MINUTES

August 29-30, 2017

The Iowa Board of Pharmacy met on August 29-30, 2017, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

TUESDAY, AUGUST 29, 2017

MEMBERS PRESENT
Edward J. McKenna, Vice-Chair
Brett Barker
LaDonna Gratias
Jason Hansel
Gayle Mayer
Joan Skogstrom

MEMBERS ABSENT
Sharon K. Meyer, Chair

STAFF PRESENT
Andrew Funk, Executive Director
Laura Steffensmeier, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Amanda Woltz, Administrative Assistant
Jennifer Tiffany, Associate Director - PMP
Becky Hall, Secretary
Christie Carlson, Compliance Officer
Curtis Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O’Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Daniel Sedlacek, Compliance Officer
James Wolfe, Compliance Officer
Ve Kheuakham, Pharmacist-Intern

Call to Order
At 9:04 a.m., Edward McKenna, Vice-Chair, called the meeting of the Iowa Board of Pharmacy to order on Tuesday, August 29, 2017.
**Closed Session**

At 9:05 a.m., on a motion by Jason Hansel, seconded by Gayle Mayer, 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.

At 3:50 p.m., while still in closed session, Brett Barker moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

In open session the following actions were taken:

1. **Closed Session Minutes.**
   
   Motion by Jason Hansel, seconded by LaDonna Gratias, to approve the Closed Session Minutes of the June 28, 2017, meeting. Motion approved unanimously.

2. **Closed Session Teleconference Minutes.**
   
   Motion by Brett Barker, seconded by Jason Hansel, to approve the Closed Session Minutes of the July 24, 2017, teleconference meeting. Motion approved unanimously.

3. **Close With No Further Action.**
   

4. **Order to Show Cause.**
   
   Motion by Jason Hansel, seconded by Gayle Mayer, to issue an Order to Show Cause in 2017-121, Joseph Shader, M.D., Controlled Substance Registration No. 1246591, Iowa City. Motion approved unanimously. A copy of the Order to Show Cause is attached as Addendum A.

5. **Notice of Hearing and Statement of Charges.**
   
   Motion by LaDonna Gratias, seconded by Gayle Mayer, to approve the Notice of Hearing and Statement of Charges in the following cases. Motion approved unanimously.
   
   A. 2017-26, Stoner Drug Co., Inc., Pharmacy License No. 371, Hamburg. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum B.
   
   B. 2017-26, Phillip Kuhr, Pharmacist License No. 15518, Hamburg. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum C.

6. **Administrative Warning.**
   
   Motion by Gayle Mayer, seconded by LaDonna Gratias, to issue an Administrative Warning to the pharmacist in charge and pharmacy in 2017-51; and pharmacist in charge and pharmacy in 2017-84. Motion approved unanimously.
7. Notice of Intent to Deny.

Motion by Brett Barker, seconded by Jason Hansel, to issue a Notice of Intent to Deny Registration in 2017-97, Virginia Rock, New Hartford. A copy of the Notice of Intent to Deny Registration is attached as Addendum D. Motion approved unanimously.


Motion by Jason Hansel, seconded by LaDonna Gratias, to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in 2017-108, Jeffrey Allen Killian, Pharmacist License No. 19549, San Diego, California. Motion approved unanimously. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum E.


Motion by Gayle Mayer, seconded by LaDonna Gratias, to issue a Letter of Education to the pharmacist and technician in 2017-103, pharmacy in 2017-17, technician in 2017-51, and pharmacist and technician in 2017-1. Motion approved unanimously.

10. Letter of Education.

Motion by Brett Barker, seconded by Gayle Mayer, to issue a Letter of Education to the pharmacist in charge and technician in 2017-106. Jason Hansel abstained. Motion passed.

11. Settlement Agreement and Final Order.

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

A. 2016-43, Charles Alan Robinson, Pharmacist License No. 13371, Estherville. A copy of the Settlement Agreement and Final Order is attached as Addendum F.

B. 2016-193, Martha Morin, Pharmacist License No. 15348, Akron. A copy of the Settlement Agreement and Final Order is attached as Addendum G.

C. 2016-193, Thorson Drug, Inc., Pharmacy License No. 457, Akron. A copy of the Settlement Agreement and Final Order is attached as Addendum H.

D. 2017-35, Walgreens #05721, Pharmacy License No. 355, Des Moines. A copy of the Settlement Agreement and Final Order is attached as Addendum I.

E. 2017-36, Peterson Drug, Pharmacy License No. 1606, Williamsburg. A copy of the Settlement Agreement and Final Order is attached as Addendum J.

F. 2017-36, Mark Vogt, Pharmacist License No. 18113, Arlington, Nebraska. A copy of the Settlement Agreement and Final Order is attached as Addendum K.

G. 2017-16, LaDona K. Hart, Pharmacy Technician Trainee Registration No. 23479, Dysart. A copy of the Settlement Agreement and Final Order is attached as Addendum L.

At 4:00 p.m. the Board recessed.
The meeting reconvened in open session on Wednesday, August 30, 2017, at 9:00 a.m.

