State of Iowa
Board of Pharmacy

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

MINUTES

November 1-2, 2016

The Iowa Board of Pharmacy met on November 1-2, 2016, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

TUESDAY, NOVEMBER 1, 2016

MEMBERS PRESENT
James Miller, Chairperson
Sharon K. Meyer, Vice-Chair
LaDonna Gratias
Jason Hansel
Kay Jessen
Edward J. McKenna

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
Daniel Sedlacek, Compliance Officer
James Wolfe, Compliance Officer

Call to Order & Announcements

At 9:00 a.m., James Miller, Chairperson called the meeting of the Iowa Board of Pharmacy to order on Tuesday, November 1, 2016.

Administrative Hearing

2014-34, Robert A. Osborn, Pharmacist License No. 19079, Rock Island, Illinois.

At 9:00 a.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Mr. Osborn appeared before the Board and was self represented. The session was conducted in the presence of the Board and was closed to the public.

The Board examined exhibits.

At 9:52 a.m., the record was closed.

At 9:53 a.m., motion by Jason Hansel, seconded by LaDonna Gratias, 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.

Meghan Gavin, Laura Steffensmeier, and the Compliance Officers left the room.

At 10:08 a.m., while still in closed session, Edward McKenna moved that the Board go into open session, seconded by Sharon Meyer. Motion approved unanimously.

Motion by Kay Jessen, seconded by Edward McKenna, to direct Administrative Law Judge LaMarche to draft the Order consistent with the Board's deliberation for case 2014-34, Robert A. Osborn. Motion approved unanimously.

Closed Session

At 10:25 a.m., on a motion by Jason Hansel, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; pursuant to Iowa Code section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings; and pursuant to Iowa Code section 21.5(1)(f), to discuss the decision to be rendered in a contested case conducted according to the provisions of Chapter 17A.

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

Administrative Hearing

2016-20 and 2016-26, Wayne Fagan, Pharmacy Support Person Registration No. 2863, Cedar Rapids.

At 1:05 p.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Laura Steffensmeier represented the State. Wayne Fagan did not appear nor did counsel represent him. The session was conducted in the presence of the Board and was open to the public.

The Board examined exhibits and heard testimony of a witness.

At 1:19 p.m., the record was closed.

At 1:20 p.m., motion by Kay Jessen, seconded by Jason Hansel, 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.

Meghan Gavin, Laura Steffensmeier, and the Compliance Officers left the room.

At 1:24 p.m., while still in closed session, Jason Hansel moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

Motion by Jason Hansel, seconded by Sharon Meyer, to direct Administrative Law Judge LaMarche to draft the Order consistent with the Board's deliberation for cases 2016-20 and 2016-26, Wayne Fagan. Motion approved unanimously.

Closed Session

At 1:40 p.m., on a motion by Jason Hansel, seconded by Kay Jessen, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; and pursuant to Iowa Code section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings. Motion approved unanimously.

At 2:15 p.m., while still in closed session, Jason Hansel, moved that the Board go into open session, seconded by Kay Jessen. Motion approved unanimously.

In open session the following actions were taken:

1. Closed Session Minutes.

   Motion by Edward McKenna, seconded by Jason Hansel, to approve the Closed Session Minutes and Deliberations of the August 30-31, 2016, meeting, and the Closed Session Minutes of the September 28, 2016, teleconference meeting. Motion approved unanimously.

2. Close With No Further Action.

   Motion by Edward McKenna, seconded by Sharon Meyer, to close with no further action the following investigative files in complaint numbers: 2013-81, 2013-129, and 2013-201. Motion approved unanimously.

3. Close With No Further Action and Refer to Another Agency.

   Motion by Jason Hansel, seconded by Kay Jessen, to close with no further action and refer to the Board of Medicine case 2016-46. Motion approved unanimously.

4. Settlement Agreement and Final Order.

   Motion by Kay Jessen, seconded by Jason Hansel, to approve the Settlement Agreement and Final Order in the following cases. Motion approved unanimously.

   A. 2015-102, Jerod Work, Pharmacist License No. 20153, Sioux Center. A copy of the Settlement Agreement and Final Order is attached as Addendum A.

   B. Benjamin Lognion, DVM, Controlled Substance Registration No. 1512025, Boone. A copy of the Settlement Agreement and Final Order is attached as Addendum B.

C. 2016-32, Norwood Pharmacy, Nonresident Pharmacy License No. 4268, Maryland Heights, Missouri. A copy of the Settlement Agreement and Final Order is attached as Addendum C.

D. 2016-39 Bellevue Pharmacy, Nonresident Pharmacy License No. 3946, Maryland Heights, Missouri. A copy of the Settlement Agreement and Final Order is attached as Addendum D.

E. 2016-40 Bellevue Pharmacy, Nonresident Pharmacy License No. 4355, Arlington Heights, Illinois. A copy of the Settlement Agreement and Final Order is attached as Addendum E.

F. 2016-50, Medaus Pharmacy, Nonresident Pharmacy License No. 3403, Birmingham, Alabama. A copy of the Settlement Agreement and Final Order is attached as Addendum F.

G. 2016-58, Life-Q LLC Pharmacy, Nonresident Pharmacy License No. 4328, Nashville, Tennessee. A copy of the Settlement Agreement and Final Order is attached as Addendum G.

5. Combined Statement of Charges, Settlement Agreement, and Final Order.

Motion by Jason Hansel, seconded by Kay Jessen, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order for the following cases. Motion approved unanimously.

A. 2016-51, Pharma Holdings US of FL, LLC, d/b/a Meds Direct Rx of FL, Nonresident Pharmacy License No. 3301, Deerfield Beach, Florida. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum H.

B. 2016-118, Precision Rx Compounding LLC, Nonresident Pharmacy License No. 4490, Tampa, Florida. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum I.

6. Rescind Statement of Charges.

Motion by Kay Jessen, seconded by LaDonna Gratias, to rescind the original Statement of Charges for Meds Direct Rx, Nonresident Pharmacy License No. 3301, Deerfield Beach, Florida. Motion approved unanimously.

7. Notice of Hearing and Statement of Charges.

Motion by LaDonna Gratias, seconded by Edward McKenna, to approve the Notice of Hearing and Statement of Charges for 2016-78, Pacifico National Inc., d/b/a Amex Pharmacy, Nonresident Pharmacy License No. 3942, Melbourne, Florida. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum J.

8. Close With No Further Action.

Motion by Jason Hansel, seconded by LaDonna Gratias, to close with no further action the following investigative files in complaint numbers: 2016-120, 2016-122, 2016-139, 2016-49, 2016-89, 2016-108, 2016-114, 2016-100, 2016-101, 2016-106, 2016-141, 2016-36, 2016-24, 2016-102, 2016-115, and 2016-138. Motion approved unanimously.

9. Letter of Education.

Motion by Edward McKenna, seconded by LaDonna Gratias, to issue a Letter of Education to the pharmacist in charge in 2016-137 and pharmacy in 2016-119. Motion approved unanimously.

10. Letter of Education.

    Motion by Jason Hansel, seconded by Edward McKenna, to issue a Letter of Education to the pharmacist in charge in 2016-127. Jessen abstains. Motion approved.

11. Draft Statement of Charges.

    Motion by Edward McKenna, seconded by LaDonna Gratias, to draft Statement of Charges against the pharmacy and pharmacist in charge in 2016-150, and pharmacy support person in 2016-133. Motion approved unanimously.

At 2:25 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, November 2, 2016, at 9:00 a.m.

WEDNESDAY, NOVEMER 2, 2016

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

MEMBERS ABSENT
Kay Jessen

SPEAKERS
Anthony Pudlo, IPA
Jonathan Franzen, Hy-Vee
Julie Panosh, Mercy Family Pharmacy
Dale Woolery, ODCP
Megan Myers, IPA
Cheri Schmit, Medicap/GRX

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
Daniel Sedlacek, Compliance Officer
James 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 on Wednesday, November 2, 2016.

Public Comments

Anthony Pudlo – The Iowa Pharmacy Association's (IPA) Legislative Committee and Board of Trustees established a draft of legislative and regulatory priorities for 2017. A copy of the draft was provided for review.

Approval of Minutes

The minutes of the August 30-31, 2016, open session meeting and the September 28, 2016, teleconference open session meeting were reviewed.

Motion by Sharon Meyer, seconded by Edward Maier, to approve the open session minutes of the August 30-31, 2016, meeting, and the open session minutes of the September 28, 2016, teleconference meeting as presented. Motion approved unanimously.

Reports

1. Executive Director's Report –

Office Update

A. The Prescription Monitoring Program and Controlled Substance Compliance Specialist position has been approved. The position will be sent to the pharmacists within the board staff to see if there is any interest in the position for a lateral transfer, if there is no interest in the position, Director Funk will proceed to gather public applications.

B. Debbie Jorgenson, Administrative Assistant with the Board will be retiring from the board office on December 30, 2016. Her position is currently pending review by the Department of Management and Department of Administrative Services (DAS) for approval.

C. Curt Gerhold completed NABP's Critical Point's Sterile Compounding Inspector Certification Training in early October 2016.

Database Update

Board staff recently reviewed proposals from the two vendors that were recommended by the Office of the Chief Information Officer (OCIO) - Communication Systems and Data Centers (CSDC) and SalesForce. Both vendors appear to be able to meet the Board's business requirements, but there was concern regarding the pricing of the proposals. The five year total implementation cost for SalesForce is $1,700,000 and CSDC $694,000. CSDC's proposal did not include a cloud based database. A new proposal to include a cloud based database will be resubmitted by CSDC for board staff to review. The new estimated project completion date for the database is scheduled for May 2018.

Office Lease

DAS negotiated and signed a seven year lease contract with Hubbell Realty for the Iowa Board of Pharmacy, Iowa Dental Board, Board of Medicine, and Board of Nursing to remain in their current locations.

Meetings and Travel

A. NABP's Board Member Interactive Forum will be held in Mount Prospect, Illinois on November 30 - December 1, 2016. Jason Hansel plans to attend the meeting.

B. The 51st ASHP Midyear Clinical Meeting will be held in Las Vegas, Nevada on December 4-6, 2016. Sharon Meyer plans to attend the meeting.

C. The January board meeting is scheduled for January 4-5, 2017, in Des Moines at the board office.

D. The Iowa Pharmacy Association Legislative Day is scheduled for February 7, 2017, in Des Moines.

E. The Midwest Pharmacy Expo is scheduled for February 17-19, 2017, in Des Moines.

F. The Iowa Board of Pharmacy will be hosting the NABP District 5 Meeting at the Holiday Inn in West Des Moines on August 3-5, 2017.

2. Iowa Monitoring Program for Pharmacy Professionals (IMP3) Report – Amy VanMaanen.

   Amy VanMaanen provided a summary of the IMP3 Report.

3. NAPLEX/MPJE 2016 Graduate Performance Data.

   Inquiries have been made to the National Association of Boards of Pharmacy (NABP) regarding the recent passing rates for the North American Pharmacist Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE). A memo from NABP regarding NAPLEX and MPJE performance outcomes was provided for review.

4. Federal Drug Administration's (FDA) 2016 Intergovernmental Working Meeting on Pharmacy Compounding.

   Sue Mears and Laura Steffensmeier provided summaries of the FDA meeting they attended on September 20-21, 2016, in Silver Springs, Maryland.

5. Hy-Vee Pharmacy Fulfillment Center's 2016 Quarter Two Error Report.

   Hy-Vee Pharmacy Fulfillment Center submitted their 2016 Quarter Two Error Report for review.

6. Mapping Prescription Drug Monitoring Program (PMP) Enrollment and Use.

   A map of the PMP Enrollment and Utilization Patterns for the United States was provided for review.

7. Mercy Family Pharmacy, Dyersville – Phase Four, Quarter One Report – New Practice Model for Community Pharmacy - Julie Panosh, Dyersville.

   Mercy Family Pharmacy submitted their Phase Four, Quarter One Report for the New Practice Model for Community Pharmacy for review.

8. New Online Tools Offer Path to Lower Drug Prices – The New York Time.

   Informational item.

9. Iowa's Medication Disposal Program for Non-Controlled Substances Quarterly Report for July – October 2016 – Anthony Pudlo, IPA.

   IPA provided their Quarterly Report for Iowa's Medication Disposal Program for Non-Controlled Substances. Anthony Pudlo provided a summary of the report.

10. Iowa Pharmaceutical Collection and Disposal Drug Enforcement Administration (DEA) Compliant Collection Receptacles Quarter One Progress Report for FY 2016/2017 – Jennifer Tiffany.

    The Iowa Pharmaceutical Collection and Disposal DEA Compliant Collection Receptacles Quarter One Progress Report was provided for review. Jennifer Tiffany provided a summary of the report.

11. DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017.

    Informational item.

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

    IPA provided their Phase Three, Quarter One Report and Phase Four, Quarter One Report for the New Practice Model for Community Pharmacy. Megan Myers provided a summary of the report.

Requests

1. Request for Waiver – All Administrative Rules That Do Not Convey Iowa Code Requirements - Matrix Pharmacy, Tampa, Florida.

   Motion by Edward Maier, seconded by Jason Hansel, to deny the request for waiver. Motion approved unanimously.

2. Request for Waiver – 657 I.A.C. 20.4 Sterile Compounding, CHI Health Mercy, Corning.

   Motion by Edward Maier, seconded by Sharon Meyer, to approve the request for waiver until March 31, 2017. Motion approved unanimously.

3. Request for Waiver – 657 I.A.C. 9.1 Purpose and Scope – DeliverCareRx Pharmacy LLC, Skokie, Illinois.

   Motion by Edward Maier, seconded by Edward McKenna, to deny the request for waiver. Motion approved unanimously.

4. USP General Chapter <800>, Hazardous Drugs – Handling in Healthcare Settings.

   The Board took no action on this request. The Board will continue to monitor the progress and recommendations from various stakeholders and referred to the Rules Committee for further discussion.

5. Request for Internship Credit – Ernane C. de Souza, Jr., Iowa City.

   Motion by Edward Maier, seconded by LaDonna Gratias, to grant Mr. de Souza 750 hours of internship credit for his life experience, requiring him to complete an additional 750 hours of internship within three years. Motion approved unanimously.

6. Request Early Release from Probation – Gary D. Cottington, Pella.

   Motion by Edward Maier, seconded by Jason Hansel, to table this request. Motion approved unanimously.

7. Request for Modification to Stipulation and Consent Order – Diane Simko , Urbandale.

   Motion by Jason Hansel, seconded by Sharon Meyer, to modify Ms. Simko's Stipulation and Consent Agreement by removing condition of working no more than 20 hours of employment during the first six months of employment during probation and modify respondent's period of probation from five years to one year of pharmacist-type employment. Motion approved unanimously.

Requests

At 11:00 a.m., motion by Edward Maier, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential according to the provisions of Chapter 17A.

At 11:13 a.m., while still in closed session, Edward Maier moved that the Board go into open session, seconded by Sharon Meyer. Motion approved unanimously.

Motion by Jason Hansel, seconded by Sharon Meyer, to approve the requests that were discussed in closed session. Motion approved unanimously.

Rules

1. Notice of Intended Action - Amend Chapter 37, "Iowa Prescription Monitoring Program."

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

2. Proposed Bill Prefile to Amend Iowa Code Chapter 124, Prescription Monitoring Program.

   Motion by Sharon Meyer, seconded by Jason Hansel, to approve the Proposed Bill Prefile to amend Iowa Code Chapter 124. Motion approved unanimously. A copy is attached as Addendum L.

3. Proposed for Adoption and Filing, Rescinding Chapter 30, "Impaired Pharmacy Professionals and Technician Recovery Program," and Adopt new Chapter 30, "Iowa Monitoring Program for Pharmacy Professionals."

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

4. Emergency Adoption After Notice – Amend Chapter 8, "Universal Practice Standards."

   Motion by Edward Maier, seconded by Jason Hansel, to approve the Emergency Adoption After Notice with amendments. Motion approved unanimously. A copy is attached as Addendum N.

Closed Session

At 12:39 p.m., on a motion by Jason Hansel, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code section 21.5(1)(a), to review or discuss records which are required or authorized by state or federal law to be kept confidential; and pursuant to Iowa Code section 21.5(1)(d), to discuss whether to initiate licensee disciplinary investigations or proceedings.

At 12:51 p.m., while still in closed session, Jason Hansel moved that the Board go into open session, seconded by Edward Maier. Motion approved unanimously.

Motion by Jason Hansel, seconded by Edward Maier, to close 2016-117, My Matrixx Pharmacy. Motion approved unanimously.

Rules

1. Notice of Intended Action – Amend Chapter 8, Universal Practice Standards," and Adopt new Chapter 13, "Telepharmacy Practice."

   Motion by Edward Maier, seconded by Jason Hansel, to approve for filing Notice of Intended Action as amended. Motion approved unanimously. A copy is attached as Addendum O.

2. Notice of Intended Action – Amend Chapter 10, "Controlled Substances," and Chapter 100, "Iowa Real-Time Electronic Pseudoephedrine Tracking System."

   Motion by Jason Hansel, seconded by Edward McKenna, to approve for filing Notice of Intended Action as amended. Motion approved unanimously. A copy is attached as Addendum P.

3. Notice of Intended Action – Amend Chapter 20, "Compounding Practices," and Adopt new Chapter 41, "Outsourcing Facilities."

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

4. Notice of Intended Action – Rescind Chapter 19, "Nonresident Pharmacy Practice," and Adopt new Chapter 19, "Nonresident Pharmacy Practice."

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

5. Notice of Intended Action – Amend Chapter 11, "Drugs in Emergency Medical Service Programs."

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

6. Notice of Intended Action – Amend Chapter 2, "Pharmacist Licenses."

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

   Motion, by Edward McKenna, seconded by Edward Maier, to extend board staff's authority to approve the NAPLEX waiting period from 91 days to 45 days until the new rule goes into effective. Motion approved unanimously.

Legislation

1. Iowa Code 124 - Changes Regarding Precursor Substances, to the Controlled Substance Schedules, and Providing Penalties.

   Motion by Edward Maier, seconded by LaDonna Gratias, to approve for legislative prefiling. Motion approved unanimously. A copy is attached as Addendum U.

2. Iowa Code 155A – Alternate Board Members, Drug Disposal Program Funding, Impaired Professionals Program, Pharmacy Internet Sites, and the Definition of "Practitioner."

Motion by Edward McKenna, seconded by Edward Maier, to amend the proposed prefile by striking Section 147.14, subsection 1, paragraph "e". Motion approved unanimously.

Motion by Edward Maier, seconded by Edward McKenna, to approve the proposed legislative prefile as amended. Motion approved unanimously. A copy is attached as Addendum V.

Licensure and Registrations

Preliminary Notice of Intent to Deny License - Pacifico National, Inc., d/b/a Amex Pharmacy, Melbourne, Florida.

Motion by Jason Hansel, seconded by Edward Maier, to approve Preliminary Notice of Intent to Deny License. Motion approved unanimously. A copy of the Preliminary Notice of Intent to Deny License is attached as Addendum W.

Complaints Against Non-Licensees

1. 2016-96, Priority Care Pharmacy Solutions, Amory, Mississippi.

   Motion by Jason Hansel, seconded by Edward Maier, to close. Motion approved unanimously.

2. 2016-105, Priority Care Pharmacy at Cotton Gin Point, Amory, Mississippi, and 2016-107, Smart Pharmacy Inc., d/b/a Cordette Pharmacy, New York, New York.

   Motion by Edward Maier, seconded by Jason Hansel, to close. Motion approved unanimously.

3. 2016-110, Mabile's Corner Pharmacy, Coushatta, Louisiana.

   Motion by Sharon Meyer, seconded by Edward Maier, to close. Motion approved unanimously.

4. 2016-111, Vincent Priority Care Pharmacy, Vincent, Alabama.

   Motion by Sharon Meyer, seconded by Edward Maier, to close. Motion approved unanimously.

   Motion by Sharon Meyer, seconded by Edward Maier, to grant, for one year, board staff the authority to review and close complaints against non-licensees. Motion approved unanimously.

5. 2016-124, Ramona Wallesch, Blue Grass.

   Motion by Jason Hansel, seconded by Sharon Meyer, to close. Motion approved unanimously.

Meeting adjourned at 2:55 p.m. on November 2, 2016.

Becky Hall
Becky Hall
Recording Secretary

Andrew Funk
Executive Director

James Miller
Board Chair

APPROVED THIS 4th DAY OF January, 2017.

ADDENDUM A

SETTLEMENT AGREEMENT AND FINAL ORDER

JEROD WORK
PHARMACIST LICENSE NO. 20153
SIOUX CENTER, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of **JEROD WORK** License No. 20153 Respondent.	))))))	CASE NO. 2015-102 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Jerod Work ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on March 8, 2016.

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. 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 shall pay a **CIVIL PENALTY** in the amount of one-thousand dollars ($1,000) within sixty (60) 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.

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

a. Respondent shall not serve as a pharmacist-in-charge or pharmacist preceptor while on probation.

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

c. Respondent shall submit semiannual reports to the Board describing his current employment and compliance with these probationary terms, and shall provide updates regarding any changes in contact information. Said semiannual reports are due on January 15 and July 15 of each calendar year during the probationary period.

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 26th day of October, 2016.

JEROD WORK
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copies to:

Laura Steffensmeier
Office of the Attorney General of Iowa
Licensing and Administrative Law Division
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Michael J. Jacobsma
JACOBSMA & CLABAUGH PLC
81 West 1st St.
P.O. Box 226
Sioux Center, IA 51250
ATTORNEY FOR RESPONDENT

ADDENDUM B

SETTLEMENT AGREEMENT AND FINAL ORDER

BENJAMIN LOGNION, DVM
CONTROLLED SUBSTANCE REGISTRATION NO. 1512025
BOONE, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2015-206
Controlled Substances Act Registration of	)	
	)	**SETTLEMENT AGREEMENT**
BENJAMIN LOGNION, DVM	)	**AND FINAL ORDER**
Registration No. 1512025	)	
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 Benjamin Lognion ("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 Order to Show Cause against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed an Order to Show Cause on June 30, 2016. Respondent was granted an extension of time to file a request for a hearing. Respondent filed a timely request for hearing on September 16, 2016. A hearing is currently scheduled for November 1, 2016.

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

3. Respondent acknowledges that the allegations co ntained in the Order to Show Cause, 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 Controlled Substances Act 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.

14. Respondent agrees not to prescribe or administer controlled substances in Iowa unless his registration is reinstated. Respondent may request reinstatement of his Iowa Controlled Substances Act registration after one (1) year 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. 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 2nd day of October, 2016.

