3, 2015, a hearing was held before the Iowa Board of Pharmacy (Board) on the Reinstatement Application filed by Kevin J. O'Rourke (Respondent). The following members of the Board presided at the hearing: James Miller, Chairperson; Edward Maier; Edward McKenna; Sharon Meyer; Jason Hansel; and LaDonna Gratiias. Assistant Attorney General Meghan Gavin represented the state. Respondent appeared and was self-represented. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. The hearing was closed to the public, pursuant to Iowa Code section 272C.6(1)(2015), and was recorded by a certified court reporter. 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 its decision. The administrative law judge was instructed to prepare the written decision for Board approval, in conformance with the Board's deliberations.

THE RECORD

The record includes the Notice of Hearing; testimony of Respondent; State Exhibits 1-9 (See Exhibit Index for description) and Respondent Exhibits A-F.

FINDINGS OF FACT

1. On July 1, 1977, the Board issued Respondent license number 15064 to engage in the practice of pharmacy, subject to the laws of the state of Iowa and the rules of the Board.

On October 25, 1990, the Board issued Findings of Fact, Conclusions of Law, Decision and Order that placed Respondent's license on probation for three (3) years, subject to terms and conditions. This discipline was based on findings that Respondent diverted Schedule II controlled substances from the pharmacy where he worked and illegally used the controlled substances while working as a pharmacist. Respondent was

required to abstain from the use of controlled substances unless properly prescribed, to continue under psychiatric care and to continue to obtain counseling, to attend aftercare support groups, and to have random urine screenings. (State Exhibits 1, 2, 6)

2. On March 13, 2007, the Board filed a second Statement of Charges asserting that Respondent had violated Minnesota law while practicing in that state as a pharmacist, was professionally incompetent, and was unable to practice pharmacy with reasonable skill and safety due to chemical abuse. The Statement of Charges alleged that Respondent opened capsules of Adderall (a controlled substance) and removed the active ingredient prior to dispensing the capsules to patients. Respondent had surrendered his Minnesota license on August 11, 2006. On June 5, 2007, the Iowa Board accepted Respondent's voluntary surrender of his Iowa license. The Order Accepting Surrender of Pharmacist License stated that the surrender shall be considered a revoked license with respect to any future request for reinstatement. (State Exhibits 3, 4)

3. On May 3, 2011, Respondent filed his first request to reinstate his Iowa pharmacist license following the voluntary surrender. The Board denied that request following an evidentiary hearing. (State Exhibit 6).

4. On September 12, 2013, Respondent filed his second request to reinstate his Iowa pharmacist license. Once again, the Board denied Respondent's reinstatement request following an evidentiary hearing. The Board concluded that Respondent had not presented sufficient evidence to establish that he was currently able to practice pharmacy safely. Respondent had not submitted a current substance abuse evaluation and the most recent documentary evidence concerning Respondent's substance abuse was from his treatment program in 2006. (State Exhibit 7)

5. On September 10, 2015, Respondent filed his third reinstatement request. (Notice of Hearing). At hearing, Respondent submitted the following documentation:

a) A written report from a substance abuse evaluation that was completed on August 7, 2015. The evaluation report concluded that Respondent does not currently meet the criteria for a substance abuse disorder. The evaluator did not recommend any treatment for Respondent. (State Exhibit 8)

b) A letter from Respondent's family physician for the past five years. The letter was dated October 13, 2015 and states that Respondent has not shown any narcotic seeking behavior and has not had any further instances of substance abuse, to the best of his physician's knowledge. Respondent's physician asked the Board to consider allowing Respondent to return to the practice of pharmacy. (Respondent Exhibit B)

c) Verification of Respondent's attendance at Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) meetings during the past four months. (Respondent Exhibits C-F)

6. Respondent has been employed in construction since 2006. The work is seasonal, and Respondent is currently laid off. If Respondent is allowed to return to the practice of pharmacy, he hopes to eventually gain employment as a relief pharmacist in the Iowa City area. In preparation for returning to the profession, Respondent has completed approximately 120 hours of continuing education in the last eighteen months. Respondent has been attending AA and NA and has been working through the 12 steps. Respondent testified that he last used controlled substances, not properly prescribed, in June 2006. Respondent further testified that he has had an occasional beer since that time but that he stopped drinking alcohol on June 27, 2015. Respondent reports that he receives support for maintaining his sobriety from his church, his family, and his fellow members of AA. (Respondent testimony)

CONCLUSIONS OF LAW

657 Iowa Administrative Code 36.13 provides, in relevant part:

657-36.13(17A,124B,147,155A,272C) Reinstatement. Any person whose license to practice pharmacy...has been revoked or suspended shall meet the following eligibility requirements for reinstatement:

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

reinstatement may not be made until one year has elapsed from the date of the board's order or the date of voluntary surrender.