WEDNESDAY, AUGUST 30, 2017

MEMBERS PRESENT
Edward J. McKenna, Vice-Chair
Brett Barker
LaDonna Gratias
Jason Hansel
Gayle Mayer
Joan Skogstrom

MEMBERS ABSENT
Sharon K. Meyer, Chair

SPEAKERS
Tah Tangyie, Iowa City
Helen Eddy, Hy-Vee
Anthony Pudlo, IPA
Kate Gainer, IPA
Megan Myers, IPA
Cheri Schmit, Medicap/GRX
Julie Panosh, Dyersville
Steven Martens, NuCara
Angie Nelson, Hy-Vee

STAFF PRESENT
Laura Steffensmeier, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Amanda Woltz, Administrative Assistant
Jennifer Tiffany, Associate Director - PMP
Becky Hall, Secretary
Christie Carlson, Compliance Officer
Curtis Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jennifer O'Toole, Compliance Officer
Jean Rhodes, Compliance Officer
Daniel Sedlacek, Compliance Officer
James Wolfe, Compliance Officer
Ve Kheuakham, Pharmacist-Intern

STAFF ABSENT
Andrew Funk, Executive Director

Call to Order and Announcements
At 9:00 a.m., Edward J. McKenna, Vice-Chair, called the meeting of the Iowa Board of Pharmacy to order on Wednesday, August 30, 2017.

Introductions
Christie Carlson has accepted the position of Compliance Officer with the Board and began her position on Friday, August 11, 2017.

Ve Kheuakham is the current APPE student from the University of Iowa and will complete a five week rotation with the board office.

Public Comments
No public comments.

Approval of Open Session Minutes
The minutes of the June 28, 2017, Open Session Meeting and July 24, 2017, Teleconference Open Session were reviewed.
Motion by Brett Barker, seconded by Joan Skogstrom, to approve the Open Session Minutes of the June 28, 2017, meeting as presented. Motion approved unanimously.

Motion by Jason Hansel, seconded by Joan Skogstrom, to approve the Open Session Minutes of the July 24, 2017, teleconference meeting as presented. Motion approved unanimously.

**Requests**

1. Request to Delegate Authority to Staff to Approve Request to Extend Internship Hours to Obtain Licensure in Iowa.
   
   Motion by Brett Barker, seconded by Gayle Mayer, to approve request to delegate authority to staff to approve requests to extend internship hours to obtain licensure in Iowa. Motion approved unanimously.

2. Request to Extend Internship Hours - Tah Tangie, Iowa City.
   
   Motion by Jason Hansel, second by Brett Barker, to approve Mr. Tangie’s request extending his internship hours until December 23, 2017, to obtain licensure in Iowa. Motion approve unanimously.

   
   The Board requested additional information from Ms. Jumah and delegated authority to board staff to administratively approve her request to extend her internship hours to obtain licensure in Iowa once the additional information is received and reviewed by board staff.

**Licensure/Registration Application Review**

1. Application for Pharmacy Technician Trainee Registration – Ann Bishop, Indianola.
   
   Motion by Brett Barker, seconded by Joan Skogstrom, to approve the Application for Pharmacy Technician Registration. Motion approved unanimously.

2. Iowa Wholesale Drug License Application – Premier Distribution, West Des Moines.
   
   Motion by Brett Barker, seconded by Jason Hansel, to deny the Iowa Wholesale Drug License Application. Motion approved unanimously.

**Reports**

1. Executive Officer’s Report -
   
   Database Update - iGov Solutions LLC, Lake Mary, Florida, was selected to be the vendor for the board office’s new database. iGov Solutions LLC is currently in the process of working on a contract. Board staff has provided them with the board office’s database information to begin the process of merging and setting up the new database. An onsite visit is scheduled for the week of October 9, 2017, to identify any issues and address the functionality of the new database.
Office Remodel – The Department of Administrative Services (DAS) and a contractor visited the board office to evaluate the remodel project. DAS will be taking over the remodel project from Hubbell. The timeline for the remodel has been extended to late September.

USP <800> - Director Funk received communication from NABP that there are no plans to delay or modify USP<800> before it goes into effect in July of 2018.


Jennifer Tiffany provided a summary of the report.

Jennifer Tiffany and Andrew Funk attended the 2nd Annual Overdose Awareness Day Event in Dubuque on August 26, 2017, representing the Board and promoting safe medication disposal.

Board staff has discussed a Prescription Monitoring Program (PMP)/Electronic Health Record (EHR) integration pilot program to include two retail and two hospital pharmacies.

The Request for Proposal (RFP) for the upgraded PMP software was published September 1, 2017. Expected vendor selection is slated for mid November 2017. It is anticipated a contract for the new system will be signed by January 1, 2018.

3. Iowa Monitoring Program for Pharmacy Professionals (IMP3) – Jennifer O’Toole.

Jennifer O’Toole provided a summary of the report.

There are currently 13 participants in the program. The Iowa Board of Pharmacy and the Iowa Pharmacy Association (IPA) are working together to offer IMP3 Live presentations throughout the state of Iowa to educate pharmacy professionals on the program.

Earlier presentations included the cities of Dubuque, Council Bluffs, Spencer, Waverly, and Iowa City. Remaining locations for 2017 are scheduled for the Quad Cities, September 2; Des Moines, October 12; and Mason City, October 19. Ms. O’Toole has also presented to Hy-Vee manager’s meetings, NuCara Pharmacy, Medicap, and will be presenting to Walgreens, Drake’s Alcohol Summit, and the University of Iowa.

4. Litigation Update – Laura Steffensmeier.

The Board currently has two pending cases.