BENJAMIN LOGAN
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copies to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

George W. Appleby
Carney & Appleby, P.L.C.
303 Locust Street, Suite 400
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

ADDENDUM C

SETTLEMENT AGREEMENT AND FINAL ORDER

NORWOOD PHARMACY LLC
NONRESIDENT PHARMACY LICENSE NO. 4268
MARYLAND HEIGHTS, MISSOURI

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-32
Nonresident Pharmacy License of	)	
	)	**SETTLEMENT AGREEMENT**
NORWOOD PHARMACY LLC	)	**AND FINAL ORDER**
License No. 4268	)	
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 Norwood Pharmacy LLC ("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 August 30, 2016.

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 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. 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** its Iowa nonresident pharmacy license to resolve this matter. Respondent has already ceased operations.

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 agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

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 27th day of October, 2016.

NORWOOD PHARMACY LLC
Respondent

By this signature, Blaine C. Smith acknowledges s/he is the Manager for Norwood Pharmacy LLC and is authorized to sign this Settlement Agreement and Final Order on behalf of Norwood Pharmacy LLC.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM D

SETTLEMENT AGREEMENT AND FINAL ORDER

BELLEVUE PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 3946
MARYLAND HEIGHTS, MISSOURI

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-39
Nonresident Pharmacy License of	)	
	)	**SETTLEMENT AGREEMENT**
BELLEVUE PHARMACY	)	**AND FINAL ORDER**
License No. 3946	)	
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 Bellevue Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on August 30, 2016.

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. 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** its Iowa nonresident pharmacy license to resolve this matter. Respondent has already ceased operations.

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 agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

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 chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of November, 2016.

BELLEVUE PHARMACY
Respondent

By this signature, Johannes (Hans) Stols acknowledges s/he is the Chief Executive Officer for Bellevue Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Bellevue Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM E

SETTLEMENT AGREEMENT AND FINAL ORDER

BELLEVUE PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 4355
ARLINGTON HEIGHTS, ILLINOIS

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-40
Nonresident Pharmacy License of	)	
	)	**SETTLEMENT AGREEMENT**
BELLEVUE PHARMACY	)	**AND FINAL ORDER**
License No. 4355	)	
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 Bellevue Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on August 30, 2016.

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. 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** its Iowa nonresident pharmacy license to resolve this matter. Respondent has already ceased operations.

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 agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

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 chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of November, 2016.

BELLEVUE PHARMACY
Respondent

By this signature, Johannes (Hans) Stols acknowledges s/he is the Chief Executive Officer for Bellevue Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Bellevue Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM F

SETTLEMENT AGREEMENT AND FINAL ORDER

MEDAUS PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 3403
BIRMINGHAM, ALABAMA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of	)	CASE NO. 2016-50
MEDAUS PHARMACY License No. 3403 Respondent.	)	**SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Medaus Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on August 30, 2016.

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. 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's license is hereby **INDEFINITELY RESTRICTED** from shipping any sterile compounded products into Iowa. Respondent shall comply with all terms of the Final Order in case number 16-0033 issued by the Alabama State Board of Pharmacy. Respondent shall notify the Board within ten (10) days of any changes regarding the status of its Alabama pharmacy permit. Respondent shall obey all laws and rules governing the practice of pharmacy. The restriction on Respondent's license shall be removed when the Board receives written verification that the Alabama State Board of Pharmacy has authorized Respondent to resume sterile compounding.

13. 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 25th day of October, 2016.

Larry D. Stephens

MEDAUS PHARMACY
Respondent

By this signature, Larry D. Stephens acknowledges s/he is the C.O.O. & PIC for Medaus Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Medaus Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copies to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

H. Hube Dodd
The Dodd Law Firm
2323 Second Avenue North Suite 111
Birmingham, AL 35203
ATTORNEY FOR RESPONDENT

ADDENDUM G

SETTLEMENT AGREEMENT AND FINAL ORDER

LIFE-Q LLC PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 4328
NASHVILLE, TENNESSEE

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-58
Nonresident Pharmacy License of	)	
	)	**SETTLEMENT AGREEMENT**
LIFE-Q LLC PHARMACY	)	**AND FINAL ORDER**
License No. 4328	)	
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 Life-Q LLC Pharmacy ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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

1. The Board filed a Notice of Hearing and Statement of Charges on August 30, 2016.

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. 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** its Iowa nonresident pharmacy license to resolve this matter. Respondent has already ceased operations.

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 agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

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 14 day of October, 2016.

Life-Q LLC Pharmacy
Respondent

By this signature, Andrew W. Miller, Jr. acknowledges s/he is the MEMBER for Life-Q LLC Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Life-Q LLC Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM H

COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER

PHARMA HOLDINGS US OF FL, LLC
d/b/a MEDS DIRECT RX OF FL
NONRESIDENT PHARMACY LICENSE NO. 3301
DEARFIELD BEACH, FLORIDA

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-51
Nonresident Pharmacy License of	)	
	)	**COMBINED STATEMENT OF**
PHARMA HOLDINGS US OF FL, LLC	)	**CHARGES, SETTLEMENT**
d/b/a MEDS DIRECT RX OF FL,	)	**AGREEMENT, AND FINAL ORDER**
License No. 3301	)	
Respondent.	)	

COME NOW the Iowa Board of Pharmacy ("Board") and Pharma Holdings US of FL, LLC d/b/a Meds Direct Rx of FL ("Respondent"), 718 S Military Trail, Deerfield Beach, Florida 33442, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), and 657 IAC 36.6. The Board has jurisdiction over Respondent and the subject matter of these cases pursuant to Iowa Code chapters 17A, 147, 155A, and 272C, and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I
FAILURE TO GIVE PROPER NOTICE OF CLOSURE TO BOARD

Respondent is charged with failing to provide 30 days advanced notice of closure to the Board in violation of 657 IAC 8.35(7)"b" and 19.2(2), pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

COUNT II
FAILURE TO GIVE PROPER NOTICE OF CLOSURE TO PATIENTS

Respondent is charged with failing to provide 30 days advanced notice of closure to Iowa patients in violation of 657 IAC 8.35(7)"d" and 19.2(2), pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

B. FACTUAL CIRCUMSTANCES

1. Respondent closed for business on March 24, 2016.

2. The Board received notice of the closure on March 28, 2016. The notice was dated March 24, 2016, and indicated the pharmacy would be closing on March 24, 2016.

3. Respondent did not provide adequate notice to Iowa patients of the pharmacy's closing.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

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

5. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

6. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, 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.

7. Respondent acknowledges that it 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 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.

10. 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.

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

12. 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.

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

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

IT IS THEREFORE ORDERED:

15. Respondent is hereby **CITED** for failing to give proper notice of closure to the Board and patients 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.

16. Respondent shall pay a **CIVIL PENALTY** in the amount of one thousand dollars ($1000) 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 check should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

17. As a result of the pharmacy's closure, Respondent consents to a non-disciplinary administrative cancellation of license number 3301.

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 Combined Statement of Charges, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 20th day of October, 2016.

Member

PHARMA HOLDINGS US OF FL, LLC
d/b/a MEDS DIRECT RX OF FL
Respondent

By this signature, _____ acknowledges s/he is the _____ for Pharma Holdings US of FL, LLC d/b/a Meds Direct Rx of FL and is authorized to sign this Settlement Agreement and Final Order on behalf of Pharma Holdings US of FL, LLC d/b/a Meds Direct Rx of FL.

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM I

COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER

PRECISION RX COMPOUNDING LLC
NONRESIDENT PHARMACY LICENSE NO. 4490
TAMPA, FLORIDA

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-118
Nonresident Pharmacy License of	)	
	)	**COMBINED STATEMENT OF**
PRECISION RX COMPOUNDING LLC	)	**CHARGES, SETTLEMENT**
License No. 4490	)	**AGREEMENT, AND FINAL ORDER**
Respondent.	)	

COME NOW the Iowa Board of Pharmacy ("Board") and Precision Rx Compounding LLC ("Respondent"), 10323 Cross Creek Blvd., Ste. A, Tampa, FL 33647, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), and 657 IAC 36.6. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 147, 155A, and 272C, and 657 IAC chapters 19 and 36.

A. STATEMENT OF CHARGES

COUNT I
FAILURE TO GIVE PROPER NOTICE OF CLOSURE TO BOARD

Respondent is charged with failing to provide 30 days advanced notice of closure to the Board in violation of 657 IAC 8.35(7)"b" and 19.2(2), pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

B. FACTUAL CIRCUMSTANCES

1. Respondent's Iowa nonresident pharmacy license number 4490 is currently active through December 31, 2016.

2. Board compliance officers arrived at Respondent's location to perform an unannounced inspection on August 2, 2016. The pharmacy was no longer in business.

3. Respondent indicated it closed in June of 2016 and had notified the Florida Board of Pharmacy, but had failed to provide notice of closing to other state licensing boards, including Iowa.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

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

5. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

6. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, 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.

7. Respondent acknowledges that it 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 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.

10. 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.

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

12. 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.

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

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

IT IS THEREFORE ORDERED:

15. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license to resolve this matter. Respondent has already ceased operations.

16. 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 agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

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

This Combined Statement of Charges, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 9th day of September, 2016.

PRECISION RX COMPOUNDING LLC
Respondent

By this signature, Nagi Youssef acknowledges s/he is the owner for Precision Rx Compounding LLC and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Precision Rx Compounding LLC.

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 1st day of November, 2016.

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM J

NOTICE OF HEARING AND
STATEMENT OF CHARGES

PACIFICO NATIONAL INC.,
d/b/a AMEX PHARMACY
NONRESIDENT PHARMACY LICENSE NO. 3942
MELBOURNE, FLORIDA

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	CASE NO. 2016-78
Nonresident Pharmacy License of	)	
	)	**NOTICE OF HEARING AND**
PACIFICO NATIONAL INC.,	)	**STATEMENT OF CHARGES**
d/b/a AMEX PHARMACY	)	
License No. 3942	)	
Respondent.	)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Pacifico National Inc. d/b/a Amex Pharmacy ("Respondent"), 1515 Elizabeth St., Ste. J, Melbourne, FL 32901, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license number 3942 is currently active through December 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 4, 2017, before the Board. The hearing shall be held during the morning session beginning at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

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

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 chapter 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 chapter 36.

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

C. CHARGES

COUNT I
OUT-OF-STATE DISCIPLINE

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

COUNT II
FAILURE TO NOTIFY

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

D. FACTUAL CIRCUMSTANCES

1. On February 29, 2016, the State of Florida Department of Health issued an Order of Emergency Restriction of Permit, which restricted Respondent from compounding sterile preparations for human use in the State of Florida. The emergency restriction was lifted on April 22, 2016. An administrative complaint in case no. 2015-06647 remains pending in Florida.

2. On March 31, 2016, the North Carolina Board of Pharmacy approved Respondent's Voluntary Surrender of Permit for Cause.

3. On April 7, 2016, the State Board of Pharmacy of South Carolina issued an Order restricting Respondent from shipping compounded products into South Carolina.

4. On July 1, 2016, the Alabama State Board of Pharmacy issued a Final Order suspending Respondent's non-resident permit for 5 years and imposing a $9000 administrative fine.

5. Respondent did not report any of these actions to the Board within 30 days.

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 1st day of November, 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
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE

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 K

NOTICE OF INTENDED ACTION

CHAPTER 37, "IOWA PRESCRIPTION MONITORING PROGRAM"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 124.554, the Board of Pharmacy and the Prescription Monitoring Program Advisory Council hereby give Notice of Intended Action to amend Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy. The amendments were approved by the Prescription Monitoring Program Advisory Council at their meeting on October 11, 2016.

The proposed amendments are the result of a review of the chapter pursuant to the requirements of Iowa Code subsection 17A.7(2). The proposed amendments also are intended to implement Iowa Code changes passed by the Legislature in Senate File 2102. Proposed amendments include:

- New definitions for electronic health record system or EHRS, electronic pharmacy information system or e-pharmacy system, electronic system, and health information exchange or HIE and clarifying amendments to the definitions of health care professional, PMP administrator, and practitioner's agent;
- Clarifications regarding exemption from reporting dispensed prescriptions to the PMP and the procedures for requesting exemption;
- Clarification of the required data elements and procedures for submission by a pharmacy of records of dispensed prescriptions or of reports that no qualifying prescriptions were dispensed during a reporting period;
- Clarifications regarding the PMP records and information that is deemed confidential;

- An increase in the number of agents that a practitioner may authorize to access the PMP on behalf of the practitioner and the procedures for registration of a practitioner's agent, removal of alternate procedures relating to a practitioner without Internet access, and reference to and clarification of the procedures for a patient to obtain a copy of the patient's prescription history;
- Clarifications of the procedures for a regulatory agency or board, a law enforcement agency, and researchers to request information from the Iowa PMP including provisions regarding charging a fee for the preparation and release of PMP information and reports;
- New provisions relating to the establishment of facility users and the integration of PMP access into EHRS, HIE, and e-pharmacy systems including contract and agreement requirements for such integration; and
- Correction of rule references and the implementation clause.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 10, 2017. 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 email 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 124.550 to 124.558 as amended by 86GA, SF2102.

The following amendments are proposed.

Item 1. Amend rule 657—37.2(124) by adding the following new definitions:

"Electronic health record system" or *"EHRS"* means a real time, patient-centered health record system that makes patient health information and other health care tools and resources readily and securely available to authorized providers in a digital format capable of being shared with other providers across one or more health care organizations or facilities.

"Electronic pharmacy information system" or *"e-pharmacy system"* means a real-time electronic patient prescription record system that includes, at a minimum, patient profiles and prescription dispensing information and that may enable shared access to included information by multiple pharmacies, such as a chain of pharmacies using the same e-pharmacy system.

"Electronic system" means an electronic health record system, an electronic pharmacy information system, or a health information exchange. *"Electronic systems"* refers to a combination of two or more of these types of systems.

"Health information exchange" or *"HIE"* means a system that allows health care professionals to appropriately access and securely share a patient's vital medical information and records as that electronic information is instantly updated and simultaneously available to each of the health care professionals across organizations, often within a region, community, or health care system.

Item 2. Amend rule 657—37.2(124) by amending the following definitions:

"DEA number" means the registration number issued to an individual or pharmacy by

the U.S. Department of Justice, Drug Enforcement Administration (DEA) authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Health care professional" means a person who, by education, training, certification, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. "Health care professional," other than a licensed prescriber or pharmacist, may include, but is not limited to, a certified pharmacy technician or a registered technician trainee, a nurse, ~~or~~ a certified medical assistant, or ~~supervised trainee such as~~ a pharmacist-intern ~~or student, a medical student, or a nursing student~~.

"PMP administrator" means the board staff person or persons designated to manage and administer the PMP under the direction and oversight of the board and the council.

"Practitioner's agent" means a health care professional who is employed by or under the direct supervision of a ~~health care~~ PMP-registered practitioner and who is authorized by the practitioner to access PMP information as provided in subrule 37.4(1).

Item 3. Amend rule 657—37.3(124) as follows:

657—37.3(124) Requirements for the PMP. Each dispenser, unless identified as exempt from reporting and who has applied for and been granted an exemption from reporting to the PMP pursuant to subrule 37.3(1), shall submit to the PMP administrator either a record of each reportable prescription dispensed during a reporting period or a zero report pursuant to subrule 37.3(5), as appropriate. A dispenser located outside the state of Iowa, unless identified as exempt from reporting and who has applied for and been

granted an exemption from reporting to the PMP pursuant to subrule 37.3(1), shall submit to the PMP administrator either a record of each reportable prescription dispensed during a reporting period to a patient located in Iowa or a zero report pursuant to subrule 37.3(5), as appropriate.

37.3(1) *Exemptions.* The dispensing of a controlled substance as described in this subrule shall not be considered a reportable prescription. A dispenser engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in paragraphs 37.3(1)"*a*," ~~or~~ 37.3(1)"*b*," ~~shall so notify the PMP administrator and shall be exempt~~ or 37.3(1)"c," or that is not registered to handle controlled substances as described in paragraph 37.3(1)"d," may apply for an exemption from reporting to the PMP. A dispenser claiming exemption pursuant to this subrule shall certify to the board, on a form provided by the board, the basis for exemption from reporting to the PMP. The PMP administrator is hereby authorized to approve or deny the pharmacy's request for exemption from reporting to the PMP.

a and b. No changes.

c. A nonresident pharmacy that does not distribute controlled substances to patients located in Iowa shall not be required to report to the PMP. A nonresident pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the nonresident pharmacy does not dispense controlled substances to patients located in Iowa.

d. A licensed pharmacy that does not handle controlled substances and that is not registered to handle controlled substances with the federal DEA shall not be required to

report to the PMP. A pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the pharmacy does not dispense controlled substances.

~~c.~~*e.* A prescriber or other authorized person who administers or dispenses a controlled substance, including samples of a controlled substance, for the purposes of outpatient care shall not be required to report such administration or dispensing. A prescriber shall not be required to submit a form or notification claiming exemption from reporting to the PMP. This exception shall not apply to a pharmacist who administers a controlled substance, as directed by the prescriber, pursuant to a prescription.

~~d.~~*f.* A wholesale distributor of a controlled substance shall not be required to report the wholesale distribution of such a substance. A wholesale distributor shall not be required to submit a form or notification claiming exemption from reporting to the PMP.

37.3(2) *Data elements.* The information submitted for each prescription shall include, at a minimum, the following items:

a. Dispenser DEA number.

b. Date the prescription is filled.

c. Prescription number.

d. Indication as to whether the prescription is new or a refill.

e. NDC number for the drug dispensed.

f. Quantity of the drug dispensed.

g. Number of days of drug therapy provided by the drug as dispensed.

h. Patient ~~name~~ first and last names.

i. Patient address including street address, city, state, and ZIP code.

j. Patient date of birth.

k. Patient gender.

l. Prescriber DEA number.

m. Date the prescription was issued by the prescriber.

n. Method of payment ~~as either third-party payer or patient cash payment~~.

37.3(3) *Reporting periods.* A record of each reportable prescription dispensed shall be submitted by each dispenser at least weekly. Records may be submitted with greater frequency than required by this subrule. Records of reportable prescriptions dispensed between Sunday and Saturday each week shall be submitted no later than the following Wednesday. However, a pharmacy that is currently submitting prescription dispensing records to another state's PMP on an alternative weekly reporting schedule may request authority to submit records to the Iowa PMP pursuant to that established schedule. The request shall be submitted in writing via e-mail, fax, or regular mail to the PMP administrator. The request shall identify the pharmacy by name, address, and Iowa pharmacy license number and shall define the alternative reporting period and the reason for the requested alternative reporting period. The PMP administrator is hereby authorized to ~~accept~~ approve or deny the pharmacy's alternative weekly reporting schedule.

37.3(4) *Transmission methods.* Prescription information shall be transmitted using one of the following methods:

a. Data upload to a reporting Web site via a secure Internet connection or by utilizing the secure FTP procedure. The PMP administrator or designee will provide dispensers with

initial secure login and password information. Dispensers will be required to register on the reporting Web site prior to initial data upload.

b. Electronic media including CD-ROM, DVD, or diskette, accompanied by a transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media as directed by the PMP administrator or designee.

c. If a dispenser does not have an automated record-keeping system capable of producing an electronic report as provided in this rule, the dispenser may submit prescription information on the industry standard universal claim form. The dispenser may complete and submit the claim form on the reporting Web site or, if the dispenser does not have Internet access, the completed paper claim form may be submitted as directed by the PMP administrator or designee.

d. Chain pharmacies and pharmacies under shared ownership may submit combined data transmissions on behalf of all facilities by utilizing the secure FTP procedure. Combined data transmissions shall identify the specific pharmacy that dispensed each individual prescription record included in the combined data transmission.

37.3(5) *Zero reports.* If a dispenser has not been identified as exempt from reporting to the PMP and the dispenser did not dispense any reportable prescriptions during a reporting period, the dispenser shall submit a zero report via the established reporting Web site or secure FTP procedure. ~~If such a dispenser does not have Internet access, the dispenser shall notify the PMP administrator via mail or facsimile transmission that the dispenser did not dispense any reportable prescriptions during the reporting period.~~ The schedule

identified in subrule 37.3(3) shall determine timely submission of zero reports.

Item 4. Amend rule 657—37.4(124) as follows:

657—37.4(124) Access to database information. All information contained in the PMP database, including prescription information submitted for inclusion in the PMP database, communications or notifications to PMP users and dispensers via the database, and records of requests for PMP information, shall be privileged and strictly confidential and not subject to public or open records laws. The board, council, and PMP administrator shall maintain procedures to ensure the privacy and confidentiality of patients, prescribers, dispensers, practitioners, practitioners' agents, and patient information collected, recorded, transmitted, and maintained in the PMP database and to ensure that program information is not disclosed to persons except as provided in this rule.

37.4(1) *Prescribers and pharmacists.* A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care. A practitioner may authorize no more than ~~three~~ six health care professionals to act as the practitioner's agents for the purpose of requesting PMP information regarding a practitioner's patients. A practitioner's agent shall be licensed, registered, certified, or otherwise credentialed as a health care professional in a manner that permits verification of the health care professional's credentials.

a. Prior to being granted access to PMP information, a practitioner ~~or~~ and a practitioner's agent shall submit an individual request for registration and program access. The PMP administrator shall take reasonable steps to verify the identity of a practitioner or

practitioner's agent and to verify a practitioner's or practitioner's agent's credentials prior to providing a practitioner or practitioner's agent with a secure login and initial password.

(1) A practitioner ~~or a practitioner's agent with Internet access may~~ shall register via a secure Web site established by the board for that purpose. ~~A practitioner without Internet access shall submit a written registration request on a form provided by the PMP administrator. A practitioner without Internet access shall not authorize a~~

(2) A practitioner's agent ~~to~~ shall register for ~~or to~~ access to PMP information on behalf of the supervising practitioner by completing and submitting a hard-copy registration form, provided by the board, that requires the signatures of both the supervising practitioner and the practitioner's agent. ~~The PMP administrator shall take reasonable steps to verify the identity of a practitioner or practitioner's agent and to verify a practitioner's credentials prior to providing a practitioner or practitioner's agent with a secure login and initial password.~~

b. Each practitioner or practitioner's agent registered to access PMP information shall securely maintain and use the login and password assigned to the individual practitioner or practitioner's agent. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner or practitioner's agent, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to an unregistered agent. A registered practitioner's agent shall not delegate PMP information access to another individual.

~~b.~~c. A practitioner or practitioner's agent ~~with Internet access~~ may submit a request for

PMP information via a secure Web site established by the board for that purpose. The requested information shall be provided to the requesting practitioner or practitioner's agent in a format established by the board and shall be delivered via the secure Web site.

~~*c.* A practitioner without Internet access may submit to the PMP administrator a written request for PMP information via mail or facsimile transmission. The written request shall be in a format established by the board and shall be signed by the requesting practitioner. Prior to processing a written request for PMP information, the PMP administrator shall take reasonable steps to verify the request, which may include but not be limited to a telephone call to the practitioner at a telephone number known to be the number for the practitioner's practice.~~

d. No change.

e. A practitioner or practitioner's agent shall not provide the patient with a copy of a report generated by the PMP. A patient may receive a report of the patient's own prescription history pursuant to subrule 37.4(4).