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

36.13(3) *Proceedings.* The respondent shall initiate all proceedings for reinstatement by filing with the board an application for reinstatement of the license...Such application shall be docketed in the original case in which the license, registration, or permit was revoked, suspended, or relinquished. All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board...

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

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

The Board's rules establish a heavy burden on a person seeking reinstatement of a revoked or surrendered license. The applicant for reinstatement must present persuasive evidence that the issues leading to the loss of the license have been fully resolved and that it is in the public interest for the license to be reinstated. Upon reviewing the record, the Board was persuaded that Respondent has resolved the issues that led to the surrender of his license and is now ready to begin the process to return to the practice pharmacy. Due to the length of time (over 9 years) that Respondent has been away from pharmacy practice, the Board has determined that Respondent will be required to complete a 500 hour internship, under supervision, prior to being allowed to sit for the NAPLEX and MPJE examinations. During this time, Respondent will be monitored by the Board. Upon successful completion of the supervised internship and

successful completion of the NAPLEX and MPJE examinations, Respondent's license will be reinstated on probation, subject to terms and conditions.

DECISION AND ORDER

IT IS THEREFORE ORDERED that prior to reinstatement of his license, Respondent Kevin J. O'Rourke must first comply with the following requirements:

A. Respondent must register as an intern, pay any applicable fee, and successfully complete a 500 hour internship at an Iowa site(s) approved by the Board. The 500 hour internship must be completed within one (1) year of the issuance of this Decision and Order. During the internship, Respondent shall be required to:

- Notify all prospective preceptor(s) and any pharmacist-in-charge of the terms, conditions, and restrictions imposed on Respondent by this Reinstatement Order. Notification shall be made no later than the time of interview. Within fifteen (15) days of starting a new internship, Respondent shall cause his preceptor(s) and the pharmacist-in-charge to report to the Board in writing, acknowledging that the preceptor and pharmacist-in-charge have read this Decision and Order of the Board and understand it.
- Ensure that his preceptor(s) file a quarterly written report with the Board concerning Respondent's performance and progress as a pharmacist-intern. The first report shall be due three (3) months after Respondent begins the internship;
- Abstain from the use of alcohol and from the use of controlled substances not properly prescribed by a licensed treating health provider;
- Attend Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) on a weekly basis and obtain written verification of attendance;
- Participate in the Board's Impaired Pharmacy Professional Recovery Program (IPRN);
- File written, sworn quarterly reports with the Board no later than March 5, June 5, September 5, and December 5 of each year of Respondent's internship. The quarterly reports shall include Respondent's current place of employment, home address, home telephone number or work

telephone number, written verification of his weekly attendance at AA or NA, and a list of Respondent's current prescriptions;

- Provide witnessed blood, hair or urine specimens on demand by the Board or its agents. Respondent shall participate in the Board's approved alcohol and drug screening program (NTS) and will be responsible for any costs of compliance with that program. All costs related to participation in the NTS program and all costs relating to the collection and analysis of such specimens shall be paid by Respondent.

Upon completion of the 500 hour internship, Respondent may apply to take the licensing examinations (NAPLEX and MPJE).

B. Respondent must take and pass the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition, as required by Iowa Code section 657 IAC 36.13(2). Respondent must successfully complete the examinations within one (1) year of completing his internship.

Upon timely completion of the required examinations, Respondent's pharmacist license no. 15064 will be REINSTATED and shall immediately be placed on PROBATION for a term of five (5) years. IT IS FURTHER ORDERED that Respondent's probation will be subject to the following terms and conditions:

A. Respondent shall notify all prospective pharmacy or pharmacy-related employers, including any pharmacist-in-charge, of the terms, conditions, and restrictions imposed on Respondent by this Reinstatement Order. Notification shall be made no later than the time of interview. Within fifteen (15) days of undertaking new employment as a pharmacist or in a pharmacy-related business, Respondent shall cause his pharmacy employer and any pharmacist-in-charge to report to the Board in writing, acknowledging that the pharmacy employer and pharmacist-in-charge have read this document and understand it.