- Carl Olsen vs the Iowa Board of Pharmacy. Mr. Olsen appealed the Board’s 2015 recommendation to the legislature regarding marijuana scheduling. The Court of Appeals on August 2, 2017, affirmed the Board’s decision. Mr. Olsen filed an application for further review to the Iowa Supreme Court. The Iowa Supreme Court will make the decision whether or not to hear the application for further review.
• Wells Pharmacy vs the Iowa Board of Pharmacy regarding a contested case. Wells Pharmacy is appealing the Board’s decision. This case has been submitted to the Court of Appeals as a non-oral submission.

5. Hy-Vee Pharmacy Fulfillment Center’s 2017 Quarter Two Error Report.

Hy-Vee Pharmacy Fulfillment Center submitted their 2017 Quarter Two Error Report for review. Helen Eddy provided a summary of the report.

6. UnityPoint Health – Allen Hospital’s 2017 Tech-Check-Tech Quarter Two Report.

UnityPoint Health – Allen Hospital submitted their 2017 Quarter Two Tech-Check-Tech Report for review.

7. Iowa’s Medication Disposal Program for Non-Controlled Substances Quarterly Report for April-June 2017 – Iowa Pharmacy Association (IPA.)

IPA provided their Quarterly Report for Iowa’s Medication Disposal Program for Non-Controlled Substances for review. Anthony Pudlo provided a summary of the report and addressed the Board regarding any questions they may have concerning the report.

8. New Practice Model for Community Pharmacy – Phase Three, Quarter Four Report and Phase Four, Quarter Four Report – IPA.

Kate Gainer shared the history, timeline, and future vision for the New Practice Model for Community Pharmacy. Ms. Gainer discussed the reason why IPA started a new practice task force and new practice pilot proposal to address the needs of community based pharmacists. A legislative change would be necessary to move forward and IPA plans to make this one of their legislative priorities.

IPA provided their Phase Three, Quarter Four Report and Phase Four, Quarter Four Report for review. Megan Myers provided a summary of the report and addressed the Board regarding any questions they may have concerning the report.


Mercy Family Pharmacy submitted their Phase Four, Quarter Four Report for review. Julie Panosh was present and provided a summary of the report.


NuCara submitted their 2017 Quarter Two Telepharmacy Report for review. Steven Martens was present to address questions from the Board.

Rules

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


Motion by Brett Barker, seconded by Gayle Mayer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as addendum N.

3. Proposed for Adoption and Filing – Amending Chapter 34, “Rules for Waivers and Variances.”

Motion by Joan Skogstrom, seconded by Gayle Mayer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum O.


Motion by Jason Hansel, seconded by Joan Skogstrom, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum P.


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


Motion by Brett Barker, seconded by Joan Skogstrom, to approve for Notice of Intended Action. Motion approved unanimously. A copy is attached as Addendum R.


Motion by Joan Skogstrom, seconded by Brett Barker, to approve for Notice of Intended Action. Motion approved unanimously. A copy is attached as Addendum S.


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

9. Notice of Intended Action – Amending Chapter 6, “General Pharmacy Practice.”

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

Motion by Joan Skogstrom, seconded by Brett Barker, to approve for Notice of Intended Action. Motion approved unanimously. A copy is attached as Addendum V.

New Business
Application for Iowa Telepharmacy License and Board Action on Process to Transition Current Pilot Programs.
Motion by Jason Hansel, seconded by Gayle Mayer, to extend the current telepharmacy pilot programs until January 1, 2018. Brett Barker abstained. Motion passed.

Request
Motion by Jason Hansel, seconded by Gayle Mayer, to approve the waiver request until January 1, 2018. Brett Barker abstained. Motion passed.

New Business
1. Pharmacy Benefit Managers and Insulin Pens.
   Discussion was held regarding Pharmacy Benefit Managers (PBM)s wanting packages of insulin pens opened and dispensed separately to comply with the PBM}s day supply limitations. If packages are opened by the pharmacy and the pens are dispensed separately the manufacturer will not always reimburse or replace malfunctioning pens. IPA plans to follow-up and gather more information on this issue.
2. Future Board Meeting Schedule Preferences.
   Discussion was held regarding the Board’s preference concerning the scheduling of board meetings. The Board was asked if they would prefer separate hearing dates between board meeting dates or if they would prefer to continue with their current schedule. The Board was in consensus to keep the board meetings at the current schedule and the scheduling of hearing dates will be determined as needed.

Closed Session
At 11:15 a.m., on a motion by Jason Hansel, seconded by Brett Barker, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section 21.5(1)d, to discuss whether to initiate licensee disciplinary investigations or proceedings.
At 11:58 a.m., while still in closed session, Brett Barker moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

Administrative Hearing
At 1:05 p.m., Laura Lockard, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Laura Steffensmeier represented the State. J&P Enterprise Wholesale, Inc., did not appear nor did counsel represent them. The session was conducted in the presence of the Board and open to the public.

At 1:50 p.m., motion by Brett Barker, 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.

At 2:10 p.m., while still in closed session, Brett Barker moved that the Board go into open session, seconded by Jason Hansel. Motion approved unanimously.

Motion by LaDonna Gratias, seconded by Gayle Mayer, to direct Administrative Law Judge Lockard to draft the Order consistent with the Board’s deliberation in case 2017-65, J&P Enterprise Wholesale, Inc.

Motion by Brett Barker, seconded by Jason Hansel, to adjourn at 2:11 p.m. on August 30, 2017.