37.4(2) *Regulatory agencies and boards.* Professional licensing boards and regulatory agencies that supervise or regulate a health care ~~practitioner~~ professional or that provide payment for health care services shall be able to access information from the PMP database only pursuant to an order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. The Board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

a. Prior to accepting and processing a request for PMP database information from the

director or director's designee of a licensing board or other authorized regulatory agency, the director or director's designee shall complete and submit a hard-copy registration form, provided by the board, that requires the signatures of both the director and the director's designee, as appropriate. The PMP administrator shall take reasonable steps to verify the identity of the director or director's designee prior to providing a director or director's designee with a secure login and initial password.

~~a.~~*b.* A director of a licensing board with jurisdiction over a ~~practitioner~~ health care professional, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, email, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

~~b.~~*c.* A director of a regulatory agency with jurisdiction over a ~~practitioner~~ health care professional or with jurisdiction over a person receiving health care services pursuant to one or more programs provided by the agency, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, email, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

d. The requested information shall be provided to the requesting director or director's

designee in a format established by the board and shall be delivered via the secure Web site or by an alternate delivery method determined by the PMP administrator to be appropriate.

37.4(3) *Law enforcement agencies.* Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of any state or federal law relating to controlled substances shall be able to access information from the PMP database by order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. The Board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

a. Prior to accepting and processing a request for PMP database information from a law enforcement officer, the officer shall complete and submit a hard-copy registration form, provided by the board, that requires the signatures of both the officer and the officer's direct superior. The PMP administrator shall take reasonable steps to verify the identity of the officer and the officer's direct superior prior to providing the officer with a secure login and initial password.

b. A law enforcement officer shall submit to the PMP administrator in a format established by the board a written request via mail, email, facsimile, or personal delivery. The request shall be signed by the requesting officer or the officer's superior. The request shall be accompanied by an order, subpoena, or warrant issued by a court or legal authority that requires a determination of probable cause and shall be processed by the PMP administrator.

c. A report identifying PMP information relating to the specific individual identified by the order, subpoena, or warrant ~~may~~ shall be delivered to the law enforcement officer via ~~mail or alternate secure delivery~~ the secure Web site or by an alternate delivery method determined by the PMP administrator to be appropriate.

37.4(4) *Patients.* A patient or the patient's agent may request and receive PMP information regarding prescriptions reported to have been dispensed to the patient.

a. A patient may submit a signed, written request for records of the patient's prescriptions dispensed during a specified period of time. The board shall provide the patient with a request ~~shall identify~~ form requiring identification of the patient by name, including any aliases used by the patient, and ~~shall include~~ the patient's date of birth and gender. The request form shall also ~~include~~ require any address where the patient resided during the time period of the request and the patient's current address and daytime telephone number. A patient may personally deliver the completed request to the PMP administrator or ~~authorized staff member~~ designee at the offices of the board located at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The patient will be required to present current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification and request shall be maintained in the records of the PMP.

b and c. No changes.

d. A report prepared pursuant to this subrule shall be delivered to the patient or the patient's agent, as appropriate, by personal delivery or via mail or alternate secure delivery.

37.4(5) *Court orders and subpoenas.* The PMP administrator shall provide PMP

information in response to court orders and county attorney or other subpoenas issued by a court upon a determination of probable cause. The Board may charge a fee for the preparation and release of PMP information and reports as provided in rule 657—37.5(124).

37.4(6) *Statistical data.* The PMP administrator or designee, ~~following review and approval by the patients rights committee,~~ may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes. Prior to the release of any such data, the PMP administrator or designee shall remove any personal identifying information or verify that any personal identifying information that could be used to identify an individual patient, prescriber, dispenser, practitioner, or other person who is ~~the subject of~~ identified in the PMP information or data has been removed from the PMP information or data. The Board may charge a fee for the preparation and release of statistical data as provided in rule 657—37.5(124).

37.4(7) *PMP administrator access.* Other than statistical data as described in subrule 37.4(6) and technical, error, and administrative function reports and information needed by PMP support staff to determine that records are received and maintained in good order or to review or resolve issues of reported or suspected erroneous data as provided in rule 657—37.7(124), any other reports concerning the information received from dispensers shall only be prepared at the direction of the board, the council, or the PMP administrator. The board and the council may compile statistical reports from PMP information for use in determining the advisability of continuing the PMP and for use in preparing required reports to the governor and the legislature. The reports shall not include information that would

identify any patient, prescriber, dispenser, practitioner, practitioner's agent, or other person who is ~~the subject of~~ identified in the PMP information or data.

37.4(8) *Electronic health and pharmacy information systems.* The board may contract with electronic health record systems, health information exchanges, and electronic pharmacy information systems to securely integrate into those electronic systems access to patient prescription histories and other PMP information available to authorized practitioners and practitioners' agents. Institutional users may be established to identify the facilities and contracted electronic systems and to facilitate secure access by the prescribing practitioners and pharmacists authorized to access PMP information by and through the electronic systems.

a. EHRS, HIE, and e-pharmacy system integration contracts or agreements shall ensure protection of confidential information contained in and received from the PMP.

b. EHRS, HIE, and e-pharmacy system integration contracts or agreements shall restrict access to PMP information to authorized practitioners and practitioner agents as provided by these rules except that individual user registration with the PMP may not be required if the identity of the specific individual receiving or requesting information from the PMP, including a record of the patient whose record is requested, is logged and maintained in an alternate record and is available to the PMP administrator upon request.

c. PMP and electronic system integration may require a separate contract or agreement with a third-party interface or translation service provider to facilitate integration of the PMP into the electronic system. The contract with the service provider shall provide that translation, transmission, or other data integration services provided under the contract are

accomplished via a secure encrypted channel that ensures the confidentiality of all information exchanged between the PMP and the electronic system.

Item 5. Amend rule 657—37.5(124) as follows:

657—37.5(124) Fees. The board may charge a fee and recover costs incurred for the provision of PMP information, including statistical data, except that no fees or costs shall be assessed to a dispenser for reporting to the PMP or to a practitioner or practitioner's agent for querying the PMP regarding a practitioner's patient. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

Item 6. Amend 657 subrule 657—37.9(1) as follows:

37.9(1) *Confidentiality.* A pharmacy, pharmacist, practitioner, or practitioner's agent who knowingly fails to comply with the confidentiality provisions of the law or these rules or who delegates PMP information access to another individual, except as provided in paragraph ~~37.4(1)"a,"~~ 37.4(1)"b," is subject to disciplinary action by the appropriate professional licensing board. The PMP administrator or a member of the program staff who knowingly fails to comply with the confidentiality provisions of the law or these rules is subject to disciplinary action by the board. In addition to any disciplinary action or sanctions imposed by a professional licensing board, a pharmacy, pharmacist, practitioner, practitioner's agent, PMP administrator, or member of the PMP program staff who knowingly accesses, uses, or discloses program information in violation of Iowa law or these rules is subject to criminal prosecution as provided in ~~2011~~ Iowa Code ~~Supplement~~ section 124.558.

Item 7. Amend the implementation clause at the end of the chapter as follows:

These rules are intended to implement Iowa Code sections ~~124.551, 124.552, and 124.554 to 124.557 and 2011 Iowa Code Supplement sections 124.553 and~~ 124.550 to 124.558 as amended by 86GA, SF2102.

ADDENDUM L

BILL PREFILE TO AMEND
CHAPTER 124, "PRESCRIPTION MONITORING PROGRAM"

NOVEMBER 2, 2016

An Act relating to the Iowa drug prescribing and dispensing information program, commonly known as the Iowa prescription monitoring program or PMP, required reporters and schedules of controlled substances to be reported, unsolicited reports, exchange of information with other state PMPs, goals of the program, and providing penalties for noncompliance with program requirements.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.552, Iowa Code 2016, is amended to read as follows:

124.552 Information reporting.

1. ~~Each~~ Unless otherwise prohibited by federal or state law, each licensed pharmacy that dispenses controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*, to patients in the state, and each licensed pharmacy located in the state that dispenses such controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*, to patients inside or outside the state, unless specifically excepted in this section or by rule, and each prescribing practitioner furnishing, dispensing, or supplying drugs to the prescribing practitioner's patient, shall submit the following prescription information to the program:

a. Pharmacy identification.

b. Patient identification.

c. Prescribing practitioner identification.

d. The date the prescription was issued by the prescribing practitioner.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Type of payment for the prescription.

l. Other information identified by the board and advisory council by rule.

2. Information shall be submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.

3. Information shall be timely transmitted as designated by the board and advisory council by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy or prescribing practitioner suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's or practitioner's control.

b. The board is unable to receive electronic submissions.

4. This section shall not apply to ~~a prescribing practitioner furnishing, dispensing, supplying, or administering drugs to the prescribing practitioner's patient, or to~~ dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 2. Section 124.553, subsection 1, Iowa Code 2016, is amended by adding the following new paragraph:

NEW PARAGRAPH: f. By targeted distribution of unsolicited reports, a prescribing practitioner or a pharmacist who has been involved in authorizing or

dispensing controlled substances to a patient who has been identified, based on thresholds or criteria designed to identify doctor or pharmacy shopping or the patient's excessive use of a controlled substance, as an at-risk patient who may be abusing or misusing controlled substances or who may be in jeopardy of overdose or addiction to controlled substances.

Sec. 3. Section 124.553, subsection 2, Iowa Code 2016, is amended to read as follows:

2. The board shall maintain a record of each person that requests information from the program and of all unsolicited reports distributed as provided in 124.553, subsection 1, paragraph "f". Pursuant to rules adopted by the board and advisory council under section 124.554, the board may use the records to document and report statistical information, and may provide program information for statistical, public research, public policy, or educational purposes, after removing personal identifying information of a patient, prescribing practitioner, dispenser, or other person who is identified in the information.

Sec. 4. Section 124.553, subsection 3, Iowa Code 2016, is amended to read as follows:

3. Information contained in the program and any information obtained from it, and information contained in the records of requests for information from the program and of unsolicited reports distributed to prescribing practitioners and dispensing pharmacists, is privileged and strictly confidential information. Such information is a confidential public record pursuant to section 22.7, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information

from the program shall not be released, shared with an agency or institution, or made public except as provided in this division.

Sec. 5. Section 124.553, subsection 8, Iowa Code 2016, is amended to read as follows:

8. The board may enter into an agreement with a prescription database or monitoring program operated in ~~a state bordering this state or in the state of Kansas~~ any state for the mutual exchange of information. Any agreement entered into pursuant to this subsection shall specify that all the information exchanged pursuant to the agreement shall be used and disseminated in accordance with the laws of this state.

Sec. 6. Section 124.55, Iowa Code 2016, is amended to read as follows:

124.554 Rules and reporting.

1. The board and advisory council shall jointly adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

a. Identifying each patient about whom information is entered into the program.

b. An electronic format for the submission of information from pharmacies and prescribing practitioners.

c. A waiver to submit information in another format for a pharmacy or prescribing practitioner unable to submit information electronically.

d. An application by a pharmacy or prescribing practitioner for an extension of time for transmitting information to the program.

e. The submission by an authorized requestor of a request for information and a procedure for the verification of the identity of the requestor.

f. Use by the board or advisory council of the program request records required by section 124.553, subsection 2, to document and report statistical information.

g. Including all schedule II through IV controlled substances and ~~those substances in schedules III and IV that the advisory council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescribing practitioner~~ schedule V controlled substances except when dispensed by a pharmacist without a prescription.

h. Access by a pharmacist or prescribing practitioner to information in the program ~~pursuant to a written agreement with the board and advisory council~~.

i. The correction or deletion of erroneous information in the program.

j. The establishment of thresholds or other criteria or measures to be used in identifying an at-risk patient as provided in section 124.553, subsection 1, paragraph "f," and the targeted distribution of unsolicited reports suggesting review of the patient's prescription history.

2. Beginning January ~~1, 2007~~ 15, 2018, and annually by January ~~1~~ 15 thereafter, the board and advisory council shall present to the general assembly and the governor a report prepared consistent with section 124.555, subsection 3, paragraph *"d"*, which shall include but not be limited to the following:

a. The cost to the state of implementing and maintaining the program.

b. Information from pharmacies, prescribing practitioners, the board, the advisory council, and others regarding the benefits or detriments of the program.

c. Information from pharmacies, prescribing practitioners, the board, the advisory council, and others regarding the board's effectiveness in providing information from the program.

Sec. 7. Section 124.555, subsection 2, Iowa Code 2016, is amended to read as follows:

2. The council shall advance the goals of the program, which include identification of misuse and diversion of controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*, reduction of drug overdose and death attributable to prescription drug use and abuse, and enhancement of the quality of health care delivery in this state.

Sec. 8. Section 124.558, subsection 1, Iowa Code 2016, is amended to read as follows:

1. *Failure to comply with requirements.* A pharmacist, pharmacy, prescribing practitioner, or agent of a pharmacist or prescribing practitioner who knowingly fails to comply with the confidentiality requirements of this division or who delegates program information access to another individual except as provided in section 124.553, is subject to disciplinary action by the appropriate professional licensing board. A prescribing practitioner, pharmacist, or pharmacy that knowingly fails to comply with other requirements of this division is subject to disciplinary action by the board. Each licensing board may adopt rules in accordance with chapter 17A to implement the provisions of this section.

EXPLANATION

The bill adds dispensing prescribers, unless otherwise prohibited by federal or state law, to those required to submit to the Iowa Prescription Monitoring Program (PMP) any reportable controlled substances dispensed or distributed to patients in Iowa. Dispensing prescribers are added to respective sections and paragraphs regarding extensions of time to submit required records, form of record submission, and penalties for failing to submit required records to the Iowa PMP.

The bill authorizes the board and the PMP advisory council to establish criteria for the identification of patients whose use of controlled substances may raise concerns about the safety of the patients' drug regimens and use patterns for the purpose of communicating those concerns with the prescribers and pharmacists involved in the patients' care. This process is referred to as *targeted unsolicited reporting* because notification that the patient's record should be reviewed prior to prescribing controlled substances is sent only to those practitioners currently providing health care services to the patient. The information is not available to law enforcement, regulatory boards and agencies, or other nonpractitioner users.

The bill permits the board to interconnect with any other state PMP for the sharing of patient prescription records on condition that the other state PMP agrees to comply with Iowa laws and rules regarding the access to, distribution of, and use of Iowa PMP information and data. The bill also authorizes the collection of dispensing records for all Schedule II, III, IV, and V controlled substances except when the Schedule V controlled substance is dispensed by a pharmacist without a prescription.

The bill adds to the goals of the program the reduction of overdoses and deaths as a result of prescription controlled substance use and abuse. The bill also changes

the due date for annual reports to the Governor and the Legislature from January 1 to January 15 to provide sufficient time to compile prior calendar year data and statistics to be included in the annual report.

ADDENDUM M

ADOPTION AND FILING

RESCIND CHAPTER 30, "IMPAIRED PHARMACY PROFESSIONALS AND TECHNICIAN RECOVERY PROGRAM," AND ADOPT new CHAPTER 30, 'IOWA MONITORING PROGRAM FOR PHARMACY PROFESSIONALS"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 272C.3, the Board of Pharmacy hereby rescinds Chapter 30, "Impaired Pharmacy Professionals and Technician Recovery Program," and adopts new Chapter 30, "Iowa Monitoring Program for Pharmacy Professionals," Iowa Administrative Code.

The amendment rescinds current Chapter 30 regarding the Impaired Pharmacy Professional and Technician Recovery Program and adopts new Chapter 30 establishing the Iowa Monitoring Program for Pharmacy Professionals. The program and committee established pursuant to the new chapter are intended to support the evaluation and monitoring of licensees who are impaired as a result of alcohol or drug abuse, dependency, or addiction, or by any mental or physical disorder or disability, while protecting the health, safety and welfare of the public. The program will provide an alternative to formal disciplinary actions against pharmacists, pharmacist-interns, and pharmacy technicians who recognize their impairment and seek assistance and monitoring under the guidance of the program committee. The rules identify the members of the program committee, the organization of the committee, and the length of appointment terms.

Impaired professionals' eligibility requirements and terms for participation and continued monitoring under the program are established. The rules define actions that constitute noncompliance with the terms of participation in the program and the consequences of noncompliance. The rules identify the circumstances under which

program participant records and information may be disclosed to parties other than members of the committee. The rules also authorize the committee to enter into 28E agreements with other health professional licensing boards to share administrative personnel to evaluate, assist, and monitor eligible program participants and to report noncompliant participants to the appropriate licensing board for appropriate action.

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

Notice of Intended Action was published in the August 3, 2016, Iowa Administrative Bulletin as ARC 2662C. The Board received one written comment from the Iowa Pharmacy Association. The Association suggested amending the membership of the committee established pursuant to subrule 30.3(1) to include "one pharmacist intern from each college of pharmacy in Iowa." The Board elected not to amend the committee membership in this manner. The colleges of pharmacy are represented on the committee as identified in the subrule. The adopted amendment is identical to that published under Notice.

The amendments were approved during the November 2, 2016, meeting of the Board of Pharmacy.

After analysis and review of this rule making, the Board has determined that the effect of this rule making on jobs cannot be accurately predicted. One of the goals of the Iowa Monitoring Program for Pharmacy Professionals is to encourage pharmacists, pharmacist-interns, and pharmacy technicians who recognize their impairment and who seek assistance and monitoring under the terms of the program to remain in practice

within the profession. The continued employment and professional practice afforded these individuals, under the guidance and monitoring provided by this program, should have a positive impact on jobs in Iowa.

This amendment is intended to implement Iowa Code section 272C.3.

This amendment will become effective on January 11, 2017.

The following amendment is adopted.

Rescind 657—Chapter 30 and adopt the following **new** chapter in lieu thereof:

CHAPTER 30

IOWA MONITORING PROGRAM FOR PHARMACY PROFESSIONALS

657—30.1(272C) Iowa monitoring program for pharmacy professionals committee. Pursuant to the authority of Iowa Code section 272C.3(1)*"k,"* the board establishes the committee for the Iowa monitoring program for pharmacy professionals. The purpose of the committee is to provide a program to support the evaluation and monitoring of licensees who are impaired as a result of alcohol or drug abuse, dependency, or addiction, or by any mental or physical disorder or disability, while protecting the health, safety and welfare of the public.

657—30.2(272C) Definitions. For purposes of these rules, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Committee" means the Iowa monitoring program for pharmacy professionals committee.

"Contract" means the written document executed by an applicant or licensee and the

committee after the committee receives a report from an approved treatment provider, which establishes the terms for participation in the program.

"Impairment" means an inability, or significant potential for inability, to practice with reasonable safety and skill as a result of a diagnosed substance use disorder or any diagnosed mental or physical health condition.

"Initial agreement" means the written document establishing the initial terms for participation in the program.

"Licensee" means a pharmacist licensed by the board, a pharmacist-intern registered with the board, or a pharmacy technician registered with the board.

"Participant" means an applicant or licensee who does any of the following: self-reports an impairment to the program, is referred to the program by the board, signs an initial agreement with the committee, or signs a contract with the committee.

"Program" means the Iowa monitoring program for pharmacy professionals.

"Self-report" means that an applicant or licensee provides written notification to the committee that the applicant or licensee has been, is, or may be impaired. Information related to impairment or a potential impairment which is provided on a license application or renewal form may be considered a self-report.

657—30.3(272C) Organization of the committee. The board shall appoint the members of the Iowa monitoring program for pharmacy professionals committee.

30.3(1) *Membership.* The membership of the committee includes, but is not limited to:

a. The executive director of the board or the director's designee from board staff;

b. One representative from the Drake University College of Pharmacy and Health Sciences;

c. One representative from the University of Iowa College of Pharmacy;

d. One board of pharmacy licensee who has maintained sobriety for a period of no less than two years following successful completion of a recovery program;

e. One health care professional with expertise in substance use disorders;

f. One health care professional with expertise in mental health; and

g. One public member.

30.3(2) *Officers.* At the last meeting of each calendar year, the committee shall elect a chairperson and a vice chairperson, each of whom will begin serving a one-year term on January 1.

a. The chairperson is responsible for offering guidance and direction to staff between regularly scheduled committee meetings, including guidance and direction concerning program descriptions, interim restrictions on practice, and negotiation and execution of initial agreements and contracts on behalf of the committee. The committee retains authority to review all interim decisions at its discretion.

b. The vice chairperson is responsible for providing guidance and direction to staff between regularly scheduled committee meetings if the chairperson is unavailable or unable to assist in a particular matter.

30.3(3) *Terms.* Committee members, except the executive director or designee, shall be appointed for three-year terms and shall serve for a maximum of three terms. Each term shall expire on December 31 of the third year of the term.

657—30.4(272C) Eligibility.

30.4(1) *Self-report.* An applicant or a licensee shall self-report an impairment or potential impairment directly to the program.

30.4(2) *Board referral.* The board may refer an applicant or licensee to the program if a complaint or investigation reveals an impairment or potential impairment and the board determines that the individual is an appropriate candidate for review by the committee. The board may refer a licensee to the program in a public disciplinary order or other public order.

30.4(3) *Review by the committee.* The committee will determine on a case-by-case basis whether an applicant or licensee who self-reports or is referred by the board is an appropriate candidate for participation in the program. Several factors may lead to the committee's determination that an applicant or licensee is ineligible to participate in the program, including but not limited to if the committee finds sufficient evidence that the applicant or licensee:

a. Diverted drugs for distribution to third parties or for personal profit;

b. Adulterated, misbranded, or otherwise tampered with drugs intended for a patient;

c. Provided inaccurate, misleading, or fraudulent information or failed to fully cooperate with the committee;

d. Participated in the program, or a similar program offered by another state, without success; or

e. Failed to sign an initial agreement or a contract when offered by the committee.

30.4(4) *Discretion.* Eligibility of a person to participate in the program is at the sole discretion of the committee. No person is entitled to participate in the program.

30.4(5) *Authority and jurisdiction.* Participation in the program does not divest the board of its authority or jurisdiction over the participant. A participant with an impairment or potential impairment may be eligible to participate in the program while being subject to investigation or discipline by the board for matters other than the alleged impairment.

657—30.5(272C) Terms of participation. A participant shall agree to comply with the program terms of participation established in the initial agreement and the contract. Participants will be responsible for all expenses incurred to comply with the terms imposed by the program. Terms of participation specified in the contract shall include, but not be limited to:

30.5(1) *Duration.* The length of time a participant may participate in the program shall be determined by the committee in accordance with the following:

a. Participation in the program for participants impaired as a result of a substance use disorder is set at a minimum of three years. The committee may offer a contract with a shorter duration to a participant who can demonstrate successful participation in another state's monitoring program, who can document similar experience, or who, as a board referral, has successfully completed a portion of the monitoring period established in the board order.

b. Length of participation in the program for participants with impairments resulting from mental or physical conditions will vary depending upon the recommendations

provided by health care providers and the determination of the committee following review of all relevant information.