B. Respondent shall not consume alcohol and shall not use any controlled substances or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for him by a licensed, treating physician or other qualified health care provider. Respondent shall

inform any treating physician or other treating health care provider of his medical and substance abuse history, including his history of drug diversion.

C. Respondent shall provide witnessed blood, hair or urine specimens on demand by the Board or its agents. Respondent shall participate in the Board's approved alcohol and drug screening program (NTS) and will be responsible for any costs of compliance with that program. All costs related to participation in the NTS program and all costs relating to the collection and analysis of such specimens shall be paid by Respondent.

D. Respondent shall continue regular weekly attendance at Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) and shall provide documentation of attendance in his quarterly reports to the Board.

E. Respondent shall file written, sworn quarterly reports with the Board attesting to his compliance with all the terms and conditions of his probation. The reports shall be filed no later than March 5, June 5, September 5, and December 5 of each year of Respondent's probation. The quarterly reports shall include Respondent's current place of employment, home address, home telephone number or work telephone number, written verification of attendance at weekly AA/NA meetings, and a current list of all of Respondent's prescribed medications.

F. Respondent shall not supervise any registered pharmacist-intern and shall not perform any of the duties of a pharmacy preceptor.

G. Respondent shall not own or manage a pharmacy, nor serve as the pharmacist in charge of a pharmacy.

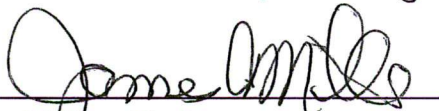
H. During probation, Respondent shall inform the Board in writing within ten (10) days of any change of home address, employment status, place of employment, home telephone number or work telephone number.

I. Respondent shall obey all federal and state laws and regulations related to the practice of pharmacy and the distribution of controlled substances.

J. Respondent shall appear informally before the Board or a Board committee upon request for the purpose of reviewing his performance as a pharmacist during the probationary period. The Board shall give Respondent reasonable notice of the date, time, and location for such appearances.

K. Should Respondent violate or fail to comply with any of the terms or conditions of probation, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacist license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 IAC 36.

Dated this 12th day of January, 2016.



James Miller, Chairperson
Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General

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

ADDENDUM R

IOWA BOARD OF PHARMACY

CONTRACT #IPA-2016

**TITLE: PHARMACEUTICAL COLLECTION AND DISPOSAL
(DRUG TAKE-AWAY) PROGRAM**

BETWEEN

**IOWA BOARD OF PHARMACY AND IOWA PHARMACY
ASSOCIATION**

ADDENDUM
IOWA BOARD OF PHARMACY
CONTRACT #IPA-2016
TITLE: PHARMACEUTICAL COLLECTION AND DISPOSAL
(DRUG TAKE-AWAY) PROGRAM
Between
IOWA BOARD OF PHARMACY and IOWA PHARMACY ASSOCIATION

This Contract Addendum received approval of the Iowa Board of Pharmacy on January 13, 2016. This Addendum modifies the original Contract, executed by Board and Contractor on June 30, 2015, and ending June 30, 2016, as provided herein.

Pursuant to section 8.2 of the Contract, Contractor submitted a proposed budget amendment to expand the services provided through the Drug Take-Away Program. Section 4 and Section 5 of the Contract are amended as indicated herein by the addition of the underscored language. Section 5 is amended by adding the Addendum Budget, which increases the total budget for Contract to \$175,000. All other sections of Contract, including Sections 1 through 3 and Sections 6 through 8 are unchanged from original Contract as a result of this Addendum.

This Addendum does not change any of the terms or conditions of the original Contract. This Addendum adds new tasks and services to the Statement of Work and provides additional funding to pay for those additional tasks and services.

Section 4 **STATEMENT OF WORK**

4.1 Statement of Work. Contractor shall complete work items and shall comply with provisions identified in this Statement of Work. Items may be amended by mutual written agreement between the parties. Additional or amendment work items relative to the Addendum to Contract are identified by underscored language.