_______________________
Becky Hall,
Recording Secretary

_________________________
Andrew Funk
Executive Director

_________________________
Sharon K. Meyer
Board Chair

APPROVED THIS 1ST DAY OF NOVEMBER, 2017.
ADDENDUM A

ORDER TO SHOW CAUSE

JOSEPH SHADER, M.D.,
CONTROLLED SUBSTANCE REGISTRATION NO. 1246591
IOWA CITY, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

RE:
Controlled Substances Registration of

JOSEPH SHADER, MD
Registration No. 1246591
Respondent

CASE NO. 2017-121

ORDER TO SHOW CAUSE

COMES NOW the Iowa Board of Pharmacy ("Board") and issues this Order to Show Cause against Joseph Shader, MD ("Respondent"), pursuant to Iowa Code section 124.305 and 657 IAC 10.12(5). Respondent is ordered to show cause why the Board should not INDEFINITELY SUSPEND his controlled substances registration.

A. LEGAL GROUNDS

Pursuant to Iowa Code section 124.304(1)(e) and 657 IAC 10.12(1)"e", the Board may suspend, revoke, or restrict a controlled substances registration upon a finding that, if the registrant is a licensed health care professional, the registrant has had the registrant’s professional license revoked or suspended or has been otherwise disciplined in a way that restricts the registrant’s authority to handle or prescribe controlled substances.

B. FACTUAL CIRCUMSTANCES

1. Respondent holds Iowa license number MD-42131 to practice medicine, which expired on March 1, 2017.

2. Respondent’s Iowa controlled substances registration number 1245691 is currently active through February 28, 2018.

3. On June 30, 2017, the Iowa Board of Medicine issued an Order that indefinitely suspended Respondent’s Iowa medical license.

4. Respondent’s Iowa medical license is currently suspended.

C. SCHEDULED HEARING

Hearing. Respondent shall appear before the Board on October 31, 2017, at 1:00 p.m. in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th Street, Suite E, Des Moines, Iowa, 50309 for a contested case hearing regarding this Order to Show Cause.
Answer. Within twenty (20) days of the date you are served this Order to Show Cause, 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 A and B of this Order to Show Cause.

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

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 allegations 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 Order to Show Cause. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Order to Show Cause. 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.
D. ORDER TO SHOW CAUSE

1. Respondent is hereby ordered to show cause why his controlled substances registration should not be **INDEFINITELY SUSPENDED** at the hearing described in Section C above. If Respondent fails to appear at the scheduled hearing, controlled substances registration number 1245691 will be indefinitely suspended.

2. Respondent may waive his opportunity for a hearing by consenting in writing to an indefinite suspension of his controlled substances registration. Respondent should execute the attached waiver of show cause hearing form to elect this process.

Date issued: ____August 31, 2017________

________________________________________
Andrew Funk
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

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).
WAIVER OF SHOW CAUSE HEARING

I, Joseph Shader, MD, have read and agree to all of the following:

1. It is my desire to have my controlled substances registration indefinitely suspended effective immediately.

2. The indefinite suspension of my controlled substances registration is voluntary and not the result of force, threats, or promises.

3. I am of sound mind and have the mental capacity to understand the consequences of my controlled substances registration being indefinitely suspended.

4. I understand that I have an opportunity to be heard and to contest the allegations against me in a contested case hearing before the Board, but waive the right to a hearing and all attendant rights, including the right to present evidence, cross-examine witnesses, and seek judicial review, by agreeing to an indefinite suspension of my controlled substances registration.

5. I understand that I have the right to be represented by counsel in this matter.

6. I understand the indefinite suspension of my controlled substances is considered adverse action.

7. I understand the Board is required by federal law to report this indefinite suspension to the National Association of Boards of Pharmacy’s Disciplinary Clearinghouse and the National Practitioner Data Bank.

8. After I sign this document, I do not have the ability to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities, or conduct chemical analysis with controlled substances in Iowa unless and until my controlled substances registration is reinstated.

9. I understand that the indefinite suspension of my controlled substances registration will remain in effect until such time as my Iowa medical license is reinstated with full authority to prescribe controlled substances. I understand that I must notify the Board of Pharmacy when this occurs, and that my controlled substances registration will be administratively reinstated at that time.

10. I understand this document is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapter 22.

_________________________________________  ______________________________
Signature       Date
ADDENDUM B

NOTICE OF HEARING AND STATEMENT OF CHARGES

STONER DRUG CO., INC.
PHARMACY LICENSE NO. 371
HAMBURG, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

RE:
Pharmacy License and
Controlled Substances Registration of

STONE DRUG CO. INC.,
License No. 371
Registration No. 1106060
Respondent

CASE NO. 2017-26
NOTICE OF HEARING, STATEMENT OF CHARGES, AND ORDER TO SHOW CAUSE

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Stoner Drug Co. Inc. ("Respondent"), 1105 Main St, Hamburg IA 51640, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), 124.305, 272C.3(1)"e", and 657 IAC 10.12, 35.5, and 36.5. Respondent’s Iowa wholesale drug license number 5456 is currently active through December 31, 2017, and Respondent’s controlled substances registration number 1106060 is currently active through February 28, 2018.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on October 31, 2017, before the Board. The hearing shall begin 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, 124, 155A, and 272C (2017).

**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 124, 155A, and 272C, and 657 IAC chapters 10 and 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. STATEMENT OF CHARGES**

**COUNT I**

**FAILURE TO PERFORM ANNUAL INVENTORY**

Respondent is charged with failing to take a new inventory of all stocks of controlled substances on hand at least annually in violation of 657 IAC 10.35(3), and may be disciplined
pursuant to Iowa Code sections 124.304(1)(d), 155A.15(2)(c), and (h), and 657 IAC 10.12(1)d", 36.1(4)"u", and "ac".