30.5(2) *Requirements.* The committee shall establish terms of participation designed to meet the specific needs of a participant. The committee shall determine the type of recovery, rehabilitation, or maintenance program required to treat the participant's impairment. The contract shall provide a detailed description of the goals of the program, the requirements for successful participation, and the participant's obligations therein. The committee may establish terms of participation specific to a participant's impairment including, but not limited to, the following: treatment, aftercare, worksite monitoring, chemical screening, further evaluations, structured recovery meetings, therapy, and medication management.

30.5(3) *Practice restrictions.* The committee may impose restrictions on the license to practice as a term of the initial agreement or contract until such time as the committee receives a report from an approved evaluator, and the committee determines, based on all relevant information, that the participant is capable of practicing with reasonable skill and safety. As a condition of participation in the program, a licensee is required to agree to restricted practice in accordance with the terms specified in the initial agreement or contract. In the event the licensee refuses to agree to or comply with the practice restrictions, the committee shall refer the licensee to the board for appropriate action.

30.5(4) *Noncompliance.* Noncompliance is the failure to adhere to the terms of the initial agreement or contract. Participants shall promptly notify the committee of any

instances of noncompliance, including relapse. Any instances of significant noncompliance shall be reported by the committee to the board. The report shall include a description of the noncompliance and the committee's recommendation as to whether the participant should remain in the program.

657—30.6(272C) Confidentiality. Information in the possession of the board or the committee shall be subject to the confidentiality requirements of Iowa Code section 272C.6. Information about participants in the program shall not be disclosed except as provided in this rule.

30.6(1) The committee is authorized, pursuant to Iowa Code section 272C.6(4), to communicate information about a current or former program participant to the applicable regulatory authorities or licensee monitoring programs in the state of Iowa and in any jurisdiction of the United States or foreign nations in which the participant is currently licensed or in which the participant seeks licensure. Program participants must report their participation to the applicable monitoring program or licensing authority in any state in which the participant is currently licensed or in which the participant seeks licensure.

30.6(2) The committee is authorized to communicate information about a program participant to any person assisting in the participant's treatment, recovery, rehabilitation, monitoring, or maintenance for the duration of the contract.

30.6(3) The committee is authorized to communicate information about a program participant to the board in the event a participant does not comply with the terms of the contract as set forth in rule 657—30.5(272C). The committee may provide the

board with a participant's program file in the event the participant does not comply with the terms of the contract and the committee refers the case to the board for the filing of formal disciplinary charges or other appropriate action. If the board initiates disciplinary action against a licensee for noncompliance with the terms of the contract, the board may include in the public disciplinary documents information about a licensee's participation in the program. The committee is also authorized to communicate information about a participant to the board in the event that the participant is under investigation by the board.

30.6(4) The committee is authorized to communicate information about a current or former program participant to the board if reliable information held by the committee reasonably indicates that a significant risk to the public exists. If the board initiates disciplinary action based upon this information, the board may include in the public disciplinary documents information about a licensee's participation if necessary to address impairment issues related to the violations which are the subject of the disciplinary action.

657—30.7(28E) Authority for 28E agreements. The committee may enter into 28E agreements with other health professional licensing boards to evaluate, assist, and monitor impaired licensees from other health professions who self-report and to report to those professional licensing boards regarding the compliance of individual licensees. In the event of noncompliance, the licensee may be referred to the appropriate licensing board for appropriate disciplinary action.

These rules are intended to implement Iowa Code section 272C.3(1)"*k.*"

ADDENDUM N

EMERGENCY ADOPTION AFTER NOTICE

CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Emergency Adoption after Notice

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

The adopted rules implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV, which permits the possession and administration of opioid antagonist medications by certain eligible persons and allows the distribution of such medications by pharmacists pursuant to a standing order or collaborative agreement or pursuant to a prescription issued in the name of a law enforcement agency, fire department, or emergency medical service program. The amendments also remove the requirement for a pharmacy to include the address of a facility, school district, or accredited nonpublic school on the label of epinephrine dispensed to those entities.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2721C** on September 28, 2016.

The board received two comments regarding these amendments. The Iowa Medical Society submitted a comment in support of the rulemaking. The Iowa Pharmacy Association submitted comments in support of the rulemaking but with suggested modifications specifically related to the reporting requirements. The requirement of a pharmacy to submit the assessment form to the Iowa Department of Public Health ("Department") for the purpose of data analysis was directly from the Department and the Board worked collaboratively with the Department to determine the best means for submission of the data for the Department's analysis. The only non-substantive change made as a result of these comments comes in subrule 8.31(8) to make clear that the assessment form is provided by the Board. The adopted rules also reflect the original

language approved by the Board in its Notice of Intended Action with respect to the individual eligible to obtain an opioid antagonist pursuant to a standing order. One definition was added to provide clarity. The Board, on its own initiative, removed from subrule 8.31(2), the requirement for an authorized pharmacist to complete one hour of continuing education each license renewal period.

Pursuant to Iowa Code section 17A.5(2)"b"(1), the Pharmacy Board finds that the normal effective date of these amendments, 35 days after publication, should be waived and the amendments be made effective upon filing. The Board finds that opioid-related overdose constitutes a growing risk to the health and welfare of the people of Iowa. The immediate effectiveness of these rules will allow first responders to combat imminent health emergencies. The rules confer a benefit on the general public at risk of opioid-related overdose. The Board is unaware of any reason to delay the availability of this lifesaving medication. The Board will make reasonable efforts prior to indexing and publication to make affected parties aware of the effective date of these rules.

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

The Pharmacy Board adopted these amendments on November 2, 2016.

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

These amendments are intended to implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV.

These amendments become effective November 3, 2016.

The following amendments are adopted.

ITEM 1. 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 and in subrule 8.19(8) for opioid antagonists.

a. to *d.* No change.

ITEM 2. Amend subrule 8.19(7) as follows:

8.19(7) *Epinephrine auto-injector prescription issued to school or facility.* A physician, an 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.

ITEM 3. Adopt the following **new** subrule 8.19(8):

8.19(8) *Opioid antagonist prescription issued to law enforcement, fire department, or service program.* A physician, an advanced registered nurse practitioner, or a physician assistant may

issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—8.31(135,147A). 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 law enforcement agency, fire department, or service program 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 an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

ITEM 4. Adopt the following **new** rule 657—8.31(135,147A):

657—8.31(135,147A) Opioid antagonist dispensing by pharmacists by standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's Web site, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or

facility.

8.31(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"Department" means the Iowa department of public health.

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a fire fighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"Licensed health care professional" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"Opioid antagonist" means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

"Opioid-related overdose" means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a

position to render aid to a person at risk of experiencing an opioid-related overdose.

"Recipient" means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"Standing order" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

8.31(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

8.31(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

8.31(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

8.31(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient that includes, but is not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but it shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

8.31(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

8.31(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

8.31(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.

ADDENDUM O

NOTICE OF INTENDED ACTION

CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS,"
AND
ADOPT new CHAPTER 13, "TELEPHARMACY PRACTICE"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, "Universal Practice Standards," and to adopt new Chapter 13, "Telepharmacy Practice," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendment to subrule 8.35(2) identifies a telepharmacy practice as a defined subset of a limited use pharmacy license type. The proposed rules in new Chapter 13 provide standards for the provision of pharmaceutical services to patients through the use of audio-visual technologies that link the telepharmacy site with a managing pharmacy, allowing a verifying pharmacist at the remote pharmacy to oversee and verify the dispensing processes performed by the technician at the telepharmacy site. The audio-visual technology also ensures that the patient and the pharmacist are able to converse, face-to-face over secure connections, about the patient's drug treatment plan.

The proposed rules define terms used in the chapter and assign responsibilities for various aspects of the practices involved. The proposed rules require a written agreement between the managing pharmacy and the telepharmacy site, identifying specific required provisions and contents of the written agreement and what must occur in case the agreement is terminated or either pharmacy closes. The proposed rules identify the general requirements for a telepharmacy site, a managing pharmacy, a verifying pharmacist, and a telepharmacy technician, including addressing specific training and experience requirements for those personnel.

The required information to be provided with the initial application for a limited use

pharmacy license as a telepharmacy site and the minimum information to be provided in a request for waiver of the minimum distance between a proposed telepharmacy site and an existing pharmacy that dispenses prescription drugs to outpatients are identified. Specific application and notification requirements in the case of a change of telepharmacy site or managing pharmacy name, location, ownership, or pharmacist in charge are identified. The proposed rules provide that the opening of a new pharmacy within 10 miles of an existing telepharmacy site does not force the closing of the telepharmacy site.

Subjects to be addressed by policies and procedures to be adopted and implemented by both the telepharmacy site and the managing pharmacy are listed and information and reports required of a telepharmacy site or managing pharmacy are identified. The proposed rules identify specific records that must be maintained by and available at a telepharmacy site including the monthly inspection of the telepharmacy site by a pharmacist from the managing pharmacy.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34. Requirements for waiver of the specific restrictions regarding location of a telepharmacy site within 10 miles of another pharmacy that dispenses prescription drugs to outpatients are identified in subrule 13.16(8).

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 10, 2017. 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 email to terry.witkowski@iowa.gov.

A public hearing was held on August 30, 2016, during a regularly held meeting of the Board. Numerous written and oral comments, objections, and suggestions were received both by persons attending the hearing and other interested persons. The Board considered all of those comments

when composing these rules.

After analysis and review of this rule making, The Board has been unable to determine whether the adoption of these rules will have an impact on jobs or the net result of any possible impact. The establishment of telepharmacy sites where a pharmacy currently does not exist may create jobs for pharmacy technicians and also for verifying pharmacists. However, the establishment of a telepharmacy site in place of an existing pharmacy that intends to close, as a means of preserving the availability of pharmacy services in a community or area, may still result in the overall reduction in the number of jobs in that area.

These amendments are intended to implement Iowa Code sections 124.301, 155A.6A, 155A.14, 155A.19, 155A.28, 155A.31, and 155A.41, and Iowa Code sections 147.107, 155A.3, 155A.13, and 155A.33 as amended by S.F. 453, 86 G.A., sections 1, 2, 3, and 7.

The following amendments are proposed.

Item 1. Amend subrule 8.35(2) as follows:

8.35(2) Limited use pharmacy license. Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, telepharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

Item 2. Adopt new 657—Chapter 13, Telepharmacy Practice, as follows:

Chapter 13

Telepharmacy Practice

657—13.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for the provision of telepharmacy services to patients. These rules provide for pharmaceutical care services at a telepharmacy site utilizing audio-visual technologies that link the telepharmacy site

with a managing pharmacy and one or more verifying pharmacists. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.

657—13.2(155A) Definitions. For purposes of this chapter, the following definitions shall apply.

"Board" means the board of pharmacy.

"CSA" or *"CSA registration"* means a registration issued pursuant to Iowa Code section 124.303 and 657—Chapter 10.

"DEA" means the Drug Enforcement Administration of the U. S. Department of Justice.

"Managing pharmacy" means a licensed pharmacy located in Iowa that oversees the activities of one or more telepharmacy sites.

"Telepharmacy" means the practice of pharmacy where pharmaceutical care services are provided using audio-visual technologies linking a telepharmacy site with the managing pharmacy.

"Telepharmacy site" means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more telepharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug utilization review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

"Verifying pharmacist" means a remote Iowa-licensed pharmacist or pharmacists who perform any step in the prescription verification and dispensing process including but not limited to: verification of data entry; product selection, packaging, and labeling; drug utilization review; and patient counseling.

657—13.3(124,155A) Written agreement. The managing pharmacy and the telepharmacy site shall execute and maintain a current written agreement between the pharmacies. If there is no

current written agreement between the pharmacies, the telepharmacy site shall immediately notify the board and shall discontinue operations as a telepharmacy site until a current written agreement between the managing pharmacy and the telepharmacy site is executed.

13.3(1) Contents of agreement. The written agreement between the managing pharmacy and a telepharmacy site shall include, but may not be limited to, the following:

a. Staffing, to include telepharmacy technician staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. Hours of operation of the telepharmacy site and hours of availability of pharmacists at the managing pharmacy.

c. Emergency contact information for the managing pharmacy and the telepharmacy site.

d. Complete description of the audio-visual technology to be utilized to link the managing pharmacy and the telepharmacy site.

e. A provision that, in the event that the telepharmacy technician is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audio-visual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of the technician, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site of a pharmacist to provide onsite pharmacy services.

f. Activities and services to be provided by the managing pharmacy at the telepharmacy site.

g. Identification of contact persons to receive, on behalf of the managing pharmacy and the telepharmacy site, notifications and official communications regarding the written agreement. Identification of contact persons shall include delivery addresses and preferred methods of delivery of the written communications required by this rule and any other communications

affecting the written agreement between the managing pharmacy and the telepharmacy.

h. Pharmacy locations, other than the managing pharmacy, where verifying pharmacists may be based or located.

13.3(2) Termination of agreement. A managing pharmacy shall provide written notice to the Board and to the telepharmacy site 90 days in advance of the managing pharmacy's intent to terminate the agreement between the telepharmacy site and the managing pharmacy. A telepharmacy site shall provide written notice to the Board and to the managing pharmacy 90 days in advance of the telepharmacy site's intent to terminate the agreement between the managing pharmacy and the telepharmacy site.

a. New agreement. A new written agreement between a managing pharmacy and the telepharmacy site, including the filing of a new pharmacy license application identifying the new pharmacist in charge, shall be executed within the 90-day advance notification period.

b. No new agreement. If the telepharmacy site is unable to contract with a new managing pharmacy, the telepharmacy site shall, 30 days prior to the expiration of the 90-day advance notification period, implement the prior notification requirements for closing a telepharmacy site as provided in subrule 13.3(3). The telepharmacy site shall cease operations and close at the end of that 30-day closing notification period unless a new written agreement is executed.

13.3(3) Closing of telepharmacy site. A telepharmacy site that intends to close the telepharmacy site shall provide written notification to the managing pharmacy and the board as provided in 13.3(2). In addition, the telepharmacy site shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7).

13.3(4) Closing of managing pharmacy. A managing pharmacy that intends to close the

managing pharmacy shall provide written notification to the telepharmacy site and the board as provided in 13.3(2). In addition, the managing pharmacy shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in subrule 657—8.35(7). A telepharmacy site that has been managed by the closing pharmacy shall comply with the provisions of subrules 13.3(2) and 13.3(3), as applicable.

657—13.4(155A) Responsible parties. The responsibilities identified and assigned pursuant to rule 657—8.3(155A) shall be assigned, as appropriate, to the managing pharmacy and the telepharmacy site, by and through their respective owners or license holders, to the pharmacist in charge, and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge, the telepharmacy site, and the verifying pharmacist, as assigned in rule 657—8.3(155A), for all functions assigned to and performed by the telepharmacy technician.

657—13.5 to 13.7 Reserved.

657—13.8(124,155A) General requirements for telepharmacy site. The telepharmacy site shall maintain a pharmacy license issued by the board. If the telepharmacy site plans to dispense controlled substances, the telepharmacy site shall also maintain a CSA registration and a DEA registration.

13.8(1) Located in Iowa. A telepharmacy site shall be located within the state of Iowa.

13.8(2) Pharmacist in charge. The pharmacist in charge of the telepharmacy site shall be the pharmacist in charge of the managing pharmacy.

13.8(3) Security. A telepharmacy site shall employ methods to prevent unauthorized access to prescription drugs, devices, and pharmacy and patient records. Such methods may include an alarm system and shall include other security systems and methods as provided by these rules.

Alarm systems and entry system locks should be disarmed when the telepharmacy site is staffed and open for business. Minimum security methods shall include:

a. Electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy, including the date and time of access. Complete access records shall be maintained for a minimum two years beyond the date of access.

b. Secure storage such as a safe.

c. Controlled access to computer records.

d. A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum 60 days following the date of the recording.

13.8(4) Telepharmacy site signage. In addition to the patient counseling sign required pursuant to subrule 13.8(5), one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, shall inform the public that the location is a telepharmacy site supervised by a pharmacist at a remote location. Signage shall include the name, location, and telephone number of the managing pharmacy. The telepharmacy site shall also prominently post the days and times that the telepharmacy is open for business.

13.8(5) Patient counseling. Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audio-visual technology employed between the telepharmacy site and the managing pharmacy. Every telepharmacy site shall post in every prescription pickup area, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a telepharmacy site with the required signage.

13.8(6) Label requirements. In addition to the label requirements identified in subrule 657—

6.10(1), the label affixed to or on the dispensing container of any prescription drug or device dispensed by a telepharmacy site pursuant to a prescription drug order shall include, on the primary label or affixed by use of an auxiliary label, the following:

a. The name, telephone number, and address of the telepharmacy site;

b. The name and telephone number of the managing pharmacy.

13.8(7) Prohibited activities. In the physical absence of a pharmacist, the following activities are prohibited:

a. Practice of pharmacist-interns or pharmacy support persons at the telepharmacy site.

b. Advising patients regarding OTC products unless that advice is communicated directly by a pharmacist to the patient.

c. Dispensing or delivering prescription medications packaged by a technician into patient med paks unless an onsite pharmacist has verified the drugs in the patient med paks.

d. Tech-check-tech practice.

e. Compounding, unless an onsite pharmacist has verified the accuracy and completeness of the compounded drug product.

f. All judgmental activities identified in rule 657—3.23(155A) that a pharmacy technician is prohibited from performing in the practice of pharmacy.

13.8(8) Continuous quality improvement. A telepharmacy site shall implement and participate in a continuous quality improvement program pursuant to rule 657—8.26(155A).

13.8(9) Technology failure. If the audio-visual technology between the telepharmacy site and the managing pharmacy or the verifying pharmacist is not operational, no prescriptions shall be dispensed from the telepharmacy site to a patient unless a pharmacist is physically present at the telepharmacy site.

13.8(10) Perpetual controlled substances inventory. A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. The perpetual inventory record requirement shall apply to all controlled substances maintained and dispensed by the telepharmacy site and shall not be limited only to Schedule II controlled substances.

b. The perpetual inventory record format and other requirements provided in rule 657—10.33(124,155A) shall apply to the telepharmacy site's perpetual inventory record of controlled substances, with the following exceptions:

(1) The perpetual inventory record shall contain records for all controlled substances, not just Schedule II controlled substances, and

(2) Audit of the perpetual inventory record shall be completed and the physical and perpetual inventories shall be reconciled pursuant to the requirements of subrule 10.33(4) each month as part of the inspection of the telepharmacy site.

657—13.9(155A) General requirements for managing pharmacy.

13.9(1) Distance to telepharmacy site. A managing pharmacy shall be located in Iowa and, in case of an emergency requiring the physical presence of an Iowa-licensed pharmacist at the telepharmacy site, shall ensure the pharmacist's arrival at the telepharmacy site within one hour of identification of the need. The managing pharmacy shall be able to ensure timely arrival at the telepharmacy site of other necessary personnel or the delivery to the telepharmacy site of necessary supplies within one hour of the identification of an emergency need.

13.9(2) Pharmacist in charge. Pharmacist in charge of the managing pharmacy shall be the pharmacist in charge of the telepharmacy site.

13.9(3) Adequate audio-visual connection. The pharmacist in charge shall ensure adequate

audio-visual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(4) Monthly inspection. The pharmacist in charge or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

a. Audit and reconciliation of controlled substances perpetual and physical inventories;

b. Audit of electronic entry system and records;

c. Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording;

d. Compilation of a record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.

e. Review of written policies and procedures and verification of compliance with those policies and procedures;

f. Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents;

g. Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with recordkeeping requirements;

h. Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs;

i. Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment,

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(5) Onsite pharmacist staffing. Minimum onsite pharmacist staffing shall be no less than 16 hours per month to complete onsite inspections of the telepharmacy site. Additional onsite pharmacist staffing and services, such as immunizations, shall be provided as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.

a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.

b. Signage identifying the days and times when a pharmacist is onsite and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.

c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted onsite availability shall be provided to the public in advance of the absence.

657—13.10(155A) General requirements for verifying pharmacist. A verifying pharmacist shall maintain a current and active license to practice pharmacy in Iowa.

13.10(1) Location of verifying pharmacist. The verifying pharmacist who is performing

patient counseling shall be physically located within the managing pharmacy or another pharmacy licensed in Iowa.

13.10(2) Adequate audio-visual connection. The verifying pharmacist shall ensure adequate audio-visual connection with the telepharmacy site during all periods when the pharmacist is responsible for verifying telepharmacy site activities and practices including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.10(3) Verifying pharmacist training. A verifying pharmacist shall be adequately trained on the use of the technology to ensure accurate verification and patient counseling and shall review and understand the policies and procedures of the managing pharmacy and the telepharmacy site.

13.10(4) Patient refusal of counseling. If a patient or patient's care giver refuses patient counseling, the refusal shall be directly communicated by the patient or patient's care giver to the pharmacist through audio-visual communication; a technician may not accept and communicate a refusal of patient counseling from the patient or patient's care giver to the pharmacist.

13.10(5) Reference library. A verifying pharmacist shall have access to all required references applicable to the telepharmacy services provided at the telepharmacy site.

657—13.11(155A) General requirements for telepharmacy technician. A telepharmacy technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

13.11(1) Practice experience. Before practicing in a telepharmacy site, a telepharmacy technician shall have completed one year of full time employment consisting of a minimum of 2,000 hours practice experience as a certified pharmacy technician, at least 1,000 of which shall be practicing in the managing pharmacy.

13.11(2) Training. In addition to training required of all pharmacy technicians, a telepharmacy technician shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of this telepharmacy technician training shall be documented and maintained by the telepharmacy site.

a. Review and understanding of the policies and procedures of the managing pharmacy.

b. Review and understanding of the policies and procedures of the telepharmacy site.

c. Review and understanding of these rules for telepharmacy practice.

d. Review and understanding of pharmacy technician rules, 657 – Chapter 3.

e. Understanding of the operation of the audio-visual technologies to be utilized at both pharmacies.

f. Training at the telepharmacy site under the direct supervision of an onsite verifying pharmacist. Training shall include operation and use of the audio-visual technology and other means of communication between the telepharmacy site and the managing pharmacy and all daily operations from unlocking and opening the telepharmacy site to closing and locking the telepharmacy site at the end of the business day. If the telepharmacy site is protected by one or more alarm systems, training shall include how to disarm and engage the alarm system or systems.

13.11(3) Continuing education. Beginning with the first full two-year continuing education period for renewal of the technician's national pharmacy technician certification after beginning practice as a telepharmacy technician, and for each subsequent renewal of national certification for as long as the technician continues to practice as a telepharmacy technician, the technician shall complete two hours of continuing education in each of the following activities. These continuing education requirements shall not be in addition to the total continuing education

credits required to maintain national certification.

a. Patient safety/medication errors and

b. Pharmacy law.