4.2 Contractor shall:

- 4.2.1** Comply with applicable state and federal regulations pertaining to the collection and disposal of unwanted pharmaceuticals;
- 4.2.2** Not collect, receive, or dispose of any controlled substances except as authorized under federal DEA regulations for controlled substances collectors and by implementing and utilizing approved controlled substances collection and disposal containers and systems;
- 4.2.3** Ensure that any pharmacy or other site that intends to participate in the Drug Take-Away Program and intends to collect controlled substances is appropriately registered with the federal DEA as an authorized collector;
- 4.2.4** Partner with Sharps Environmental Services, Inc. and others as necessary for the administration and continuation of the Drug Take-Away Program;
- 4.2.5** Solicit for increased pharmacy participation in the program;
- 4.2.6** Ensure geographic distribution of participating pharmacies;
- 4.2.7** Identify the name and address of each pharmacy that participates in the program;

- 4.2.8** Provide, within the limits of available funding, educational materials and assistance to participating pharmacies, the public, and other healthcare professionals regarding the Drug Take-Away Program and the dangers of improper disposal of pharmaceuticals;
- 4.2.9** Distribute to participating pharmacies, as needed, prepaid and pre-addressed collection boxes with shipping through UPS to Sharps Environmental Services, Inc.;
- 4.2.10** Ensure Sharps Inc. provides witnessed incineration of collection boxes and their contents;
- 4.2.11** Obtain certificates of destruction from Sharps Environmental Services, Inc. for all unwanted pharmaceuticals shipped to Sharps Environmental Services, Inc. for destruction through this program;
- 4.2.12** Ensure collection boxes are secured from public access during times collection boxes are not supervised by the participating pharmacies;
- 4.2.13** Ensure controlled substances collection boxes and sites that are implemented, installed, and participating as part of the program are installed, maintained, monitored, and prepared for destruction in compliance with federal DEA regulations regarding controlled substances collection programs;
- 4.2.14** Provide a detailed report of all aspects of the program during the term of Contract including the following information:
- materials developed and distributed to solicit pharmacy participation
 - the number and locations of participating pharmacies including the number of TakeAway boxes provided to each pharmacy under the current Contract and Addendum
 - materials developed to educate pharmacies, households, and healthcare professionals in participating in the collection and disposal program
 - total amount (pounds or similar measure) of unwanted pharmaceuticals collected and disposed
 - amount (pounds or similar measure) of unwanted controlled substances collected and disposed, if possible to separately identify this quantity
 - the number and locations of participating pharmacies that elected to include the collection of controlled substances at their registered collection site
 - the number and locations of participating pharmacies into which MedSafe receptacles for the collection of controlled substances were installed under the current Contract and Addendum
 - the number and locations of participating pharmacies who are participating in the controlled substances collection activities by distributing TakeAway envelopes including the number of envelopes distributed to these pharmacies under the current Contract and Addendum
 - the number of pharmacies indicating a desire to continue with the collection and disposal program after this Contract has concluded
 - the number of pharmacies, including the geographical distribution of those pharmacies, that indicate a willingness to continue the program at the pharmacy's expense
 - the number and location of long term care facilities that participated in the program

- the number and locations of events at which a Pill Dude mascot appeared and participated

4.2.15 Recommend change(s) to state law, the Drug Take-Away Program, or other, that would facilitate an on-going statewide collection and disposal program for unwanted pharmaceuticals, including identification of alternate sources for future funding

Section 5 ADDENDUM BUDGET and PAYMENT

5.1 Budget. The budget for this Contract Addendum shall be as follows. This Addendum budget is in addition to the budget included in the current Contract, increasing the total budge for Contract to \$175,000. Any equipment, materials, or supplies that remain in the possession of Contractor at the termination of this Contract, if such equipment, materials, or supplies were purchased with funds provided under this Contract or Addendum, shall be surrendered to Board within ten days of termination of Contract.