COUNT II
FAILURE TO MAINTAIN RECEIPT AND DISBURSEMENT RECORDS
Respondent is charged with failing to maintain records of receipt or disbursement of controlled substances as required by 657 IAC 10.34(4), and may be disciplined pursuant to Iowa Code sections 124.304(1)(d), 155A.15(2)(c), and (h), and 657 IAC 10.12(1)d", 36.1(4)"u", and "ac".

COUNT III
IMPROPER DISPOSAL OF CONTROLLED SUBSTANCES
Respondent is charged with disposing of controlled substances in a manner inconsistent with 657 IAC 10.18(1), and may be disciplined pursuant to Iowa Code sections 124.304(1)(d) and 155A.15(2)(c), and 657 IAC 10.12(1)d" and 36.1(4)"u".

COUNT IV
FAILURE TO MAINTAIN DRUG SUPPLIER INVOICES
Respondent is charged with failing to maintain supplier invoices with the date of receipt and responsible person clearly recorded in violation of 657 IAC 8.9(1), and may be disciplined pursuant to Iowa Code sections 155A.15(2)(c) and (h), and 657 IAC 36.1(4)"u" and "ac".

D. FACTUAL CIRCUMSTANCES

In March of 2017, Respondent underwent an inspection. The following deficiencies were discovered during the inspection:

a. The pharmacy lacked a pseudoephedrine inventory for 2015.
b. The pharmacy lacked a controlled substances inventory for 2016.
c. The controlled substances inventory for 2015 appeared to have been changed.
d. The pharmacy sold pseudoephedrine to other pharmacies without providing invoices.
e. The pharmacy destroyed its own stock supply of pseudoephedrine.
f. The pharmacy’s invoices for its receipt of pseudoephedrine were not signed or dated.

E. ORDER TO SHOW CAUSE

1. Pursuant to Iowa Code section 124.304(1)(d) and 657 IAC 10.12(1)d", the Board may suspend, revoke, or restrict a controlled substances registration upon a finding that the
registrant has committed such acts as would render the registrant’s registration under Iowa Code section 124.303 inconsistent with the public interest as determined under that section.

2. A registrant’s compliance with applicable state and local laws is a factor to be considered when determining whether a registration is inconsistent with the public interest, pursuant to Iowa Code section 124.303(1)(b) and 657 IAC 10.12(4)“b”.

3. The Statement of Charges and Factual Circumstances described in sections C and D above render Respondent’s registration inconsistent with the public interest and serve as the basis for this Order to Show Cause.

4. Respondent is ordered to show cause why its controlled substances registration should not be suspended, revoked, or restricted at the hearing described in section A above.

F. 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.

G. FINDING OF PROBABLE CAUSE

On this 29th day of August, 2017, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing, Statement of Charges, and Order to Show Cause.

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 C

NOTICE OF HEARING AND STATEMENT OF CHARGES

PHILLIP KUHR
PHARMACIST LICENSE NO. 15518
HAMBURG, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

RE: Pharmacist License of
PHILLIP KUHR,
License No. 15518
Respondent

CASE NO. 2017-26
NOTICE OF HEARING AND
STATEMENT OF CHARGES

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Phillip Kuhr ("Respondent"), 301 Moody Dr, Hamburg IA 51640, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), 272C.3(1)"e", and 657 IAC 35.5, and 36.5. Respondent’s Iowa pharmacist license number 15518 is currently active through June 30, 2018.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on October 31, 2017, before the Board. The hearing shall begin 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 (2017).

**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. STATEMENT OF CHARGES**

**COUNT I**

**VIOLATING THE DUTIES OF PHARMACIST IN CHARGE**

Respondent is charged with violating the duties of pharmacist in charge, specifically by violating 657 8.3(1), 8.3(4)"h", "i", and "j", and may be disciplined pursuant to Iowa Code sections 155A.12(1), (4), (5), and 657 IAC 36.1(4)"u" and "ac".
D. FACTUAL CIRCUMSTANCES

1. Respondent is the pharmacist in charge at Stoner Drug Co. Inc. in Hamburg, Iowa.

2. As pharmacist in charge, Respondent is responsible for the violations of Iowa pharmacy laws and regulations identified in the Statement of Charges and Order to Show Cause filed against Stoner Drug Co. Inc. in case number 2017-26, which are incorporated by reference.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On this 29th day of August, 2017, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

[Signature]
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 D

NOTICE OF INTENT TO DENY REGISTRATION

VIRGINIA ROCK
NEW HARTFORD, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

NOTICE OF INTENT TO DENY REGISTRATION

COMES NOW the Iowa Board of Pharmacy ("Board") and issues this Notice of Intent to Deny Registration to Virginia Rock ("Applicant"), 30954 Willow Ave, New Hartford IA 50660, pursuant to Iowa Code sections 17A.17 and 155A.6A. This Notice of Intent to Deny Registration is based on the following:

A. LEGAL GROUNDS

1. Applicants for an Iowa pharmacy technician trainee registration must apply in accordance with Iowa Code section 155A.6A and 657 IAC chapter 3.

2. The Board has the authority to deny a pharmacy technician trainee registration for violating any rules of the Board. See Iowa Code § 155A.6A(5) and 657 IAC 3.29.

3. The Board may deny an application 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 registration to practice as 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. See 657 IAC 36.1(4)"a".