13.11(4) Identification. The telepharmacy technician shall, at all times when the technician is practicing at the telepharmacy site and the telepharmacy site is open for business, wear a name badge or tag identifying the technician. The badge or tag shall include, at a minimum, the technician's first name and title. The name badge or tag shall be so designed and worn that the technician's name and title are clearly visible to the public at all times.

13.11(4) Adequate audio-visual connection. The telepharmacy technician shall ensure adequate audio-visual connection with the managing pharmacy during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

657—13.12 to 13.15 Reserved.

657—13.16(124,155A) Telepharmacy site – initial application.

13.16(1) License application. A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information identified in this rule.

13.16(2) CSA registration application. If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy license application and fee, the CSA registration application and fee as provided in rule 657—10.1(124).

13.16(3) Identification of managing pharmacy. The telepharmacy site application shall

include identification of the managing pharmacy including pharmacy name, license number, address, telephone number, pharmacist in charge, and a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site.

13.16(4) Distance to nearest general pharmacy. The telepharmacy site application shall identify the nearest licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus and services will be limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) Written agreement. The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

13.16(6) Key personnel. The telepharmacy site application shall identify key personnel

including the pharmacist in charge of the managing pharmacy and the telepharmacy site and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel.

13.16(7) Audio-visual technology. A description of the audio-visual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. Requiring a verifying pharmacist to review and compare the electronic image of any new prescription presented to the telepharmacy technician for filling with the data entry record prior to the prescription being filled and to authorize the telepharmacy site's system to print a prescription label at the telepharmacy site before the label may be printed.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to filling the prescription at the telepharmacy site.

d. Ensuring the telepharmacy site's system prevents a prescription from being sold and delivered to a patient prior to the verifying pharmacist performing a final verification of the accuracy of the prescription and releasing the prescription for sale and delivery at the telepharmacy site.

13.16(8) Request for distance waiver. The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to

pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver or variance identified in 657 Chapter 34.

b. In addition to the requirements of 657 Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(3) That access to the nearest currently licensed general pharmacy that dispenses prescription drugs to outpatients is limited and a description of how the proposed telepharmacy site will improve patient access to pharmacy services.

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed general pharmacy, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public health.

(1) The director shall have the power to approve, modify, or veto the board's proposed decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

657—13.17(124,155A) Telepharmacy site or managing pharmacy changes. Except as specifically provided by these rules, a change to a telepharmacy site shall require compliance with the licensure and notification requirements of the specific type of change identified in 657 subrules 8.35(6) and 8.35(7). A change affecting the CSA registration shall comply with the appropriate requirements of rule 657—10.11(124).

13.17(1) Change of pharmacist in charge. A change of pharmacist in charge shall require submission of a pharmacy license application for the managing pharmacy and the telepharmacy site as provided by subrule 657—8.35(6).

13.17(2) Closing or selling pharmacy. A telepharmacy site or managing pharmacy that

intends to close or sell the pharmacy practice shall comply with all requirements for closing or selling a pharmacy found at 657 subrules 8.35(6) and 8.35(7) regarding ownership change and closing a pharmacy, including all advance notification requirements. A purchaser of a telepharmacy site shall complete and submit applications and supporting information as provided in rule 657—13.16(124,155A). A closing pharmacy shall also comply with the requirements of subrule 13.3(3) or 13.3(4), as appropriate.

13.17(3) Location change. A telepharmacy site that intends to move to a new location that is outside the community wherein the telepharmacy site has been located, if the telepharmacy site intends to provide telepharmacy services from the new location, shall comply with the requirements of subrule 13.17(2) for closing a pharmacy and shall submit applications and supporting information as provided in rule 657—13.16(124,155A). A managing pharmacy that intends to move to a new location shall comply with the requirements of 657 subrules 8.35(5), 8.35(6), and 8.35(7), as appropriate.

657—13.18(155A) Traditional pharmacy opening. If a pharmacy, licensed as a general, hospital, or limited use pharmacy, opens for business within 10 miles of an existing and operating telepharmacy site, the telepharmacy site may continue to operate as a telepharmacy site and shall not be required to close due to the proximity of the new pharmacy.

657—13.19 to 13.20 Reserved.

657—13.21(124,155A) Policies and procedures. In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations. Policies and procedures shall be available for inspection and copying by the board or the board's

representative at the location to which the policies and procedures apply. Policies and procedures shall define the frequency of review and written documentation of review by the pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

- Procedures ensuring a record identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription container, and the appropriateness of the prescription container, is made and retained.
- Procedures ensuring a record identifying the pharmacist who performed the drug utilization review as provided by rule 657—8.21(155A) is made and retained.
- Procedures ensuring a record identifying the pharmacist who provided counseling to the patient or the patient's caregiver pursuant to rule 657—6.14(155A) is made and retained.
- Procedures ensuring a record identifying the technician who filled the prescription is made and retained.
- Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.
- Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.
- Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site including appropriate temperature controls.
- Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist including requirements for documentation and retention of the results of each inspection.

- Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.
- Procedures and documentation required in the case of return to the telepharmacy of a drug or device.
- Procedures for drug and device recalls.

657—13.22(155A) Reports to the board. The board may periodically request information regarding the services provided by a telepharmacy site. A telepharmacy site shall complete and submit the requested information in a timely manner as requested by the board. The board shall allow a reasonable amount of time for a telepharmacy site to complete and submit the requested information. Information requested may include, but may not necessarily be limited to, the following:

13.22(1) Prescriptions dispensed. The number of prescriptions dispensed from the telepharmacy site over a specified period of time.

13.22(2) Pharmacist hours. The number of hours a pharmacist was physically present at the telepharmacy site over a specified period of time.

13.22(3) Telepharmacy site hours. The number of hours the telepharmacy site was open for business over a specified period of time.

657—13.23(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the telepharmacy site and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10. Specific records required to be maintained by and available

at a telepharmacy site shall include but are not limited to the following:

13.23(1) Dispensing record. As provided in rule 657—13.21(124,155A), a written or electronic record identifying the pharmacist who verified the prescription, the pharmacist who provided counseling to the patient or the patient's caregiver, and the pharmacy technician who filled the prescription shall be maintained for every prescription fill dispensed by the telepharmacy site.

13.23(2) Onsite pharmacist staffing. A written or electronic record of the number of prescriptions filled, the number of onsite pharmacist hours, and the number of hours the telepharmacy site was open for business each month.

13.23(3) Pharmacy access. Records identifying, by unique identification of the individual accessing the pharmacy department, including the date and time of access, shall be maintained for two years beyond the date of access.

13.23(4) Monthly inspection. Reports of the monthly inspection of the telepharmacy site shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy for two years following the date of the inspection.

These rules are intended to implement Iowa Code sections 124.301, 155A.6A, 155A.14, 155A.19, 155A.28, 155A.31, and 155A.41, and Iowa Code sections 147.107, 155A.3, 155A.13, and 155A.33 as amended by S.F. 453, 86 G.A., sections 1, 2, 3, and 7.

ADDENDUM P

NOTICE OF INTENDED ACTION

CHAPTER 10, "CONTROLLED SUBSTANCES,"
AND
CHAPTER 100, "IOWA REAL-TIME ELECTRONIC PSEUDOEPHEDRINE TRACKING SYSTEM"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, "Controlled Substances", Iowa Administrative Code, and Chapter 100, "Iowa Real-Time Electronic Pseudoephedrine Tracking System," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendments are the result of a general review of administrative rules pursuant to Iowa Code subsection 17A.7(2), in collaboration with the Governor's Office of Drug Control Policy. The amendments remove reference to the pseudoephedrine advisory council, which was repealed by 2013 Acts, ch 68, §2, and allow a pharmacy technician to approve a purchase under the direct supervision of a pharmacist.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 10, 2017. 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 email 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 124.212, 124.212A, 124.212B, 124.213, and 17A.7(2).

The following amendments are proposed.

Item 1. Amend rule 657—10.32(124,155A) as follows:

657—10.32(124,155A) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist, pharmacist-intern, or pharmacy technician to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist, ~~or~~ by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, or by a registered pharmacy technician under the direct supervision of a pharmacist, except as authorized in 657—Chapter 100. This subrule does not prohibit, after the pharmacist, pharmacist-intern, or pharmacy technician has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by ~~a nonpharmacist~~ another pharmacy employee.

10.32(2) to 10.32(4) No changes.

10.32(5) Identification. The pharmacist, pharmacist-intern, or pharmacy technician shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The pharmacist, pharmacist-intern, or pharmacy technician shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.32(6) Record. Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657—Chapter 100. If the real-time electronic repository is unavailable for use, the

purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. Alternate record contents. The alternate record shall contain the following:

(1) The name, address, and signature of the purchaser.

(2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

(3) The date and time of the purchase.

(4) The name or unique identification of the pharmacist, ~~or~~ pharmacist-intern, or pharmacy technician who approved dispensing of the product.

b. to c. No Changes.

10.32(7) No changes.

Item 2. Amend rule 657—100.1(124) as follows:

657—100.1(124) Purpose and scope. ~~2009~~ Iowa Code ~~Supplement~~ section 124.212B directs the governor's office of drug control policy to establish a real-time electronic repository to monitor and control the sale of Schedule V products that are not listed in another controlled substance schedule and that contain any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine. All pharmacies dispensing such products without a prescription shall electronically report all such sales to the repository. The real-time electronic repository shall be under the control of and administered by the governor's office of drug control policy. Both the governor's office of drug control policy and the board of pharmacy are directed to adopt rules relating to the real-time electronic repository and have jointly adopted these rules. These rules establish the pseudoephedrine tracking system (PTS).

Item 3. Amend rule 657—100.2(124) as follows:

657—100.2(124) Definitions. As used in this chapter:

"Attempted purchase" means a proposed transaction for the dispensing of a product that is entered by a dispenser into the electronic pseudoephedrine tracking system, which transaction is not completed because the system recommends that the transaction be denied pursuant to the quantity limits established in ~~2009~~ Iowa Code ~~Supplement~~ section 124.213.

"Board" means the board of pharmacy.

~~"Council" means the pseudoephedrine advisory council established pursuant to Iowa Code section 124.212C.~~

"Dispenser" means a licensed Iowa pharmacist, ~~or~~ a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, or a registered pharmacy technician under the direct supervision of a pharmacist, except as authorized in 657—Chapter 13.

"Law enforcement officer" means all of the following:

1. State police officer.
2. City or county police officer.
3. Sheriff or deputy sheriff.
4. State or public university safety and security officer.
5. Department of natural resources officer.
6. Certified or full-time peace officer of this or another state.
7. Federal peace officer.
8. Criminal analyst assigned to a law enforcement agency.
9. Probation or parole officer.

"Office" means the governor's office of drug control policy.

"Product" means a Schedule V drug product that is not listed in another controlled substance

schedule and that contains any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine.

"Pseudoephedrine tracking system" or "PTS" means the real-time electronic repository established to monitor and control the sale of products and administered by the governor's office of drug control policy.

"Purchaser" means an individual 18 years of age or older who purchases or attempts to purchase a product.

Item 4. Amend rule 657—100.3(124) as follows:

657—100.3(124) Electronic pseudoephedrine tracking system (PTS). Unless granted an exemption by the office pursuant to these rules, all pharmacies dispensing products as defined in rule 657—100.2(124) without a prescription are required to participate in the PTS pursuant to ~~2009~~ Iowa Code ~~Supplement~~ section 124.212B. ~~The office has established a council to provide input and advise the office regarding the implementation, maintenance, and administration of the PTS. The council also assists the office in developing guidelines to ensure patient confidentiality and the integrity of the relationship established by the patient and the patient's health care provider.~~

100.3(1) Reporting elements. The record of a completed purchase or attempted purchase of a product without a prescription shall contain the following:

a. The name and address of the purchaser.

b. A current government-issued photo identification number.

c. The electronic signature of the purchaser. If a pharmacy is not able to secure or record an electronic signature, a hard-copy signature logbook shall be utilized and maintained by the pharmacy. Each record in the logbook shall include the purchaser's signature and shall identify the purchase by transaction number.

d. Date and time of the purchase.

e. The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

f. The name or unique identification of the pharmacist, ~~or~~ pharmacist-intern, or pharmacy technician who approved the dispensing of the product.

100.3(2) No changes.

100.3(3) Denial of transactions and overrides.

a. No changes.

b. The PTS shall provide an override feature for use by a dispenser to allow completion of the sale. For security purposes and to ensure the integrity of the PTS, use of the override feature shall be restricted to authorized dispensers and may not be delegated to a pharmacy technician trainee or a pharmacy support person. A dispenser utilizing the override feature shall document the reason that, in the professional judgment of the dispenser, it is necessary to override the recommendation of the PTS to deny the transaction.

100.3(4) No changes.

Item 5. Amend subrule 100.4(4) as follows:

100.4(4) Patients. A patient may request and receive information regarding products reported to have been purchased by the patient.

a. A patient may submit a signed, written request for records of the patient's purchases and attempted purchases during a specified period of time. The request shall identify the patient by name, including any aliases used by the patient, and shall include the patient's date of birth and gender. The request shall also include any address where the patient resided during the time period of the request and the patient's current address and daytime telephone number. A patient may personally delivery

the request to the PTS administrator or authorized staff member of the office located at ~~Wallace State Office Building, 502 E. 9th Street, First Floor,~~ Pape State Office Building, 215 East 7th Street, Fifth Floor, Des Moines, Iowa 50319. The patient shall be required to present current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification shall be maintained in the records of the PTS.

b. No changes.

Item 6. Amend rule 657—100.5(124) as follows:

657—100.5(124) Violations. Violations of provisions of these rules or ~~2009~~ Iowa Code ~~Supplement section~~ sections 124.212A, 124.212B, or 124.213 may subject the violator to criminal prosecution.

Item 7. Amend implementation clause as follows:

These rules are intended to implement ~~2009~~ Iowa Code ~~Supplement~~ sections 124.212, 124.212A, 124.212B, and 124.213.

ADDENDUM Q

NOTICE OF INTENDED ACTION

AMEND CHAPTER 20, "COMPOUNDING PRACTICES," AND ADOPT new CHAPTER 41, "OUTSOURCING FACILITIES"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code sections 147.76 and 155A.13C, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 20, "Compounding Practices," and to adopt new Chapter 41, "Outsourcing Facilities," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendments are intended to implement Senate File 453, enacted by the 86th General Assembly, which identifies as a specific license category an outsourcing facility and authorizes the board to promulgate rules for such licensure and activity. The proposed amendments add references in various rules in Chapter 20 to the new proposed Chater 41 for outsourcing facilities. The amendments also introduce language, consistent with federal draft guidance, regarding criteria for the board to consider when determining if a compounded drug preparation is essentially a copy of an approved drug. Compounding of a drug that is essentially a copy of an approved drug is in violation of federal regulations.

Proposed new Chapter 41 establishes the requirements for licensure of outsourcing facilities and includes requirements relating to operations of an outsourcing facility, disclosure of inspection information including identification of determined deficiencies and the actions taken to cure those deficiencies, and disclosure of administrative and criminal actions taken against the facility and primary facility personnel.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 10, 2017. 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 email to terry.witkowski@iowa.gov.

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

These amendments are intended to implement Iowa Code sections 124.301, 155A.13, and 155A.13C.

The following amendments are proposed.

ITEM 1. Amend rule 657—20.1(124,126,155A) as follows:

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals. The requirements of 657—Chapter 41 apply to outsourcing facilities.

ITEM 2. Amend rule **657—20.2(124,126,155A)**, definition of "*Outsourcing facility" or "facility,*" as follows:

"Outsourcing facility" or "facility" means ~~a~~ any compounding facility that is ~~located at a single geographical location and has~~ registered ~~with the FDA~~ as an outsourcing facility ~~in accordance with Section 503B of the Federal Food, Drug, and Cosmetic Act~~, as defined in 21 U.S.C. §353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

ITEM 3. Amend rule 657—20.5(126,155A) as follows:

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

ITEM 4. Amend rule 657—20.6(126,155A) as follows:

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa pursuant to 657—Chapter 41 and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for ~~hospitals, practitioners, or patients in the state of~~ use in Iowa.

ITEM 5. Amend rule 657—20.11(126,155A) as follows:

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

ITEM 6. Adopt the following **new** subrules 20.12(1) and 20.12(2):

20.12(1) *"Essentially a copy."* The board may consider the existence of the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

a. the compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

b. the active pharmaceutical ingredient(s) have the same, similar, or an easily substitutable dosage strength; and

c. the commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

20.12(2) *"Clinically significant difference."* The prescription for a compounded preparation that is essentially a copy of an approved drug shall clearly indicate the relevant change and the significant clinical difference produced for the patient. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy or outsourcing facility to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference.

ITEM 7. 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 pursuant to 657—Chapter 41 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 or

outsourcing facility and sold directly to the practitioner by the ~~compounding~~ pharmacy or outsourcing facility.

20.15(3) to **20.15(4)** No change.

ITEM 8. Amend subrule 20.16(1) as follows:

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

ITEM 9. Amend paragraph **20.19(3)"*k*"** as follows:

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

ITEM 10. Amend the implementation clause as follows:

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

ITEM 11. Adopt the following **new** 657—Chapter 41:

CHAPTER 41

OUTSOURCING FACILITIES

657—41.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for outsourcing facilities that intend to provide compounding services in or into Iowa. The requirements of these rules, in addition to any other board rules applicable to the facility's operation, apply to all Iowa-licensed outsourcing facilities that provide compounded

medications in or into Iowa whether pursuant to a patient-specific prescription or not.

657—41.2(155A) Definitions. For the purposes of this chapter, these definitions shall apply.

"Board" means the Iowa board of pharmacy.

"FDA" means the United States food and drug administration.

"Home state" means the state in which an outsourcing facility is located.

"Outsourcing facility" or *"facility"* means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. §353B, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

657—41.3(155A) Outsourcing facility license. Beginning January 1, 2018, an outsourcing facility shall apply for and obtain an outsourcing facility license from the board prior to providing non patient-specific compounded human drug products in this state. The applicant shall submit a completed application along with an application fee of $400. An outsourcing facility that intends to distribute controlled substances into Iowa shall also apply for and obtain an Iowa Controlled Substances Act registration pursuant to 657—Chapter 10 prior to distributing such substances in this state.

41.3(1) *Application forms.* The application shall require demographic information about the facility, ownership information, the name, signature and home state license number for the supervising pharmacist, an attestation that the supervising pharmacist has read and understands the laws and rules relating to sterile compounding in Iowa, information about the entity's registered agent, criminal and disciplinary history information, and a description of the scope of services to be provided in Iowa. As part of the application process, the applicant shall also:

a. Submit evidence of possession of a valid registration as an outsourcing facility with the

FDA.

b. If one or more inspections have been conducted by the FDA in the five-year period immediately preceding the application, submit a copy of any correspondence from the FDA as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the FDA related to such inspections, including but not limited to formal responses and corrective action plans. In addition, the applicant shall submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the FDA.

c. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. §353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

d. Submit information to facilitate a national criminal history record check.

41.3(2) *Provision of patient-specific prescriptions.* If an outsourcing facility intends to dispense prescription drugs pursuant to patient-specific prescriptions to patients in Iowa, the outsourcing facility shall also obtain and maintain a valid Iowa pharmacy license pursuant to 657—Chapter 8 if located in Iowa or a valid Iowa nonresident pharmacy license pursuant to 657—Chapter 19 if located outside of Iowa prior to dispensing prescriptions in this state.

41.3(3) *License renewal.* The outsourcing facility license shall be renewed by January 1 of each year. The facility shall submit the license application and fee as provided in this rule. An outsourcing facility may renew its license beginning November 1 prior to license expiration. An initial outsourcing facility license issued between November 1 and December 31 shall not require renewal until the following calendar year. The fee for license renewal shall be $400.

a. Delinquent license grace period. If an outsourcing facility license has not been

renewed or cancelled prior to expiration, but the facility is in the process of renewing the license, the license becomes delinquent on January 1. An outsourcing facility that submits a completed license renewal application, application fee, and late penalty fee of $400 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of January.

b. Delinquent license reactivation beyond grace period. If an outsourcing facility license not been renewed prior to the expiration of the one month grace period identified in paragraph "*a*," the facility may not continue to provide services to Iowa customers. An outsourcing facility that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. An outsourcing facility without a current license may apply for reactivation by submitting a license application for reactivation and a $1,600 reactivation fee. As part of the reactivation application, the facility shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

41.3(4) *License changes.* If a facility has a change of name, ownership, location or supervising pharmacist, the facility shall submit to the board an outsourcing facility license application and applicable fee within 10 days of the FDA's issuance of an updated registration. Following processing of the completed license application and fee, the board shall issue a new license certificate that reflects the change or changes.

41.3(5) *License cancellation.* If a facility ceases to be registered as an outsourcing facility with the FDA, the facility shall immediately cease distribution of non patient-specific compounded drug products in or into this state and shall return its Iowa outsourcing facility license to the board within ten days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license. If a facility intends to discontinue

business in this state, it shall notify the board in writing of its intent at least 30 days in advance of the discontinuation of services and request that the license be administratively cancelled. To the extent possible to avoid unnecessary delays in obtaining product for patients, an outsourcing facility that intends to discontinue services in Iowa should provide advanced notice to its customers of the date that the outsourcing facility intends to cease distributing products in this state. The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

657—41.4(155A) Applicability of board rules. An outsourcing facility shall comply with all requirements of this chapter, 657—Chapter 20, and any other board rules relating to the services that are provided to Iowa customers, including but not limited to:

41.4(1) *Controlled substances.* An outsourcing facility providing prescription drugs to Iowa customers or patients identified as controlled substances under Iowa Code Chapter 124 shall comply with all requirements of 657—Chapter 10.

41.4(2) *Electronic data.* An outsourcing facility utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

41.4(3) *Patient-specific prescriptions.* An outsourcing facility that also provides patient-specific compounded medications pursuant to a prescription shall comply with all requirements of 657—Chapter 8, 657—Chapter 19, and 657—Chapter 20.

657—41.5(155A) Reporting discipline and criminal convictions. An outsourcing facility shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the facility no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty,

citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. An outsourcing facility shall provide written notice to the board of any criminal conviction of the facility or of any owner that is related to the operation of the facility no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

657—41.6(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.

2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.

3. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain licensure pursuant to 657—Chapter 8 or 657—Chapter 19 when dispensing compounded drugs pursuant to patient-specific prescriptions into the state.

5. Any violation of Iowa Code Chapters 155A, 124, 124A, 124B, 126, 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

These rules are intended to implement Iowa Code sections 124.301 and 155A.13C.