EXPENSES		
Drug TakeAway Systems	Additional TakeAway Systems (100 units)	\$13,333
Controlled Substance Collection & Disposal	Purchase of MedSafe (10 locations) + DEA-compliant liners (one pack of 4)	\$21,500
	TakeAway envelopes for Controlled Sustance mailback	\$5,167
Marketing	Pill Dude Mascot (3 costumes)	\$3,000
	Update marketing materials to pharmacies	\$5,000
	Controlled substance disposal marketing	\$2,000
TOTAL EXPENSE		\$50,000

A deviation of five percent (5%) or more in any line of the Estimated Expenses in this approved budget must be approved by Board’s oversight committee prior to expenditure. Expenditure of any amount in excess of the “total – not to exceed” budget expenses will not be authorized except as may otherwise be provided by Contract.

5.2 Payments. Payments to Contractor under this Contract shall not exceed \$125,000 for the term of the Contract. Payments to Contractor under this Contract shall not be made for any expenditures or claims that predate the effective date of this Contract nor for any expenditures or claims that postdate the termination date of this Contract. Additional payments to Contractor under this Addendum to the current Contract shall not exceed \$50,000. Payments to Contractor under this Addendum shall not be made for any expenditures or claims that predate the effective date of this Addendum or for any expenditures or claims that postdate the termination date of this Contract and Addendum.

5.3 Claims for Payment. Contractor shall submit to Board, on a *monthly* basis no earlier than the 1st day and no later than the 15th day of each month, a written signed invoice for services and supplies rendered during the previous month in accordance with this Contract. The invoice shall comply with all applicable rules concerning payment of such claims and shall not exceed the total amount of expenditures incurred by Contractor for the preceding month. Each invoice must be accompanied by a detailed accounting of the expenses incurred and claimed during the previous month, including copies of receipts for claimed expenditures and copies of invoices for supplies and services provided by Sharps and paid by Contractor. Each invoice may combine on a single invoice claims for services and supplies under both Contract and Addendum and the detailed accounting of expenses shall clearly and separately identify the expenses being claimed against Contract and Addendum. Board shall pay all approved invoices in arrears and in compliance with Iowa Department of Administrative Services policies relating to claims for payment against state funds.

Claims for payment shall be submitted to:

Terry Witkowski
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688

Payment shall be issued to:

Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, Iowa 50322

5.4 Other Payments. Unless otherwise agreed in writing by the parties, Contractor shall not be entitled to receive any other payment or compensation from Board for any goods or services provided by or on behalf of Contractor under this Contract and Addendum. Contractor shall be solely responsible for paying all costs, expenses, and charges it incurs in connection with its performance under this Contract and Addendum.

IN WITNESS THEREOF, the parties hereto have executed this Addendum to Contract #IPA-2016 on the day and year last specified below.

IOWA PHARMACY ASSOCIATION

IOWA BOARD OF PHARMACY

By: _____
Kate Gainer, CEO

By: _____
James A. Miller, Board Chair

Date: _____

Date: _____

ADDENDUM S
ADOPTION AND FILING
CHAPTER 4, "PHARMACIST-INTERNS"

PHARMACY BOARD[657]

Adopted and Filed

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

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

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

Notice of Intended Action was published in the December 9, 2015, Iowa Administrative Bulletin as **ARC 2301C**. The Board received numerous written comments regarding the proposed amendment; all commenters expressed support for the amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 13, 2016, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no substantial impact on jobs has been found. Changing the identification requirements for registration as a pharmacist-intern to accept either social security number or individual tax identification number (ITIN) enables a foreign student and the student's dependents to be identified and file tax returns when the student or dependents are not eligible for a social security number. The individuals identified using an ITIN may be employed or be in receipt of scholarship or fellowship funding. The Board's acceptance of the ITIN in lieu of a social security number does not create or eliminate the job; the Board's action recognizes the ITIN as a valid means of identification.

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

This amendment will become effective on March 23, 2016.

The following amendment is adopted.

Amend subrule 4.6(1) as follows:

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

[Filed 1/28/16, effective 3/23/16]

[Published 2/17/16]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM T

ADOPTION AND FILING

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

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

The amendments implement 2015 Iowa Acts, Senate File 462, which authorizes the prescribing of 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 amendments exclude such a prescription from the requirement for a preexisting patient-prescriber relationship and establish the unique prescription label and record-keeping requirements for a prescription issued to a facility, school district, or accredited nonpublic school as authorized by 2015 Iowa Acts, Senate File 462.