B. FACTUAL CIRCUMSTANCES

1. On May 1, 2017, the Board received a pharmacy technician trainee registration application from Virginia Rock.

2. The application asks the following question: have you ever been charged, convicted, found guilty of, or entered a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100)? If you respond ‘yes’, please explain on a separate sheet.

4. Applicant failed to disclose a domestic abuse assault charge from 2014.

5. On April 11, 2016, Applicant was issued pharmacy support person registration number 4428, which is currently active through December 31, 2017.

6. The pharmacy support person registration application also asked the question in paragraph 2 above.

7. On the pharmacy support person registration application, Applicant disclosed two operating while intoxicated convictions, but failed to disclose the other criminal charges and convictions described in paragraphs 3 and 4 above.

8. Applicant was asked to submit all available court documentation regarding her criminal history. To date, the Board has not received any such documentation.

C. APPEAL RIGHTS

1. Pursuant to the provisions of 657 IAC 3.29 and 36.16, you may appeal this Notice of Intent to Deny Registration 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 SW 8th St, Ste E, Des Moines IA 50309. The written notice of appeal and request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be a contested case conducted pursuant to the procedures outlined at 657 IAC chapter 35.

2. IF A WRITTEN NOTICE OF APPEAL AND REQUEST FOR HEARING IS NOT TIMELY FILED, THIS NOTICE OF INTENT TO DENY REGISTRATION WILL BECOME FINAL, AND THE IOWA PHARMACY TECHNICIAN TRAINEE REGISTRATION APPLICATION SUBMITTED BY VIRGINIA ROCK WILL BE DENIED.

Date issued: __September 2, 2017_______

Andrew Funk
Executive Director
Iowa Board of Pharmacy
ADDENDUM E

COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER

JEFFREY ALLEN KILLIAN
PHARMACIST LICENSE No. 19549
SAN DIEGO, CALIFORNIA
BEFORE THE IOWA BOARD OF PHARMACY

Re: ) CASE NO. 2017-108
Pharmacist License of ) COMBINED STATEMENT OF
JEFFREY ALLEN KILLIAN ) CHARGES, SETTLEMENT
License No. 19549 ) AGREEMENT, AND FINAL ORDER
Respondent.

COME NOW the Iowa Board of Pharmacy ("Board") and Jeffrey Allen Killian ("Respondent"), 425 W Beech-St #1258, San Diego-CA-92101, 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) (2017), 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 chapter 36.

A. STATEMENT OF CHARGES

1. Respondent is charged with having a license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to any of the grounds for disciplinary action in Iowa and may be disciplined pursuant to Iowa Code section 147.55(9) and 155A.12(8) and 657 IAC 36.1(4)"ae".

B. FACTUAL CIRCUMSTANCES

2. Respondent holds Iowa license number 19549 to practice pharmacy, which is currently active through June 30, 2019.

3. On October 16, 2015, the California Board of Pharmacy revoked Respondent’s California pharmacist license, but stayed the revocation and placed Respondent on probation for 5 years, subject to several requirements. The discipline stemmed from Respondent’s use of alcohol.

4. Respondent’s California pharmacist license is currently on probation.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

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

6. 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.

7. 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.

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

9. Respondent agrees that the State's counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

10. This Order is subject to approval by a majority of the full Board. If the Board 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.

11. 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.

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

13. 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.

14. 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.

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

IT IS THEREFORE ORDERED:

16. Respondent's license is hereby placed on PROBATION for the entirety of Respondent's probationary period in California, which is expected to last until approximately October 16, 2020. Respondent shall comply with all terms of the California Stipulated Settlement and Disciplinary Order. In addition, the following conditions shall apply:

   a. Respondent shall report any changes to his licensure status in California to the Board immediately.

   b. Respondent shall report any violations of his California probation to the Board immediately.

   c. Respondent shall notify the Board prior to engaging in the practice of pharmacy in Iowa. Respondent shall provide copies of this Order and the
California Stipulated Settlement and Disciplinary Order to any prospective employers in Iowa no later than at the time of an employment interview.

d. Respondent authorizes the release of all information and records related to compliance with the California Stipulated Settlement and Disciplinary Order in possession of the California Board of Pharmacy to the Board upon request, in order to verify compliance with this Order.

e. This Order is intended to mirror the California Stipulated Settlement and Disciplinary Order. If any conditions are added or removed by the California Board of Pharmacy, those changes shall be incorporated into this Order. If Respondent is granted early release from his California probation, Respondent's Iowa license shall also be released from probation.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 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 8th day of August, 2017.

[Signature]
JEFFREY ALLEN KILLIAN
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 30th day of August, 2017.

[Signature]
Chairperson
Iowa Board of Pharmacy
ADDENDUM F

SETTLEMENT AGREEMENT AND FINAL ORDER

CHARLES ALAN ROBINSON
PHARMACIST LICENSE NO. 13371
ESTHERVILLE, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of CHARLES ALAN ROBINSON License No. 13371 Respondent. CASE NO. 2016-43 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 Charles Alan Robinson ("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:

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

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

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

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

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

IT IS THEREFORE ORDERED:

13. Respondent is hereby CITED for failing to properly verify and document a prescription, violating the duties of pharmacist in charge, failing to perform a drug utilization review, and dispensing a Schedule II controlled substance without a prescription and WARNED that Respondent’s failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

14. Respondent agrees to pay a CIVIL PENALTY in the amount of two thousand dollars ($2000). This civil penalty shall be made payable to the Treasurer of Iowa and paid within sixty (60) days of the Board’s approval of this Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

15. Respondent shall complete an eighteen (18) hour Patient Safety and Medication Error Prevention CONTINUING EDUCATION COURSE. None of the hours used to fulfill this requirement can count towards the continuing education hours required for the 2019 renewal of Respondent’s pharmacist license. Respondent shall submit a certificate of completion to the Board as proof of successful completion of this requirement within sixty (60) days of Board approval of this Order. Respondent is responsible for all costs associated with obtaining the required continuing education.