ADDENDUM R

NOTICE OF INTENDED ACTION

RESCIND CHAPTER 19, "NONRESIDENT PHARMACY PRACTICE," AND ADOPT new CHAPTER 19, "NONRESIDENT PHARMACY PRACTICE"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code sections 147.76 and 155A.13A, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 19, "Nonresident Pharmacy Practice," and adopt a new Chapter 19, "Nonresident Pharmacy Practice," Iowa Administrative Code.

The proposed amendment was approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendment incorporates an administrative review pursuant to Iowa Code subsection 17A.7(2) as well as promulgates rules in response to Senate File 453, enacted by the 86th General Assembly. Proposed rules identify application requirements, including minimum standards for inspections of nonresident pharmacies seeking licensure in Iowa, and application and registration requirements for the pharmacist in charge of a nonresident pharmacy. Proposed new rules provide directives for nonresident pharmacies subject to disciplinary action or criminal convictions to provide timely notice to the board as well as provide further explanation of the disciplinary authority of the board.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on January 10, 2017. 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 email to terry.witkowski@iowa.gov.

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

This amendment is intended to implement Iowa Code section 155A.13A as amended by S.F. 453, 86 G.A.

The following amendment is proposed.

Rescind 657—Chapter 19 and adopt the following **new** chapter in lieu thereof:

CHAPTER 19

NONRESIDENT PHARMACY PRACTICE

657—19.1(155A) Definitions.

"Board" means the Iowa board of pharmacy.

"Home state" means the state in which a pharmacy is located.

"Nonresident pharmacy" means a pharmacy, including an Internet-based pharmacy, located outside the state of Iowa that delivers, dispenses, or distributes, by any method, prescription drugs, devices, or pharmacy services to an ultimate user physically located in this state.

"Nonresident pharmacy license" means a pharmacy license issued to a nonresident pharmacy.

"Pharmacy service" includes, but is not limited to, nonproduct services such as providing patient counseling and drug information, assessing health risks, and providing pharmaceutical care that is provided by an Iowa-licensed pharmacist or a pharmacist employed at an Iowa-licensed nonresident pharmacy.

"Registered pharmacist in charge" means the pharmacist in charge at the nonresident pharmacy that is registered with the board and is legally responsible for the operation of the nonresident pharmacy with respect to the provision of prescription drugs, devices, or pharmacy services to patients located in Iowa.

657—19.2(155A) Nonresident pharmacy license. A nonresident pharmacy shall apply for and obtain, pursuant to provisions of rule 657—8.35(155A), a nonresident pharmacy license from the board prior to providing prescription drugs, devices, or pharmacy services to an ultimate user in this state. All requirements of rule 657—8.35(155A) regarding licensure are applicable to nonresident pharmacies unless otherwise provided in this rule. Any pharmacy that dispenses controlled substances to Iowa residents shall also register pursuant to 657—Chapter 10.

19.2(1) *Inspection requirements.* In lieu of the inspection requirement identified in 657—subrule 8.35(4), a nonresident pharmacy submitting any application for licensure, except when related to a change in location, shall submit with its application and fee an inspection report that satisfies these requirements:

a. Less than two years have passed since the date of the inspection and is the most recent inspection report available that satisfies these rules.

b. The inspection occurred while the pharmacy was in operation. An inspection prior to the initial opening of the pharmacy shall not satisfy this requirement.

c. The inspection report addresses all aspects of the pharmacy's business that will be utilized in Iowa.

d. The inspection was performed by or on behalf of the home state licensing authority, if available.

19.2(2) *Qualified inspector.* If the home state licensing authority has not conducted an inspection satisfying the inspection requirements, the nonresident pharmacy shall submit an inspection report issued by one of the following:

a. The Verified Pharmacy Program offered by the National Association of Boards of Pharmacy®.

b. Another qualified entity if the entity is preapproved by the board.

c. An authorized agent of the board. The board may recover from a nonresident pharmacy, prior to the issuance of a nonresident pharmacy license, the costs associated with conducting an inspection.

19.2(3) *Corrective action.* The nonresident pharmacy shall submit evidence of corrective action taken to satisfy any deficiency identified in the inspection report and compliance with all legal directives of the home state licensing authority.

19.2(4) *Nonresident pharmacy license changes.* A nonresident pharmacy shall submit a completed application and fee pursuant to rule 657—8.35(5) except as provided in this rule.

a. Name. A change of the pharmacy name which is provided to patients shall require submission of a pharmacy license application and fee within 10 days after the home state regulatory authority issuance of a license bearing the new name.

b. Location. A change of pharmacy location shall require submission of a pharmacy license application, with the exception of the inspection requirement pursuant to 19.2(1), and fee within 10 days after the home state regulatory authority issuance of a license bearing the new address.

c. Pharmacist in charge. A change in the pharmacist in charge shall require submission of a pharmacy license application and fee within 10 days of identifying a permanent pharmacist in charge pursuant to 657—subrule 8.35(5). If a temporary pharmacist in charge is identified, written notification shall be provided to the board pursuant to 657—subrule 8.35(5) paragraph "*c.*" The temporary pharmacist in charge shall not be required to be registered pursuant to 19.3.

19.2(6) *Closing pharmacy or discontinuation of services.* If a nonresident pharmacy is closing, the pharmacy shall comply with the requirements in 657—subrule 8.35(6). If a

nonresident pharmacy is discontinuing provision of pharmacy services to Iowa, but not closing, the pharmacy shall comply with the requirements in 657—subrule 8.35(6), opening paragraph as it relates to transferring patient records to another Iowa-licensed pharmacy and paragraphs "*b*" and "*d.*" The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster. The nonresident pharmacy shall return to the board the nonresident pharmacy license certificate and, if registered, the Iowa Controlled Substances Act registration certificate within 10 days following the closure or discontinuation of service.

657—19.3(155A) Registered pharmacist in charge. The permanent pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application. Beginning January 1, 2018, the pharmacist in charge shall be registered with the board. The pharmacist in charge shall submit a completed application and a registration fee of $75. The registration shall expire on December 31 following the date of issuance of the registration. An initial pharmacist in charge registration issued between November 1 and December 31 shall not require renewal until the following calendar year.

19.3(1) *Registered pharmacist in charge application.* The pharmacist in charge of an Iowa-licensed nonresident pharmacy shall be registered with the board and shall submit to the board an application that includes the information identified herein. Registration shall not be required for a pharmacist that maintains current and active Iowa pharmacist licensure.

a. The pharmacist's name and contact information,

b. The pharmacist's license or registration number in the state in which the nonresident pharmacy is located,

c. The pharmacist's current place of employment,

d. Verification that the pharmacist's license in the state in which the nonresident pharmacy is located is current and in good standing,

e. Documentation that the applicant has successfully completed the most current educational training module approved by the board regarding the board's rules as they relate to nonresident pharmacy practice, and

f. Criminal and disciplinary history information.

19.3(2) *Registration changes and voluntary cancellation.* A registered pharmacist in charge of a nonresident pharmacy shall notify the board in writing within ten days of any change of information included on the registration application, including name, contact information, home state license or registration information or status, and place of employment. If a registered pharmacist in charge ceases to be the pharmacist in charge of an Iowa-licensed nonresident pharmacy, the pharmacist may voluntarily request the registration be cancelled and the pharmacist shall not be subject to the inactive registration and reactivation procedure as identified in subrule 19.3(3) paragraph "*b.*"

19.3(3) *Registration renewal.* The registration of a pharmacist in charge at a nonresident pharmacy shall be renewed or cancelled prior to January 1 of each year. The pharmacist in charge shall submit a completed application and fee as required in this rule.

a. Delinquent registration grace period. If a pharmacist in charge registration has not been renewed or cancelled prior to expiration, but the pharmacist is in the process of renewing the registration, the registration becomes delinquent on January 1. A pharmacist in charge that submits a completed registration renewal application, application fee, and late penalty fee of $75 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary

action for continuing to serve as pharmacist in charge without a current registration in the month of January.

b. Delinquent license reactivation beyond grace period. If a pharmacist in charge registration has not been renewed prior to the expiration of the one month grace period identified in paragraph "*a*", the nonresident pharmacy may not continue to provide services to Iowa patients. A nonresident pharmacy that continues to provide services to Iowa patients without a currently registered pharmacist in charge may be subject to disciplinary sanctions. A pharmacist in charge without a current registration may apply for reactivation by submitting a registration application for reactivation and a $300 reactivation fee. As part of the reactivation application, the nonresident pharmacy shall disclose the services, if any, that were provided to Iowa patients while the pharmacist in charge registration was delinquent.

657—19.4(124,155A) Applicability of board rules. A nonresident pharmacy shall comply with all the requirements of this chapter and of 657—Chapter 8 and other board rules relating to the services that are provided by the pharmacy to patients in Iowa.

19.4(1) *Type of pharmacy practice.* A nonresident pharmacy, based on the principal type of pharmacy practice shall comply with board rules as follows:

a. A "general pharmacy" as described in rule 657—6.1(155A) shall comply with all requirements of 657—Chapter 6.

b. A "hospital pharmacy" as described in rule 657—7.1(155A), excepting licensure pursuant to Iowa Code chapter 135B, shall comply with all requirements of 657—Chapter 7.

c. A "limited use pharmacy" as described in 657—subrule 8.35(1) shall comply with all requirements of the limited use pharmacy practice.

d. An "outsourcing facility" as described in rule 657—41.2(155A.13C) shall comply with all requirements of 657—Chapter 41 and 657—Chapter 20.

19.4(2) *Controlled substances.* A nonresident pharmacy providing prescription drugs identified as controlled substances under Iowa Code chapter 124 shall register with the board and comply with all requirements of 657—Chapter 10.

19.4(3) *Compounding.* A nonresident pharmacy engaged in the compounding of drug products as defined in rule 657—20.2(124,126,155A) shall comply with all requirements of 657—Chapter 20.

19.4(4) *Long-term care services.* A nonresident pharmacy providing services to Iowa patients in a long-term care facility as defined in 657—Chapter 23 shall comply with all requirements of 657—Chapter 22 and 657—Chapter 23.

19.4(5) *Electronic data.* A nonresident pharmacy utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

657—19.5 and **19.6** Reserved.

657—19.7(155A) Confidential data. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of rule 657—8.16(124,155A).

657—19.8(124,155A) Storage and shipment of drugs and devices. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A). Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method, and all records of such

shipment and delivery to Iowa patients shall be maintained for a minimum of two years from the date of delivery.

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

19.9(1) *Patient record system.* A patient record system shall be maintained pursuant to rule 657—6.13(155A) for Iowa patients for whom prescription drug orders are dispensed.

19.9(2) *Prospective drug use review.* A pharmacist shall, pursuant to the requirements of rule 657—8.21(155A), review the patient record and each prescription drug order before dispensing.

19.9(3) *Patient counseling.* Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).

647—19.10(155A) Reporting discipline and criminal convictions. A nonresident pharmacy or registered pharmacist in charge shall provide notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy or pharmacist in charge no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A nonresident pharmacy or pharmacist in charge shall provide written notice to the board of any criminal conviction of the pharmacy, of any pharmacy owner, or of the pharmacist in charge that is related to prescription drugs or related to the operation of the pharmacy no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

657—19.11(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a nonresident pharmacy license or pharmacist in charge registration for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.

2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the nonresident pharmacy, pharmacist in charge, or individual owner, or if the pharmacy is an association, joint stock company, partnership, or corporation, by any managing officer.

3. Refusal of access to the pharmacy or pharmacy records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Continuing to employ a pharmacist in charge without a current and active registration pursuant to 19.3.

5. Any violation of Iowa Code chapters 124, 124A, 124B, 126, 155A, 205, or rule of the board.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 155A.13, 155A.19, and 155A.35 and Iowa Code sections 155A.13A and 155A.13C as amended by S.F. 453, 86 G.A.

ADDENDUM S

NOTICE OF INTENDED ACTION

CHAPTER 11, "DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAMS,"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 11, "Drugs in Emergency Medical Service Programs," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendments are the result of a general review of administrative rules pursuant to Iowa Code subsection 17A.7(2). The amendments update language to be consistent with current Iowa Code provisions and reorganize the chapter to provide clarity. The amendments require any entity, regardless of location, whose controlled substances are stored or handled at any primary program site of an emergency medical service program that services Iowa residents to obtain and maintain an Iowa Controlled Substances Act registration at the primary program site location.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 10, 2017. 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 email 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 chapter 147A and Iowa Code sections 124.301, 155A.13, and 17A.7(2).

The following amendments are proposed.

ITEM 1. Amend rule 657—11.1(124,147A,155A) as follows:

657—11.1 (124,147A,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Adulterated" means any drug or device that consists in whole or in part of any filthy, putrid, or decomposed substance.

"Ambulance service" means any privately or publicly owned service program that utilizes ambulances, including air transport vehicles, in order to provide patient transportation and emergency medical services.

"Authorized prescriber" means any provider who has prescriptive authority in the state of Iowa.

"Board" means the board of pharmacy.

"Bureau" means the Iowa department of public health, bureau of emergency ~~medical~~ and trauma services ~~(EMS)~~ (BETS).

"Controlled substance" means any drug that is identified in Schedules I through V of Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"CSA registration" means a registration issued by the board pursuant to Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"DEA registration" means a registration issued by the DEA pursuant to 21 CFR Part 1301.

"Department" means the Iowa department of public health.

"Drug" means a substance as defined in Iowa Code section 155A.3(13) but does not include nonmedicated intravenous solutions such as saline.

"Emergency medical care provider" means an emergency medical care provider as defined in 641—131.1(147A).

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care ~~at the scene or during out-of-hospital patient transportation in an ambulance~~.

"Emergency medical technician" or *"EMT"* means any emergency medical technician or EMT as defined in 641—131.1(147A).

"Medical direction" means direction, advice, or orders provided, in accordance with written parameters and protocols, to emergency medical care personnel by a medical director, supervising physician, or physician designee.

"Medical director" means any physician licensed under Iowa Code ~~chapter~~ chapters 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Medical director-based" means that ownership of the drugs maintained in and used by the service program remains with the medical director.

"Patient care report" ~~or *"PCR"*~~ means a computerized or written report that documents the assessment and management of the patient by the emergency medical care provider ~~in the out-of-hospital setting~~.

"Pharmacy-based" means that ownership of the drugs maintained in and used by the service program remains with the pharmacy.

"Physician" means any individual licensed under Iowa Code ~~chapter~~ chapters 148, 150, or 150A.

"Physician assistant" or *"PA"* means any individual licensed under Iowa Code chapter 148C.

~~*"Physician designee"* means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician, in accordance with written policies and protocols, in directing the care provided by emergency medical care providers.~~

"Primary program site" means the physical location from which the service program is operated and at which stock supplies of prescription drugs may be maintained and distributed to a program vehicle and a program substation.

"Program substation" means the physical location from which a service program is operated as a branch or extension of a primary program site, at which an emergency kit or supply of prescription drugs is maintained, and at which a stock supply of prescription drugs is not maintained.

"Protocols" means written direction and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols shall be approved by the service program's medical director and shall address the care of both adult and pediatric patients.

"Responsible individual" ~~or *"RI,"* as this term relates to prescription drugs in a medical director-based service, means the medical director for the service. In a pharmacy-based service, "responsible individual" means the pharmacist in charge of the pharmacy~~ means the individual

that maintains legal responsibility of the prescription drugs and devices including the medical director in a medical director-based service program or the pharmacist in charge in a pharmacy-based service program.

"Service" or *"service program"* means any medical care ambulance service or nontransport service that has received authorization from the department.

"Service director" means the individual who is responsible for the operation and administration of a service program.

"Supervising physician" means any physician licensed under Iowa Code ~~chapter~~ chapters 148, 150, or 150A who supervises and is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

ITEM 2. Amend rule 657—11.2(124,147A,155A) as follows:

657—11.2 (124,147A,155A) Responsibility. ~~Pursuant to rules of the bureau, each~~ Each service program shall appoint a service director at the primary program site and shall have a responsible individual who is responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. In service programs that maintain both a pharmacy-based service program agreement and a medical director-based service program agreement, the responsible individual for each service program agreement shall be responsible for ensuring the management of drugs under that individual's ownership. If more than one pharmacy enters into an agreement with a pharmacy-based service program, the pharmacist in charge at each pharmacy is responsible for the rules and laws pertaining to the specific prescription drugs, including controlled substances, that each pharmacy provides to the service program.

~~**11.2(1)** *Pharmacy-based.* In a pharmacy-based service program, the pharmacist-in-charge shall be responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. The pharmacist-in-charge shall not serve as the service director.~~

~~**11.2(2)** *Medical director-based.* In a medical director-based service program, the medical director shall be responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations.~~

~~**11.2(3)** *Combination pharmacy-based and medical director-based.* If both pharmacy-based and medical director-based programs are in effect, the pharmacist-in-charge of the pharmacy and the medical director shall be responsible for management of the drugs owned by the pharmacy and by the medical director, respectively.~~

ITEM 3. Renumber rules 657—11.3(124,147A,155A) and 657—11.4(124,147A,155A) as 657—11.4(124,147A,155A) and 657—11.5(124,147A,155A), respectively.

ITEM 4. Adopt the following **new** rule 657—11.3(124,147A,155A):

657—11.3(124,147A,155A) Registration required. In any service program which intends to provide services in or into Iowa that includes the administration of controlled substances, the responsible individual shall ensure each primary program site, regardless of location, is registered with the board pursuant to this rule. The current registration certificate shall be available at the primary program site for inspection and copying by the board, its representative, or other authorized individual.

11.3(1) *Medical director-based program.* In a medical director-based service program, CSA and DEA registrations shall be obtained for each primary program site. CSA and DEA registrations shall be obtained prior to procurement of any controlled substances for use in the

service program. Separate registrations for program substations shall not be required. In a medical director-based service program, the CSA and DEA registrations shall be in the name of the service program, shall secondarily name the medical director, and shall be issued for the address of the service program's primary program site.

11.3(2) *Pharmacy-based program.* In a pharmacy-based service program, the CSA registration shall be in the name of the service program and shall secondarily name the provider pharmacy. The registration shall be issued for the address of the service program's primary program site and shall identify the pharmacist in charge of the provider pharmacy as the individual responsible for the controlled substances at the service program.

11.3(3) *Combination pharmacy-based and medical director-based program.* In a service program that is a combination of pharmacy-based and medical director-based and both the pharmacy and medical director provide controlled substances, each provider of controlled substances shall maintain a CSA registration with the board as provided by this rule. A medical director-based program shall also maintain a federal DEA registration as provided by this rule.

11.3(4) *Change of address of registered primary program site.* A registrant may apply to change the address of the registered primary program site by submitting a written request as provided in 657—subrule 10.11(2). The board and the DEA shall be notified in writing prior to a change of address of a registered primary program site.

11.3(5) *Discontinuation of medical director in a medical director-based service program.* If a medical director intends to terminate a written agreement with a service program pursuant to rule 11.5(124,147A,155A), the medical director shall provide written notification to the board at 400 S.W. 8th Street, Suite E, Des Moines, Iowa 50309 pursuant to 657—subrule 10.11(6) to cancel the registration, including the effective date of the termination of the agreement. The

registration certificate shall be returned to the board no later than 10 days following the effective date of the termination of the agreement.

ITEM 5. Amend renumbered rule 657—11.4(124,147A,155A) as follows:

657—11.4 (124,147A,155A) Written agreement. A signed, written ~~formal~~ agreement for the service program shall be maintained at the primary program site and be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual.

11.4(1) *Pharmacy-based service programs.* An Iowa-licensed pharmacy may enter into an agreement with a service program located in the state. The agreement with the service program shall establish that the service program is operating as an extension of the pharmacy with respect to the prescription drugs the pharmacy provides to the service program. The agreement shall be signed by the pharmacist in charge and the service director at the primary program site. A copy of this agreement shall be maintained at both the pharmacy and the primary program site while the agreement is in effect. Nothing in this rule prohibits more than one pharmacy from entering into an agreement with a service program provided that each pharmacy complies with all rules and regulations for a pharmacy-based service program, including maintenance of all required records specific to each pharmacy's drugs.

11.4(2) *Medical director-based service programs.* ~~A service program shall maintain a formal written agreement with a medical director that is signed by the medical director and the service director.~~ An Iowa-licensed physician may enter into an agreement with a service program located in the state. The agreement shall be signed by the medical director and the service director and be maintained at the primary program site while the agreement is in effect. The agreement shall include an attestation that the medical director agrees to abide by these rules.

~~The medical director of the service program shall maintain a CSA registration and a DEA registration at the primary program site as required by rule 657—11.6(124,147A,155A).~~

ITEM 6. Amend renumbered rule 657—11.5(124,147A,155A) as follows:

657—11.5 (124,147A,155A) Termination of ~~services~~ agreement. ~~EMS services~~ A written agreement may be terminated at the discretion of either the ~~EMS~~ service program or the party or parties responsible for providing drugs to the ~~EMS~~ service program. Written notification of such termination shall be provided to the other party at least 30 days prior to termination of ~~services~~ the agreement. ~~Transfer of ownership of controlled substances shall be in compliance with rule 657—10.11(124).~~

11.5(1) *Pharmacy-based service programs.* Immediately upon discontinuation of ~~services~~ a written agreement, all controlled substances shall be jointly inventoried by the pharmacist in charge of the pharmacy that owns the drugs and the service director or their respective designees. A record of this inventory shall be maintained at the pharmacy for two years from the date of the inventory and be available for inspection and copying by the board, its representative, or other authorized individual. All drugs and devices that are the property of the pharmacy shall be immediately returned to the pharmacy.

11.5(2) *Medical director-based service programs.* Immediately upon discontinuation of ~~services~~ a written agreement, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years from the date of the inventory and be available for inspection and copying by the board, ~~the board's~~ its representative, or ~~another~~ other authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

11.5(3) *Transfer of ownership.* If drugs in a service program are to be maintained under the ownership of a new pharmacy or medical director, such transfer of ownership shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations. Pursuant to rule 657—10.34(124,155A), the transfer of Schedule II controlled substances shall require an executed DEA Form 222.

ITEM 7. Rescind and reserve rule **657—11.6(124,147A,155A)**.

ITEM 8. Amend rule 657—11.8(124,147A,155A) as follows:

657—11.8 (124,147A,155A) Identification.

~~**11.8(1)**~~ A log of employees who have access to prescription drugs and to records regarding procurement, storage, and administration of prescription drugs at the service program shall be maintained for two years and be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual. This log shall include ~~the employees'~~ each employee's printed ~~names~~ name and ~~signatures~~ signature, printed and signed initials or other unique identification used in service program records, and the ~~employees'~~ employee's ~~levels~~ level of certification. A service program may maintain an electronic record of employee identification, including the employee's name, signature, any unique identification used in the service program records, and level of certification. Such log shall be maintained for at least two years from the date of the employee's last date of employment with the service program and shall be available for inspection and copying by the board, its representative, or other authorized individual.