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 December 9, 2015, Iowa Administrative Bulletin as **ARC 2288C**. The Board received one written comment regarding the proposed amendments. The single comment received expressed support for the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the January 13, 2016, 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.27 and 2015 Iowa Acts, Senate File 462.

These amendments will become effective on March 23, 2016.

The following amendments are adopted.

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. and b. No change.

c. ~~The~~ Except as provided in 657—subrule 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. to h. No change.

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. to d. No change.

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 the following **new** subrule 8.19(7):

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.

[Filed 1/28/16, effective 3/23/16]

[Published 2/17/16]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM U

ADOPTION AND FILING

CHAPTER 6, "GENERAL PHARMACY PRACTICE,"

CHAPTER 7, "HOSPITAL PHARMACY PRACTICE,"

CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS"

CHAPTER 10, "CONTROLLED SUBSTANCES,"

CHAPTER 17, "WHOLESALE DRUG LICENSES,"

AND

CHAPTER 23, "LONG-TERM CARE PHARMACY PRACTICE"

PHARMACY BOARD[657]

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

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

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

Notice of Intended Action was published in the December 9, 2015, Iowa Administrative Bulletin as **ARC 2285C**. The Board received one written comment regarding the proposed amendments. The single comment received expressed support for the amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the January 13, 2016, 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 124.301.

These amendments will become effective on March 23, 2016.

The following amendments are adopted.

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

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

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

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

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

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

ITEM 3. Adopt the following **new** subrule 8.5(9):

8.5(9) Authorized collection program. A pharmacy that is registered with the United States Department of Justice, Drug Enforcement Administration, to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 4. Amend rule 657—10.1(124) as follows:

657—10.1(124) ~~Who shall register~~ Purpose and definitions. Any person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.

10.1(1) *Who shall register.* Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.

10.1(2) *Definitions.* For the purpose of this chapter, the following definitions shall apply:

“Authorized collection program” means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant’s Iowa controlled substances Act registration shall not be required.

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

ITEM 5. Amend rule 657—10.6(124) as follows:

657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, ~~or dispensed, or collected for the purpose of disposal~~ unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3), ~~or this rule, or federal regulations.~~

10.6(1) to 10.6(5) No change.

ITEM 6. Amend subrule 10.15(1) as follows:

10.15(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. and *b.* No change.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 7. Amend rule 657—10.18(124) as follows:

657—10.18(124) Disposal of registrant stock. Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such drugs pursuant to the procedures and requirements of this rule. Disposal records shall be maintained ~~in the files of~~ by the registrant.

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

~~**10.18(3) *Previously dispensed controlled substances.*** Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to~~

the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:

- ~~a. The source of the controlled substance (patient identifier or administering practitioner, if applicable, prescription number or other unique identification number, and date of return);~~
- ~~b. The name, strength, and dosage form of the substance;~~
- ~~c. The quantity returned and destroyed or otherwise disposed of;~~
- ~~d. The date the substance is destroyed or otherwise disposed of;~~
- ~~e. The signatures or other unique identification of the pharmacist and the witness;~~
- ~~f. The name and address of the dispensing pharmacy or practitioner if the controlled substance was not dispensed by the pharmacy completing the destruction.~~

ITEM 8. Adopt the following **new** rule 657—10.19(124):

657—10.19(124) Disposal of previously dispensed controlled substances. A registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.

ITEM 9. Amend subrule 10.34(3) as follows:

10.34(3) Date of record. The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, or distribution, exportation, disposal, or transfer.

ITEM 10. Amend subrule 10.35(1) as follows:

10.35(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. and *b.* No change.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

d. and *e.* No change.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

- (1) The name of the substance;
- (2) The strength and dosage form of the substance; ~~and~~
- (3) The quantity of the substance; and
- (4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

g. and *h.* No change.

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

“*Authorized collection program*” means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations

for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa controlled substances Act registration shall not be required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. and b. No change.