16. The civil penalty and the documentation required to be submitted to the Board under paragraphs 14 and 15, should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC chapter 36.
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 28th day of August, 2017.

Charles Robinson
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 30th day of August, 2017.

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

Connie Diekema
Finley Law Firm, P.C.
699 Walnut St, Ste 1700
Des Moines IA 50309
ATTORNEY FOR RESPONDENT
ADDENDUM G

SETTLEMENT AGREEMENT AND FINAL ORDER

MARTHA MORIN
PHARMACIST LICENSE NO. 15348
AKRON, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License and MARTHA MORIN
License No. 15348
Respondent. ) CASE NO. 2016-193

) SETTLEMENT AGREEMENT
) AND FINAL ORDER

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Martha Morin ("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:


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 she has the right to be represented by counsel on this matter.

6. Respondent agrees that the State's counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent’s permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

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

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

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

IT IS THEREFORE ORDERED:

13. Respondent’s license shall be placed on PROBATION for a period of five (5) years, subject to the following conditions:

a. Within sixty (60) days, Respondent shall pay a CIVIL PENALTY in the amount of two-thousand five-hundred dollars ($2500). 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: Amanda Woltz, 400 SW Eighth Street, Suite E, Des Moines IA 50309.

b. Within ten (10) days, Respondent shall remove herself as pharmacist in charge of Thorson Drug Inc. Thereafter, Respondent shall not serve as a pharmacist in charge for any pharmacy.

c. Respondent shall not participate in the physical inventories or reconciliations required by the Settlement Agreement and Final Order for Thorson Drug Inc in case no. 2016-193. Respondent shall participate in the final inventory when she transfers the duties of pharmacist in charge to a new pharmacist.

d. Respondent agrees to provide a body fluid specimen for chemical screening purposes upon request of the assigned Board compliance officer in the event of an unexplained loss of controlled substances.

e. Respondent shall appear before the Board upon request in the event of a loss of controlled substances or an indication that Respondent may have failed to comply with the terms of probation. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
f. Respondent shall obey all Federal and State laws and regulations governing the practice of pharmacy and controlled substances.

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 25th day of August, 2017.

Martha Morin  
MARTHA MORIN  
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 25th day of August, 2017.

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

Marten A. "Mat" Trotzig  
TROTZIG & BAUERLY, P.L.C.  
PO Box 336  
Le Mars IA 51031  
ATTORNEY FOR RESPONDENT
ADDENDUM H

SETTLEMENT AGREEMENT AND FINAL ORDER

THORSON DRUG, INC.,
PHARMACY LICENSE NO. 457
AKRON, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy License and Controlled Substances Registration of THORSON DRUG INC, License No. 457, Registration No. 1106370, Respondent.

CASE NO. 2016-193

SETTLEMENT AGREEMENT AND FINAL ORDER

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Thorson Drug Inc ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

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


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

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

4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board’s actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

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

6. Respondent agrees that the State’s counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent’s permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

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

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

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

**IT IS THEREFORE ORDERED:**

13. Respondent’s license shall be placed on **PROBATION** for a period of five (5) years, subject to the following conditions:

   a. Respondent shall keep a perpetual inventory of all controlled substances. The perpetual inventory must allow an inspector to see all adjustments made to the perpetual inventory.

   b. Respondent shall conduct a physical inventory of all controlled substances every six (6) months. The inventory must be reconciled with the perpetual inventory record. Each physical inventory and documentation of reconciliation shall be sent to the assigned Board compliance officer upon completion.

   c. Within three (3) months, Respondent shall install a secure physical barrier that separates the pharmacy department from the remainder of the store. Respondent shall use the secure physical barrier to block access to the pharmacy department any time the pharmacy is closed.

   d. Within three (3) months, Respondent shall install a lockable cabinet to store all controlled substances. The cabinet shall require unique identification for access, such as a unique password for each user or biometric access. Respondent must be able to track who accesses the cabinet when it is opened.

   e. Respondent shall notify the assigned Board compliance officer immediately of any controlled substances that are unaccounted for or any irregularities pertaining to the pharmacy’s security measures.
f. Respondent shall obey all Federal and State laws and regulations governing the practice of pharmacy and controlled substances.

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 124, 155A, and 272C and 657 IAC chapters 10 and 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 24th day of Aug, 2017.

[Signature]
THORSON DRUG INC
Respondent

By this signature, Martha Morin acknowledges s/he is the President for Thorson Drug Inc and is authorized to sign this Settlement Agreement and Final Order on behalf of Thorson Drug Inc.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 30th day of Aug, 2017.

[Signature]
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
Marten A. "Mat" Trotzig
TROTZIG & BAUERLY, P.L.C.
PO Box 336
Le Mars IA 51031
ATTORNEY FOR RESPONDENT
ADDENDUM I

SETTLEMENT AGREEMENT AND FINAL ORDER

WALGREENS #05721
PHARMACY LICENSE NO. 355
DES MOINES, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy License of WALGREENS 05721 License No. 355 Respondent.