~~**11.8(2)** Policies and procedures shall be developed, implemented, and adhered to that identify at least the following:~~

~~*a.* Who has access to drugs.~~

~~*b.* Who has authority to administer drugs.~~

~~*c.* Who has authority to order, receive, and distribute prescription drugs and devices.~~

ITEM 9. Amend rule 657—11.10(124,147A,155A) as follows:

657—11.10(124,147A,155A) Ownership of prescription drugs. All prescription drugs obtained for use in a service program shall be owned either by a pharmacy or by the medical director of the service program.

11.10(1) *Pharmacy-based service programs.* If the drugs are owned by ~~the~~ a pharmacy or more than one pharmacy pursuant to these rules, the service program shall be considered a pharmacy-based service program and shall comply with these rules as they pertain to a pharmacy-based service program.

11.10(2) *Medical director-based service programs.* If the drugs are owned by the medical director, the service program shall be considered a medical director-based service program and shall comply with these rules as they pertain to a medical director-based service program.

11.10(3) *Combination pharmacy-based and medical director-based service programs.* If the service program has entered into both pharmacy-based and medical director-based service program agreements, both the pharmacy and the medical director shall retain separate ownership of the prescription drugs supplied and shall comply with these rules as applicable. The primary program site shall maintain a list that identifies which prescription drugs are owned and supplied by each responsible individual.

11.10(4) *Transfer of ownership.* Any transfer of ownership of prescription drugs and devices in a service program shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations.

ITEM 10. Amend rule 657—11.11(124,147A,155A) as follows:

657—11.11 (124,147A,155A) Policies and procedures.

11.11(1) ~~Each service program shall, jointly with the~~ The service director, medical director, and the responsible individual~~,~~ shall develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices in accordance with these rules. These policies and procedures shall be available for inspection and copying by the board, ~~the board's~~ its representative, or ~~another~~ other authorized individual. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director and shall identify the frequency of the review. Documentation of the review shall be maintained.

11.11(2) The policies and procedures shall address, at a minimum, the following:

a. Storage of drugs at the primary program site and any program substations including appropriate temperature ~~and humidity~~ controls, temperature monitoring and response when drugs are exposed to extreme temperatures ~~and security~~ pursuant to rule 657—11.13(124,147A,155A).

b. Storage of drugs at the primary program site and any program substations including adequate security to prevent diversion and unauthorized access to drugs and records pursuant to rule 657—11.13(124,147A,155A).

~~*b*~~*c.* Protocols for administration of drugs pursuant to rule 657—11.14(124,147A,155A).

~~*c*~~*d.* Administration of drugs outside the parameters of written protocols pursuant to rule 657—11.15(124,147A,155A).

e. Service program personnel matters including, but not limited to:

(1) Access to prescription drugs and records, identifying level of access based upon employee certification level and scope of practice.

(2) Authority to administer drugs based upon employee certification level and scope of practice.

(3) Authority to order, receive, and distribute prescription drugs and devices.

(4) Initial training and periodic review of the medication policies and procedures.

(5) Identification of registered nurses not employed by the service program that are authorized by the medical director pursuant to Iowa Code 147A.12 and pursuant to rules of the board of nursing to provide emergency care under the service program's protocol.

~~*d.* Record retention and format including:~~

~~(1) Ownership of drugs.~~

~~(2) Ordering of drugs and devices.~~

~~(3) Receipt of drugs and devices.~~

~~(4) Distribution or administration of drugs and devices.~~

~~(5) Inspections of the primary program site, program substations, and drug supplies.~~

~~(6) Inventories of controlled substances.~~

~~(7) Wastage resulting from the administration of a partial dose or supply of a drug.~~

~~(8) Drug or device returns.~~

ef. Process for the return of drugs pursuant to rule 657—11.22(124,147A,155A).

fg. Out-of-date and adulterated drugs pursuant to rule 657—11.23(124,147A,155A).

gh. Drug and device recalls pursuant to rule 657—11.24(124,147A,155A).

i. Monthly inspections pursuant to rule 657—11.20(124,147A,155A).

j. Record retention pursuant to rule 657—11.34(124,147A,155A) and these rules.

ITEM 11. Amend rule 657—11.13(124,147A,155A) as follows:

657—11.13 (124,147A,155A) Storage. Prescription drugs at primary program sites and program substations shall be stored in designated secure areas that are clean and free of debris, where temperature ~~and humidity are~~ is appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) *Temperature.* ~~All~~ Each ~~drugs~~ drug shall be stored ~~at~~ within the ~~proper~~ temperature range required in the manufacturer labeling. The service program shall utilize a method to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be ~~immediately removed from usable stock~~ quarantined and returned to the responsible individual for disposition. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). ~~Disposal~~ Disposition of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) *Security.* The security of prescription drugs, records for such drugs, and patient records is the responsibility of the responsible individual and shall provide for the effective control against theft of, diversion of, or unauthorized access to drugs and records. ~~Policies and procedures for the security of prescription drugs shall provide for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records. These policies and procedures shall indicate who has access to prescription~~

~~drugs.~~ Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

ITEM 12. Amend rule 657—11.14(124,147A,155A) as follows:

657—11.14 (124,147A,155A) Protocols. Every service program shall utilize department protocols as the standard of care. The service program medical director may ~~make changes to the department protocols~~ authorize an alternative protocol provided the ~~changes~~ directives are within the EMS provider's scope of practice, ~~and~~ within acceptable medical practice, and have been filed with the department. Prescription drugs shall be administered pursuant only to a written protocol or oral order by an authorized prescriber. ~~Records~~ A copy of the current ~~protocols~~ protocol shall be provided to and maintained by the responsible individual, ~~and~~ the service director, the primary program site and each program substation, and shall be available for inspection and copying by the board, its representative, or other authorized individual.

ITEM 13. Amend rule 657—11.15(124,147A,155A) as follows:

657—11.15 (124,147A,155A) Administration of drugs beyond the limits of ~~the~~ a written protocol. Drugs~~, excluding Schedule II controlled substances in a pharmacy-based service, as provided in rule 657—11.16(124,147A,155A),~~ may be administered beyond the limits of ~~the~~ a written ~~protocols~~ protocol provided that medical direction from an authorized prescriber has been obtained prior to administration. The authorization shall be recorded in the patient care report documenting the identity of the authorizing prescriber. If an agent of the authorized prescriber relayed the order, the identity of the prescriber's agent, including the agent's first and last names and title, shall also be recorded. Documentation of the administration of a Schedule II controlled substance in a pharmacy-based service program shall be pursuant to rule 657—11.16(124,147A,155A).

ITEM 14. Amend rule 657—11.16(124,147A,155A) as follows:

657—11.16 (124,147A,155A) Administration of Schedule II controlled substances—pharmacy-based service program. In a pharmacy-based service program, Schedule II controlled substances may be administered to patients under the care of a service program, including administration beyond the limits of a protocol when authorized pursuant to rule 657—11.15(124,147A,155A), provided that a signed order is delivered by the authorized prescriber to the pharmacy within ~~seven~~ 7 days of the date administration was authorized. The signed order shall contain all of the prescription information required pursuant to Iowa Code section 155A.27. The patient care report may be accepted as the required signed order if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber.

ITEM 15. Amend rule 657—11.20(124,147A,155A) as follows:

657—11.20 (124,147A,155A) Prescription drugs in ~~EMS~~ service programs. Prescription drugs maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

11.20(1) *Pharmacy-based service programs.* The pharmacist in charge, the medical director, and the service director shall jointly develop a list of drugs to be maintained for administration by the service program that is consistent with the service program's protocol. The pharmacy shall maintain ~~an~~ a ~~accurate~~ current list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided

that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date of ~~administered~~ administration. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or ~~a copy of~~ the patient care ~~record~~ report if the patient care ~~record~~ report includes the required prescription information, including an original signature of the authorizing prescriber. ~~The~~ A pharmacist shall ~~approve~~ verify the accuracy of every drug ~~taken from the pharmacy's dispensing stock prior to the transfer of the drug to the primary program site~~ to be disbursed to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Replenishment using automated medication distribution system (AMDS). A pharmacy utilizing ~~a~~ an ~~decentralized~~ automated medication distribution system (AMDS) ~~pursuant to 657—Chapter 9~~ may authorize replenishment of the service program's drug supplies from the AMDS provided that a pharmacist verifies the drugs stocked in the AMDS component before the drugs are removed from the pharmacy. Service program personnel authorized to remove drugs from the AMDS for restocking the service program's supplies shall be assigned a unique identification and access code for the purpose of accessing the AMDS. Access by authorized service program personnel shall be restricted to specific drug products authorized for use by the service program. A pharmacist shall, within 72 hours, ~~verify~~ review the access of and

removal of drugs from the AMDS by service program personnel and shall maintain documentation of that ~~verification~~ review within the pharmacy records.

c. *Inspections.* The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from ~~administration~~ service program stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years from the date of the inspection at the pharmacy. The pharmacist in charge may delegate the ~~conduct~~ completion of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or ~~the service director~~ another designee of the pharmacist in charge.

11.20(2) *Medical director-based service programs.* The medical director and the service director shall jointly develop a list of drugs to be maintained for administration by the service program that is consistent with the service program's protocol. The medical director shall maintain ~~an~~ a ~~accurate~~ current list of all prescription drugs including controlled substances that the medical director maintains at the primary program site and at any program substation. ~~EMS personnel shall have authority to handle prescription drugs and devices pursuant to their scope of practice as defined by the bureau.~~

a. *Replenishment.* All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, ~~a~~ pharmacy, or ~~an~~ authorized prescriber.

b. *Inspections.* The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated

drugs. Records of inspection shall be maintained for two years from the date of the inspection at the primary program site or the program substation. The medical director ~~or service director~~ may ~~designate EMS personnel to conduct~~ delegate the completion of the required inspections to the service director or other designee.

ITEM 16. Amend rule 657—11.22(124,147A,155A) as follows:

657—11.22 (124,147A,155A) Return of drugs. Drugs that have been removed from ~~administration~~ service program stock shall be returned to the responsible individual. In a pharmacy-based service program, drugs returned from the service program to the ~~base~~ pharmacy may be used by the pharmacy for subsequent dispensing or administration provided the drugs are not outdated or adulterated. Records of the return of prescription drugs shall be maintained by the responsible individual for two years from the date of the return.

ITEM 17. Amend rule 657—11.23(124,147A,155A) as follows:

657—11.23 (124,147A,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be administered beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from ~~administration~~ service program stock and quarantined until such drugs or devices are ~~properly disposed of or, if the service program is a pharmacy-based service,~~ returned to the ~~base pharmacy~~ responsible individual for disposition. ~~Outdated drugs are the property of the responsible individual and shall be disposed of appropriately. Outdated controlled substances shall be disposed of pursuant to rule 657—11.32(124,147A,155A).~~

ITEM 18. Amend rule 657—11.24(124,147A,155A) as follows:

657—11.24 (124,147A,155A) Product recall. ~~All~~ Each service ~~programs~~ program shall have a

~~system~~ procedure for removal from ~~administration~~ service program stock all ~~prescription~~ drugs or devices subject to a product recall. The ~~system~~ procedure shall include action appropriate to the direction or requirements of the recall.

ITEM 19. Amend rule 657—11.26(124,147A,155A) as follows:

657—11.26 (124,147A,155A) Controlled substances records.

11.26(1) *Records maintained.* Every inventory or other record required to be maintained under this chapter, 657—Chapter 10, or Iowa Code chapter 124 shall be maintained at the primary program site or the program substation and by the pharmacy if the service program is pharmacy-based. All required records shall be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual for at least two years from the date of such record. Controlled substances records shall be maintained in a readily retrievable manner. Schedule II controlled substances records shall be maintained separately from all other records of the registrant.

11.26(2) *Receipt and disbursement records in medical director-based service programs.* Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall provide to the service program a record of the disbursement and maintain a ~~records~~ record of ~~receipt and~~ the disbursement pursuant to rule 657—10.34(124,155A). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record shall ~~that~~ include the following:

a. to *e.* No changes.

ITEM 20. Amend rule 657—11.27(124,147A,155A) as follows:

657—11.27 (124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs. Except as otherwise provided by 657—subrule 10.34(7) and

under federal law, a DEA Form 222, preprinted with the address of the primary program site, is required to be maintained at the primary program site for the acquisition of each supply of a Schedule II controlled substance. The order form shall be executed only by the medical director named on the order form or by an authorized signer designated pursuant to a properly executed power of attorney. A DEA Form 222 shall be dated and signed as of the date the order is submitted for filling. A medical director or authorized signer shall not pre-sign a DEA Form 222 for subsequent completion. All Schedule II order forms shall be maintained at the primary program site and shall be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual for a period of two years from the date of the record.

ITEM 21. Amend rule 657—11.29(124,147A,155A) as follows:

657—11.29 (124,147A,155A) Schedule II controlled substances perpetual inventory. Each service program located in Iowa that administers Schedule II controlled substances shall maintain a perpetual inventory for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained at the primary program site and shall be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual for a period of two years from the date of the record.

11.29(1) *Record.* The perpetual inventory record may be maintained in a ~~manual~~ hard-copy or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed. ~~An~~ A ~~electronic~~ record entry, once recorded, shall not be changed; any adjustments or corrections shall require entry of a separate record as provided in subrule 11.29(3).

11.29(2) *Information included.* The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug name or by National Drug Code (NDC), including each patient administration, wastage, and return of a drug to the responsible individual~~, and disposal of a drug~~. The record of receipt shall also identify the source of the drug, the strength and dosage form, the quantity, the date of receipt, and the name or unique identification of the individual verifying receipt of the drug. The disbursement record shall identify where or to whom the drug is disbursed or administered, the strength and dosage form, the quantity, the date, and the name or unique identification of the individual responsible for the disbursement. Receipts and disbursements shall be recorded in the perpetual inventory as soon as practicable, but no later than 24 hours after the receipt, disbursement, or administration.

11.29(3) *Adjustments or corrections to the record.* Any adjustments or corrections made to the perpetual inventory shall include the identity of the person making the adjustment or correction and the reason for the adjustment or correction.

11.29(4) *Reconciliation.* The pharmacist in charge or designee in a pharmacy-based service program, or the medical director or designee in a medical director-based service program, shall be responsible for reconciling the ~~physical~~ perpetual inventory record of all Schedule II controlled substances with the ~~perpetual~~ physical inventory ~~balance on a periodic basis but no less frequently than~~ at least monthly. Any discrepancy shall be reported within 24 hours of the discovery to the ~~medical director and to the pharmacist in charge if the service program is a pharmacy-based program~~ responsible individual for investigation.

ITEM 22. Amend rule 657—11.30(124,147A,155A) as follows:

657—11.30 (124,147A,155A) Controlled substances annual inventory. An accurate inventory shall be taken annually of all controlled substances maintained at the primary program site and

program substations. Controlled substances in a pharmacy-based service program shall be included in the pharmacy's annual controlled substances inventory. The inventory record shall identify the drug name or National Drug Code (NDC) and the exact quantity under the control of the service program including drugs in replenishment stock and quarantined stock. The inventory record shall contain the date and time the inventory was taken and the printed name and signature of the individual or individuals responsible for the inventory record. Records of the inventory shall be maintained pursuant to rule 657—11.34(124,147A,155A).

ITEM 23. Amend rule 657—11.32(124,147A,155A) as follows:

657—11.32 (124,147A,155A) ~~Destruction or disposal~~ Disposition of controlled substances. ~~Disposal or destruction~~ Disposition of controlled substances shall be pursuant to the requirements of this rule, ~~and~~ rule 657—11.29(124,147A,155A), 657—Chapter 10, and federal regulations. Records shall be maintained at the primary program site and, if the service program is ~~a~~ pharmacy-based ~~service~~, records shall be maintained at the pharmacy.

11.32(1) *Outdated, adulterated, or unwanted supply.* ~~EMS personnel shall not destroy any controlled~~ Controlled substances shall not be destroyed except as provided in subrule 11.32(2). Any drug that requires ~~disposal or destruction~~ disposition shall be ~~removed from administration stock and~~ quarantined until the drug can be returned to the responsible individual. The responsible individual shall ~~dispose of or destroy~~ ensure the proper disposition of controlled substances according to the following procedures:

a. to *b.* No changes.

11.32(2) *Administration wastage.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient may be destroyed or otherwise disposed of by the administering ~~EMS~~

service program personnel, the medical director, or a pharmacist. Any wastage of a controlled substance shall be conducted in the presence of a responsible adult witness who is ~~a member of the EMS team~~ an authorized service program employee, a member of the professional or technician pharmacy staff, or a licensed health care professional. A written or electronic record of controlled substance wastage shall be ~~made~~ created and maintained at the primary program site and, if the service program is ~~a~~ pharmacy-based ~~service~~, at the pharmacy, for a minimum of two years following the ~~destruction or other disposal~~ disposition. The record shall include the signatures or other unique identification of the witness and of the individual destroying or otherwise disposing of the wastage of the controlled substance and shall identify the following:

a. to *d.* No changes.

e. ~~The~~ If either individual involved in the wastage is not identified in the service program identification log, the legibly printed first and last ~~names~~ name and title of the ~~person wasting the unused portions of the controlled substance and of the qualified witness~~ individual.

ITEM 24. Amend rule 657—11.33(124,147A,155A) as follows:

657—11.33 (124,147A,155A) Report of loss or theft of controlled substance. Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall ~~notify the DEA pursuant to rule 657—10.16(124) and federal regulations~~ provide notice and reporting as required in rule 657—10.16(124). ~~The responsible individual shall report in writing, on forms provided by the board or as directed by the board, any theft or significant loss of any controlled substance. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. A copy of the report shall be maintained at the primary program site and, if the program is a pharmacy-based service, at the pharmacy.~~

ITEM 25. Amend rule 657—11.34(124,147A,155A) as follows:

657—11.34 (124,147A,155A) Records. If a service program includes a primary program site and one or more program substations, ~~the~~ each ~~records~~ record ~~of the service program~~ shall identify the ~~primary program site and each program substation~~ specific location to which it applies. Records regarding service program substation activities, including drug supply and administration records, may be maintained at the primary program site but shall clearly identify the program substation to which the records apply. All records regarding prescription drugs and devices in a service program shall be maintained for two years from the date of the activity or record and be available for inspection and copying by the board, ~~or~~ its representative, or other authorized individual.

ADDENDUM T

NOTICE OF INTENDED ACTION

CHAPTER 2, "PHARMACIST LICENSES,"

NOVEMBER 2, 2016

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 2, "Pharmacist Licenses," Iowa Administrative Code.

The amendments were approved at the November 2, 2016, regular meeting of the Board of Pharmacy.

The proposed amendment decreases the waiting period for retaking the North American Pharmacist Licensure Examination (NAPLEX) from 91 days to 45 days, with a limit of three attempts to pass the NAPLEX within a 12-month period. With this decrease in the waiting period, no waivers or exceptions to the 45-day waiting period will be accepted or honored because reducing the waiting period to less than 45 days would pose a threat to the integrity of the NAPLEX. These proposed changes are the result of program changes implemented by the National Association of Boards of Pharmacy, who maintains and administers the national pharmacist license examinations.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34. However, no waivers or exceptions to the waiting periods will be accepted or honored in order to protect the integrity of the examinations.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on January 10, 2017. Such

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

After analysis and review of this rule making, no substantial impact on jobs has been found. However, reducing the waiting period between failure to pass the NAPLEX and the opportunity to retake the examination may result in an applicant for pharmacist licensure's faster entry into the practice work force.

This amendment is intended to implement Iowa Code sections 147.34 and 147.36.

The following amendment is proposed.

Amend rule 657—2.6(147) as follows:

657—2.6(147) Reexamination applications and fees. A candidate who fails to pass either the NAPLEX or the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination as provided in this rule. To ensure the integrity of the examinations, no waiver or variance of the specified waiting period between reexaminations will be granted.

2.6(1) NAPLEX. A candidate who fails to pass the NAPLEX once shall be allowed to schedule a time to retake the examination no less than ~~91~~ 45 days following administration of the failed examination. The candidate may be approved to retake the NAPLEX no more than three times in a 12-month period.

2.6(2) MPJE, Iowa Edition. A candidate who fails to pass the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination no less than 30 days following administration of the failed examination.

2.6(3) Reexamination after two or more attempts. A candidate who fails to pass either examination following a second or subsequent examination may petition the board for permission to take the examination again. Determination of a candidate's eligibility to take an examination more than two times shall be at the discretion of the board.

2.6(4) Applications and fees. Each applicant for reexamination shall file an application on forms provided by the board. Processing fees of $36 each will be charged to ~~take~~ retake NAPLEX or MPJE, Iowa Edition, and shall be paid to the board as provided in subrule 2.3(1). In addition, candidates will be required to complete the appropriate examination registration application as provided in rule 657—2.2(155A) and to pay to NABP the registration and administration fees for each examination as provided in subrule 2.3(2). All applications, registration forms, and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

ADDENDUM U

IOWA CODE 124

AN ACT REGARDING PRECURSOR SUBSTANCES, CONTROLLED SUBSTANCE SCHEDULES, AND PROVIDING PENALTIES

NOVEMBER 2, 2016

An Act regarding precursor substances, controlled substance schedules, and providing penalties.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.204, subsection 2, Code 2016, is amended by adding the following new paragraph:

NEW PARAGRAPH: bd.AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide.

Sec. 2. Section 124.204, subsection 9, Code 2016, is amended by adding the following new paragraphs:

NEW PARAGRAPH: g. N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Furanyl fentanyl.

NEW PARAGRAPH: h. N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Butyryl fentanyl.

NEW PARAGRAPH: i. N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: beta-hydroxythiofentanyl.

NEW PARAGRAPH: j. 3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: U-47700.

Sec. 3. Section 124.206, subsection 2, paragraph (a), Code 2016, is amended to read 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:

Sec. 4. Section 124.206, subsection 2, paragraph (d), Code 2016, is amended to read as follows:

d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), ~~. Decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine, are excluded from this paragraph. The following substances and their salts, optical and geometric isomers, derivatives, and salts of derivatives and optical and geometric isomers,~~ and any salt, compound, derivative, or preparation thereof that is chemically equivalent or identical to any of such substances, ~~are included in this paragraph~~ except that the substances shall not include:

(1) ~~Cocaine~~ Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(2) ~~Ecgonine~~ [\123\l]ioflupane.

Sec. 5. Section124.206, subsection 3, Code 2016, is amended by adding the following new paragraph:

NEW PARAGRAPH: ac. Thiafentanil.

Sec. 6. Section 124.208, subsection 5, paragraph (a), subparagraphs (3) and (4), Code 2015, are amended by striking the subparagraphs.

Sec. 7. Section 124.210, subsection 2, Code 2015, is amended by adding the following new paragraph:

NEW PARAGRAPH: c. 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol).

Sec. 8. Section 124.210, subsection 3, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: bb. Alfaxalone.

NEW PARAGRAPH: bc. Suvorexant.