ITEM 18. Amend rule 657—23.21(124,155A) as follows:

657—23.21(124,155A) Destruction Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring ~~destruction~~ disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating ~~destruction~~ disposal shall be ~~destroyed~~ disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

23.21(1) Destruction Disposal in the facility. In facilities staffed by one or more persons licensed to administer drugs, a licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may ~~destroy~~ dispose of controlled substances in witness of one other responsible adult. The professional ~~destroying or otherwise~~ disposing of the drug shall prepare and maintain a readily retrievable

record of the ~~destruction or other~~ disposition which shall be clearly marked to indicate the ~~destruction or other~~ disposition of resident drugs. The record shall include, at a minimum, the following:

- a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;
- b. The name, strength, and dosage form of the substance;
- c. The quantity ~~destroyed or otherwise~~ disposed of;
- d. The date the substance is ~~destroyed or otherwise~~ disposed of;
- e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;
- f. The name and address of the dispensing pharmacy or the dispensing practitioner.

23.21(2) ~~*Destruction or other disposition in the long-term care pharmacy*~~ *Authorized collection program within a facility.* ~~Controlled substances returned to the pharmacy for destruction or other disposition may be destroyed or otherwise disposed of pursuant to the requirements of 657—subrule 40.18(3).~~ Registrants registered with DEA to administer an authorized collection program may install and maintain a collection receptacle in a long-term care facility for the purpose of disposal of prescription drugs, including controlled substances, pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

[Filed 1/28/16, effective 3/23/16]

[Published 2/17/16]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM V

ADOPTION AND FILING

CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS"

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The 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 these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the December 9, 2015, Iowa Administrative Bulletin as **ARC 2307C**. The Board received no written comments regarding the proposed amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 13, 2016, 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 155A.41.

This amendment will become effective on March 23, 2016.

The following amendment is adopted.

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.

[Filed 1/28/16, effective 3/23/16]

[Published 2/17/16]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM W
ADOPTION AND FILING
CHAPTER 10, "CONTROLLED SUBSTANCES"

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.201, the Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendment rescinds current rule 657—10.38(124) and adopts new rule 657—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 I 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 it should be appropriately classified as a Schedule I 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 noncancer 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 these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the December 9, 2015, Iowa Administrative Bulletin as **ARC 2287C**. The Board received no written comments regarding the proposed amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 13, 2016, 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 124.201.

This amendment will become effective on March 23, 2016.

The following amendment is adopted.

Rescind rule 657—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. Other 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,” introductory paragraph, 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:

[Filed 1/28/16, effective 3/23/16]

[Published 2/17/16]

EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM X

ADOPTION AND FILING

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

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," Iowa Administrative Code.

The 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 complementary 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. Also, because of the removal of paragraph 22.5(8)"b," paragraph "a" is restructured.

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 December 9, 2015, Iowa Administrative Bulletin as **ARC 2289C**. The Board received no written comments regarding the proposed amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 13, 2016, meeting of the Board of Pharmacy.

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

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

This amendment will become effective on March 23, 2016.

The following amendment is adopted.

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.~~

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.

ADDENDUM Y

NOTICE OF INTENDED ACTION

CHAPTER 20, "COMPOUNDING PRACTICES"

PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 20, “Compounding Practices,” Iowa Administrative Code.

The amendments were approved at the January 13, 2016, regular meeting of the Board of Pharmacy.

The proposed amendments define the term “office use” as it relates to compounded drug products that are distributed to a qualified practitioner for administration to the practitioner’s patient in the course of the practitioner’s professional practice. The amendments also clarify that a practitioner receiving a compounded product for office use is not restricted to administration of the product to the practitioner’s patient within the brick-and-mortar confines of the practitioner’s office. If the practitioner’s practice is not confined by office walls, the practitioner may administer to a patient a product distributed to the practitioner for office use if the administration occurs in the course of the practitioner’s professional practice.

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 March 8, 2016. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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

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

The following amendments are proposed.

ITEM 1. Adopt the following **new** definition of “Office use” in rule **657—20.2(124,126,155A)**:

“*Office use*” means that a compounded product has been prepared and distributed to a practitioner for administration to a patient by the practitioner in the course of the practitioner’s professional practice. A compounded product distributed to a practitioner for “office use” shall not require a patient-specific prescription and may not be further distributed to another practitioner or dispensed to a patient for self-administration.

ITEM 2. Amend rule 657—20.15(124,126,155A) as follows:

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~~ use. 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~~ a patient in the course of the practitioner’s office professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed

to other practitioners or dispensed to patients for administration outside of the office a patient for self-administration.

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."