Sec. 9. Section 124.210, subsection 7, Code 2015, is amended by adding the following new paragraph:

NEW PARAGRAPH: c. Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers.

Sec. 10. Section 124.210, subsection 7, Code 2015, is amended by adding the following new paragraph:

NEW PARAGRAPH: d. Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide), including its salts. Other names: BRV, UCB-34714, Briviact.

Sec. 11. Chapter 124B, Code 2015, is repealed

Sec. 12. Section 155A.6, subsection 3, Code 2016, is amended to read as follows:

3. The board shall establish standards for pharmacist-intern registration and may

deny, suspend, or revoke a pharmacist-intern registration for failure to meet the standards or for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, ~~124B,~~ 126, 147, or 205, or any rule of the board.

Sec. 13. Section 155A.6A, subsection 5, Code 2016, is amended to read as follows:

5. The board may deny, suspend, or revoke the registration of, or otherwise discipline, a registered pharmacy technician for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, ~~124B,~~ 126, 147, 205, or 272C, or any rule of the board.

Sec. 14. Section 155A.6B, subsection 5, Code 2016, is amended to read as follows:

5. The board may deny, suspend, or revoke the registration of a pharmacy support person or otherwise discipline the pharmacy support person for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, ~~124B,~~ 126, 147, 205, or 272C, or any rule of the board.

Sec. 15. Section 155A.13, subsection 5, paragraph "d," Code 2016, is amended to read as follows:

d. Any violation of this chapter or chapter 124, 124A, ~~124B,~~ 126, or 205, or rule of the board.

Sec. 16. Section 155A.13C, subsection 5, paragraph "d," Code 2016, is amended to read as follows:

d. Any violation of this chapter or chapter 124, 124A, ~~124B,~~ 126, or 205, or rule of the board.

Sec. 17. EFFECTIVE UPON ENACTMENT. Being deemed of immediate importance, this Act takes effect upon enactment.

EXPLANATION

The bill modifies the controlled substance schedules, provides penalties, and repeals Iowa Code Chapter 124B, the Iowa Precursor Substances Act. Sections 12 through 16 amend the disciplinary provisions in Iowa Code Chapter 155A by eliminating references to Iowa Code Chapter 124B.

The bill classifies four synthetic opioids as schedule I controlled substances in conformance with scheduling actions taken by the U.S. Department of Justice, Drug Enforcement Administration (DEA). The bill also classifies one [micro]-opioid receptor agonist with analgesic activity similar to morphine as a schedule I controlled substance. The board of pharmacy agrees with the DEA that these substances should be classified as schedule I controlled substances because each substance has a high potential for abuse and no accepted medical use in the United States.

The bill classifies thiafentanil, a potent opioid and analogue of fentanyl as a schedule II controlled substance. The board agrees with the DEA's assessment that this substance has a high potential for abuse consistent with classification in schedule II and that the substance has accepted medical use in the United States.

The bill removes hydrocodone-combination products from the list of substances classified as schedule III controlled substances. Hydrocodone, as a single-entity substance, is currently classified as a schedule II controlled substance. The change under the bill effectively makes all hydrocodone-containing products subject to the controls, security, reporting, and penalty provisions for schedule II controlled substances.

The bill removes naloxegol, a new molecular entity and derivative of naloxone, from control as a schedule III controlled substance. The federal Food and Drug Administration (FDA) approved naloxegol for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. The bill also removes [\123\I]ioflupane from control as a schedule II controlled substance. This substance is a new molecular entity and is the active pharmaceutical ingredient in the drug DaTscan, approved by the federal Food and Drug Administration for use in diagnosis of patients suspected of Parkinson's disease. Evidence supports the removal of [\123\I]ioflupane from control as a controlled substance.

The bill also classifies the substance commonly known as tramadol, a centrally acting opioid analgesic, as a schedule IV controlled substance. This substance was previously marketed and distributed as a noncontrolled prescription drug. Effective August 18, 2014, the federal Drug Enforcement Administration classified tramadol as a schedule IV controlled substance under federal law.

The bill classifies alfaxalone, a neurosteroid with central nervous system depressant properties, as a schedule IV controlled substance. The federal Food and Drug Administration (FDA) approved this intravenous injectable anesthetic for use by or

on the order of a licensed veterinarian. Alfaxalone is not available by prescription and is approved for use in veterinary practice.

The bill classifies suvorexant, an insomnia treatment approved by the federal Food and Drug Administration, as a schedule IV controlled substance. This is a novel, first in class, chemical substance and information on actual abuse data is not available. However, data from clinical studies support the classification in schedule IV.

The bill classifies eluxadoline, a new entity with central nervous system opioid properties approved by the FDA for the treatment of irritable bowel syndrome with diarrhea, as a schedule IV controlled substance. Brivaracetam, also known as Briviact or BRV, is classified as a schedule V controlled substance. BRV is a new molecular entity with central nervous system depressant properties and has been approved as an add-on treatment to other medications to treat partial onset seizures in patients age 16 years and older with epilepsy.

It is a class "C" felony pursuant to Code section 124.401(1)(c)(8) for any unauthorized person to violate a provision of Code section 124.401, involving a classified substance placed in schedule I, II, or III pursuant to the bill. A class "C" felony for this particular offense is punishable by confinement for no more than 10 years and a fine of at least $1,000 but not more than $50,000.

It is an aggravated misdemeanor pursuant to Code section 124.401(1)(d) for any unauthorized person to violate a provision of Code section 124.401 involving a classified substance placed in schedule IV pursuant to the bill. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least $625 but not more than $6,250.

If a person possesses a controlled substance in violation of Code section 124.401(5) as a first offense, the person commits a serious misdemeanor. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least $315 but not more than $1,875.

Being deemed of immediate importance, this Act takes effect upon enactment. The provisions of the Act address imminent threats to the public safety by appropriately classifying dangerous substances as controlled substances and removes or adds substances that are approved to treat human diseases and improve patient health and welfare.

ADDENDUM V

IOWA CODE 155A

AN ACT RELATING TO ALTERNATE BOARD MEMBERS, DRUG DISPOSAL PROGRAM FUNDING, IMPAIRED PROFESSIONALS PROGRAM, PHARMACY INTERNET SITES, AND THE DEFINITION OF "PRACTIONER"

NOVEMBER 2, 2016

An Act relating to alternate board members, drug disposal program funding, impaired professionals program, pharmacy internet sites, and the definition of "practitioner."

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Chapter 155A, Iowa Code 2016, is amended by adding the following new section:

NEW SECTION: 155A.2A Board of pharmacy – alternate members.

1. Notwithstanding sections 17A.11, 69.16, 69.16A, 147.12, 147.14, and 147.19, the board may have a pool of up to seven alternate members, including members licensed to practice under this chapter and members not licensed to practice under this chapter, to substitute for board members who are disqualified or become unavailable for any other reason for contested case hearings.

a. The board may recommend, subject to approval by the governor, up to seven people to serve in a pool of alternate members.

b. A person serves in the pool of alternate members at the discretion of the board; however, the length of time an alternate member may serve in the pool shall not exceed nine years. A person who serves as an alternate member may later be appointed to the board and may serve nine years, in accordance with sections 147.12 and 147.19. A former board member may serve in the pool of alternate members.

c. An alternate member licensed under this chapter shall hold an active license and shall have been actively engaged in the practice of pharmacy in the preceding three years, with the two most recent years of practice being in Iowa.

d. When a sufficient number of board members are unavailable to hear a contested

case, the board may request alternate members to serve.

e. Notwithstanding section 17A.11, section 147.14, subsection 2, and section 272C.6, subsection 5:

(1) An alternate member is deemed a member of the board only for the hearing panel for which the alternate member serves.

(2) A hearing panel containing alternate members must include at least five people.

(3) The majority of a hearing panel containing alternate members shall be members of the board.

(4) The majority of a hearing panel containing alternate members shall be licensed to practice under this chapter.

(5) A decision of a hearing panel containing alternate members is considered a final decision of the board.

f. An alternate member shall not receive compensation in excess of that authorized by law for a board member.

Sec. 2. Section 155A.3, subsection 35, Iowa Code 2016, is amended to read as follows:

35. *"Practitioner"* means a physician, dentist, podiatric physician, veterinarian, optometrist, physician assistant, advanced registered nurse practitioner, or other person licensed or registered to prescribe, distribute, or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.

Sec. 3. Section 155A.13B, Iowa Code 2016, is repealed.

Sec. 4. Section 155A.39, Iowa Code 2016, is amended to read as follows:

155A.39 ~~Programs~~ Program to ~~aid~~ monitor impaired pharmacists, pharmacist-interns, or pharmacy technicians — ~~reporting, confidentiality,~~ immunity~~,~~ and funding.

1. ~~A person or pharmaceutical peer review committee may report relevant facts to the board relating to the acts of a pharmacist in this state, a pharmacist intern as defined in section 155A.3, subsection 30, or a pharmacy technician in this state if the person or peer review committee has knowledge relating to the pharmacist, pharmacist intern, or pharmacy technician which, in the opinion of the person or pharmaceutical peer review committee, might impair competency due to chemical abuse, chemical dependence, or mental or physical illness, or which might endanger the public health and safety, or which provide grounds for disciplinary action as specified in this chapter and in the rules of the board.~~ The board may establish a review committee and may implement a program to monitor impaired pharmacists, pharmacist-interns, and pharmacy technicians pursuant to section 272C.3, subsection 1, paragraph "k."

~~2. A committee of a professional pharmaceutical organization, its staff, or a district or local intervenor participating in a program established to aid pharmacists, pharmacist-interns, or pharmacy technicians impaired by chemical abuse, chemical dependence, or mental or physical illness may report in writing to the board the name of the impaired pharmacist, pharmacist intern, or pharmacy technician together with pertinent information relating to the impairment. The board may report to a committee of a professional pharmaceutical organization or the organization's designated staff information which the board receives with regard to a pharmacist, pharmacist intern, or pharmacy technician who may be impaired by chemical abuse, chemical dependence, or mental or physical illness.~~

~~3. Upon determination by the board that a report submitted by a peer review~~

committee or a professional pharmaceutical organization committee is without merit, the report shall be expunged from the pharmacist's, pharmacist-intern's, or pharmacy technician's individual record in the board's office. A pharmacist, pharmacist-intern, pharmacy technician, or an authorized representative of the pharmacist, pharmacist-intern, or pharmacy technician shall be entitled on request to examine the peer review committee report or the pharmaceutical organization committee report submitted to the board and to place into the record a statement of reasonable length of the pharmacist's, pharmacist-intern's, or pharmacy technician's view with respect to any information existing in the report.

4. Notwithstanding other provisions of the Code, the records and proceedings of the board, its authorized agents, a peer review committee, or a pharmaceutical organization committee as set out in subsections 1 and 2 shall be privileged and confidential and shall not be considered public records or open records unless the affected pharmacist, pharmacist-intern, or pharmacy technician so requests and shall not be subject to a subpoena or to a discovery proceeding. The board may disclose the records and proceedings only as follows:

a. In a criminal proceeding.

b. In a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order.

c. To the pharmacist licensing or disciplinary authorities of other jurisdictions.

d. To the pharmacy technician registering, licensing, or disciplinary authorities of other jurisdictions.

e. Pursuant to an order of a court of competent jurisdiction.

~~f. Pursuant to subsection 11.~~

~~g. As otherwise provided by law.~~

~~5.~~ 2. An employee or a member of the board, a peer review committee member, ~~a professional pharmaceutical organization committee member, a professional pharmaceutical organization district or local intervenor,~~ or any other person who furnishes information, data, reports, or records in good faith for the purpose of aiding the impaired pharmacist, pharmacist-intern, or pharmacy technician, shall be immune from civil liability. This immunity from civil liability shall be liberally construed to accomplish the purpose of this section and is in addition to other immunity provided by law.

~~6.~~ 3. An employee or member of the board or a peer review committee ~~or intervenor program~~ member is presumed to have acted in good faith. A person alleging a lack of good faith has the burden of proof on that issue.

~~7. The board may contract with professional pharmaceutical associations or societies to provide a program for pharmacists, pharmacist-interns, and pharmacy technicians who are impaired by chemical abuse, chemical dependence, or mental or physical illness. Such programs shall include, but not be limited to, education, intervention, and posttreatment monitoring. A contract with a professional pharmaceutical association or society shall include the following requirements:~~

~~a. Periodic reports to the board regarding education, intervention, and treatment activities.~~

~~b. Immediate notification to the board's executive secretary or director or the executive secretary's or director's designee of the identity of the pharmacist, pharmacist-intern, or pharmacy technician who is participating in a program to aid impaired~~

~~pharmacists, pharmacist-interns, or pharmacy technicians.~~

~~*c.* Release to the board's executive secretary or director or the executive secretary's or director's designee upon written request of all treatment records of a participant.~~

~~*d.* Quarterly reports to the board, by case number, regarding each participant's diagnosis, prognosis, and recommendations for continuing care, treatment, and supervision which maintain the anonymity of the participant.~~

~~*e.* Immediate reporting to the board of the name of an impaired pharmacist, pharmacist-intern, or pharmacy technician who the treatment organization believes to be an imminent danger to either the public or to the pharmacist, pharmacist-intern, or pharmacy technician.~~

~~*f.* Reporting to the board, as soon as possible, the name of a participant who refuses to cooperate with the program, who refuses to submit to treatment, or whose impairment is not substantially alleviated through intervention and treatment.~~

~~*g.* Immediate reporting to the board of the name of a participant where additional information is evident that known distribution of controlled substances or legend drugs to other individuals has taken place.~~

~~8.~~ 4. The board may add a surcharge of not more than ten percent of the applicable fee to a pharmacist license fee, pharmacist license renewal fee, pharmacist-intern registration fee, pharmacy technician registration fee, or pharmacy technician registration renewal fee authorized under this chapter to fund ~~programs~~ a program to ~~aid~~ monitor impaired pharmacists, pharmacist-interns, or pharmacy technicians.

~~9.~~ 5. The board may accept, transfer, and expend funds made available by the federal or state government or by another public or private source to be used in ~~programs~~ a

program authorized by this section. ~~The board may contract to provide funding on an annual basis to a professional pharmaceutical association or society for expenses incurred in management and operation of a program to aid impaired pharmacists, pharmacist-interns, or pharmacy technicians. Documentation of the use of these funds shall be provided to the board not less than annually for review and comment.~~

~~10.~~ 6. Funds and surcharges collected under this section shall be deposited in an account and may be used by the board to administer ~~programs~~ a program authorized by this section~~, including the provision of education, intervention, and posttreatment monitoring to an impaired pharmacist, pharmacist-intern, or pharmacy technician and to pay the administrative costs incurred by the board in connection with that funding and appropriate oversight,~~ but shall not be used for costs incurred for a participant's initial evaluation, referral services, treatment, or rehabilitation subsequent to intervention.

~~11.~~ 7. The board may disclose that the license of a pharmacist, the registration of a pharmacist-intern, or the registration of a pharmacy technician who is the subject of an order of the board that is confidential pursuant to ~~subsection 4~~ section 272C.6 is suspended, revoked, canceled, restricted, or retired; or that the pharmacist, pharmacist-intern, or pharmacy technician is in any manner otherwise limited in the practice of pharmacy; or other relevant information pertaining to the pharmacist, pharmacist-intern, or pharmacy technician which the board deems appropriate.

~~12.~~ 8. The board may adopt rules necessary for the implementation of this section.

Sec. 5. Section 155A.43, Iowa Code 2016, is amended to read as follows:

155A.43 Pharmaceutical collection and disposal program — annual allocation.

Of the fees collected by the board pursuant to sections 124.301 and 147.80 and this chapter ~~155A by the board of pharmacy,~~ and retained by the board pursuant to section 147.82, ~~not more than one hundred seventy-five thousand dollars may be allocated~~ the board may annually allocate a sum deemed by the board to be adequate for administering the pharmaceutical collection and disposal program ~~originally established pursuant to 2009 Iowa Acts, ch. 175, §9~~. The program shall provide for the management and disposal of unused, excess, and expired pharmaceuticals including the management and disposal of controlled substances pursuant to state and federal regulations. The board ~~of pharmacy~~ may ~~cooperate~~ contract with ~~the Iowa pharmacy association and may consult with the department and sanitary landfill operators in administering~~ one or more vendors for the provision of supplies and services to manage and maintain the program and to safely and appropriately dispose of pharmaceuticals collected through the program.

EXPLANATION

The bill permits the board to recommend, subject to approval by the governor, a pool of up to seven qualified individuals to serve as alternate board members to ensure the availability of an unbiased quorum of board members to hear a contested case. The bill identifies the maximum term for an alternate board member, provides that an individual who previously served on the board may serve as an alternate board member, provides for compensation when the alternate member serves on a hearing panel, establishes requirements for the composition of a hearing panel containing alternate board members, and provides that the decision of a hearing panel containing alternate board members is

considered a final decision of the board.

The bill amends the definition of "practitioner" to specifically identify the licensed health care practitioners that are authorized under Iowa law to prescribe, distribute, or dispense prescription drugs and devices to patients in the course of professional practice in this state.

The bill also amends provisions regarding the program to monitor impaired pharmacists, pharmacist-interns, and pharmacy technicians, eliminating duplicative and confusing provisions relating to the program and directing that the program be implemented pursuant to Iowa Code section 272C.3, subsection 1, paragraph "k," which authorizes all Iowa health licensing boards to establish similar programs. The amendments regarding this program retain existing provisions regarding immunity from civil liability and presumed good faith actions, the authority of the board to impose a surcharge not exceeding ten percent of the applicable fee for pharmacist license and renewal fees, pharmacist-intern registration fee, and pharmacy technician registration and renewal fees. Also retained is the authority of the board to receive, transfer, and expend funds from any public or private source to be used to support the program and provides that program funds be deposited in an account established for the administration of the program. The bill specifically identifies the limited information that may be disclosed regarding the license or registration of any individual subject to monitoring under the program and authorizes the board to adopt rules to implement the section.

The bill amends provisions of the pharmaceutical collection and disposal program to authorize the board to allocate a sum from fees retained by the board to support board activities that the board has determined to be adequate for administering the

pharmaceutical collection and disposal program. The bill further authorizes the board to contract with one or more vendors to manage and maintain the program in compliance with federal and state regulations.

The bill repeals all provisions regarding the registration and regulation of Internet pharmacy sites and pharmacies associated or aligned with Internet pharmacy sites. Since enactment of this section, the board has identified and registered a total of five such sites and the board believes that the federal Food and Drug Administration, Customs Department, and the National Association of Boards of Pharmacy are better situated and equipped to identify, monitor, and regulate Internet pharmacy sites.

ADDENDUM W

PRELIMINARY NOTICE OF INTENT TO DENY LICENSE

PACIFICO NATIONAL INC.,
d/b/a AMEX PHARMACY
MELBOURNE, FLORIDA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Iowa Wholesale Drug License Application of **PACIFICO NATIONAL INC.,** **d/b/a Amex Pharmacy** Applicant.	)))))))	**PRELIMINARY NOTICE OF INTENT TO DENY LICENSE**

TO: Pacifico National, Inc.
d/b/a Amex Pharmacy
1515 Elizabeth St., Ste. J
Melbourne, FL 32901

YOU ARE HEREBY NOTIFIED that on the 31st day of August, 2016, the Iowa Board of Pharmacy ("Board") voted to deny your application for an Iowa wholesale drug license. The intent to deny license is based upon the following:

FACTUAL CIRCUMSTANCES

1. On July 20, 2016, the Board received an Iowa wholesale drug license application from Pacifico National, Inc.

2. On the license application, Applicant answered "No" to the question "Have any of the applicant(s) and/or manager(s) in charge had: 1) any convictions relating to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension or revocation of licensure for the manufacture or distribution of drugs by federal, state, or local laws of any license currently or previously held by the applicant(s) or manager(s) in charge in any of the United States? Have any applications for licensure been denied by any federal or state agency?"

3. The following actions have been taken against licenses or registrations held by Applicant:

a. On February 29, 2016, the State of Florida Department of Health issued an Order of Emergency Restriction of Permit, which restricted Applicant from compounding sterile preparations for human use in the State of Florida. The emergency restriction was lifted on April 22, 2016. An administrative complaint in case no. 2015-06647 remains pending in Florida.

b. On March 31, 2016, the North Carolina Board of Pharmacy approved Applicant's Voluntary Surrender of Permit for Cause.

c. On April 7, 2016, the State Board of Pharmacy of South Carolina issued an Order restricting Applicant from shipping compounded products into South Carolina.

d. On July 1, 2016, the Alabama State Board of Pharmacy issued a Final Order suspending Applicant's non-resident permit for 5 years and imposing a $9000 administrative fine.

LEGAL GROUNDS

4. Applicants for an Iowa wholesale drug license must apply for a license in accordance with Iowa Code section 155A.17 and 657 IAC chapter 17.

5. The Board has the authority to deny an Iowa wholesale drug license for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States relating to prescription drugs, devices, or controlled substances, or for a violation of chapters 124, 124A, 124B, 126, 155A, 205, or a rule of the board. *See* Iowa Code section 155A.17(2) and 657 IAC 17.18.

6. Pursuant to 657 IAC 36.1(4)"ad", the board may deny a license for violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state. The actions taken by the State of Florida Department of Health, the North Carolina Board of Pharmacy, the State Board of Pharmacy of South Carolina, and the Alabama State Board of Pharmacy Applicant's serve as a basis for denying its application.

7. Pursuant to 657 IAC 36.1(4)"a", the board may deny a registration for fraud in procuring a license. Fraud in procuring a license includes but is not limited to an intentional perversion of the truth in making application for a license to practice pharmacy, to operate a pharmacy doing business in this state, or to operate as a wholesale drug distributor doing business in this state, or in making application for a registration to practice as a pharmacist-intern, a pharmacy technician, or a pharmacy support person. It includes false representations of a material fact, whether by word or conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application, or attempting to file or filing with the board any false or forged diploma, certificate, affidavit, identification, or qualification in making application for a license or registration in this state. Applicant's failure to disclose the above described actions serve as a basis for denying its application.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of 657 IAC 36.16, you may appeal the Board's preliminary notice of denial of license by serving a written notice of appeal and request for hearing upon the Board not more than thirty (30) days following the date of service of this notice. Applicant's written notice of appeal and request for a hearing should be directed to Andrew Funk, Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The written notice of appeal and request for hearing shall specifically describe the

facts to be contested and determined at the hearing. The hearing shall be a contested case conducted pursuant to the procedures outlined in 657 IAC chapter 35.

If a written notice of appeal and request for hearing is not timely filed, this preliminary notice of intent to deny license will become final, and the Iowa wholesale drug license application for Pacifico National, Inc. will be DENIED.

DATED this 3 day of November, 2016.

Andrew Funk, Pharm.D., Executive Director
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Office of the Attorney General of Iowa
1305 E. Walnut St.
Des Moines, IA 50319
ATTORNEY FOR THE STATE