CASE NO. 2017-35

SETTLEMENT AGREEMENT

AND FINAL ORDER

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 lAC 36.6, the Iowa Board of Pharmacy ("Board") and Walgreens 05721 ("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:


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, for the purpose of settlement, that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

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

6. Respondent agrees that the State's counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

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

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

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

**IT IS THEREFORE ORDERED:**

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

   a. Respondent shall pay a CIVIL PENALTY in the amount of two-thousand five hundred dollars ($2,500) 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: Amanda Woltz, 400 SW Eighth Street, Suite E, Des Moines IA 50309.

   b. Respondent shall complete self-inspections on a monthly basis and submit documentation of each self-inspection at quarterly intervals as directed by the Board no later than the tenth (10th) day of the month following the third monthly inspection of each quarter. Board compliance officers may conduct on-site inspections at any time. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during a self-inspection or Board inspection are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion may be considered a violation of this Order.

   c. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.

   d. The Board may, in its discretion, decrease the frequency of the required self-inspections during the probationary period based on satisfactory performance by Respondent, and the Board may, in its discretion, consider a reduction in the length of probation, based on satisfactory performance by Respondent.
14. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 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 [date] day of [August], 2017.

RINA SHAH, VP Pharmacy
WALGREENS 05721
Respondent

By this signature, [Signature] acknowledges s/he is the VP Pharmacy for Walgreens 05721 and is authorized to sign this Settlement Agreement and Final Order on behalf of Walgreens 05721.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 30th day of [August], 2017.

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

SETTLEMENT AGREEMENT AND FINAL ORDER

PETE RSON DRUG
PHARMACY LICENSE NO. 1606
WILLIAMSBURG, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: ) CASE NO. 2017-36
Pharmacy License of )
) SETTLEMENT AGREEMENT
PETERSON DRUG )
License No. 1606 ) AND FINAL ORDER
Respondent. )

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Peterson Drug ("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:


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

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

4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board’s actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

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

6. Respondent agrees that the State’s counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

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

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

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

IT IS THEREFORE ORDERED:

13. Respondent is hereby CITED for failing to timely submit an application for pharmacy license changes, failing to complete an inventory upon a change in ownership, and inadequately storing pharmacy records and WARNED that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

14. Respondent agrees to pay a CIVIL PENALTY in the amount of five-thousand dollars ($5,000) within ninety (90) days of the Board's 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: Amanda Woltz, 400 SW Eighth Street, Suite E, Des Moines IA 50309.

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 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 26th day of July, 2017.

[Signature]
PETERSON DRUG
Respondent

By this signature, [Mark Vogt] acknowledges s/he is the [owner] for Peterson Drug and is authorized to sign this Settlement Agreement and Final Order on behalf of Peterson Drug.
This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 38th day of [Date], 2017.

[Signature]
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 K

SETTLEMENT AGREEMENT AND FINAL ORDER

MARK VOGT
PHARMACIST LICENSE NO. 18113
ARLINGTON, NEBRASKA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of MARK VOGT License No. 18113 Respondent. ) ) ) ) ) ) CASE NO. 2017-36 SETTLEMENT AGREEMENT AND FINAL ORDER

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Mark Vogt ("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:


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 is hereby CITED for failing to timely submit an application for pharmacy license changes, failing to complete an inventory upon a change in ownership, engaging in misrepresentative deeds, and inadequately storing pharmacy records and WARNED that Respondent’s failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

14. Respondent agrees to pay a CIVIL PENALTY in the amount of ten-thousand dollars ($10,000) within ninety (90) days of the Board’s 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: Amanda Woltz, 400 SW Eighth Street, Suite E, Des Moines IA 50309.

15. Respondent shall complete six (6) hours of CONTINUING EDUCATION pertaining to pharmacy law and/or ethics within ninety (90) days of the Board’s approval of this Order. None of the hours used to fulfill this requirement can count towards the continuing education hours required for the 2019 renewal of Respondent’s pharmacist license. Respondent shall submit certificates of completion to the Board as proof of successful completion of this requirement within ninety (90) days of Board approval of this Order. The documentation may be emailed to Amanda.Woltz@iowa.gov or mailed to the address in paragraph 14. Respondent is responsible for all costs associated with obtaining the required continuing education.

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

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 24th day of July, 2017.
This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 30th day of August, 2017.

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 L

SETTLEMENT AGREEMENT AND FINAL ORDER

LADONA K. HART
PHARMACY TECHNICIAN TRAINEE REGISTRATION NO. 23479
DYSART, IOWA
BEFORE THE IOWA BOARD OF PHARMACY

Re: Technician Trainee Registration of LADONA HART Registration No. 23479 Respondent. ) CASE NO. 2017-16 ) SETTLEMENT AGREEMENT ) AND FINAL ORDER

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2017), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and LaDona Hart ("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:


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 she has the right to be represented by counsel on this matter.

6. Respondent agrees that the State’s counsel may present this Order to the Board and may have ex parte communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent’s permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

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

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

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

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

**IT IS THEREFORE ORDERED:**

13. Respondent agrees to VOLUNTARILY SURRENDER her technician trainee registration to resolve this matter. 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 work in a pharmacy in any capacity in Iowa unless her technician registration is reinstated. Respondent may not request reinstatement for at least five (5) years from the date of this Order.

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 chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 29th day of August, 2017.

[Signature]
LADONA HART
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 31st day of August, 2017.
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

Chairperson
Iowa Board of Pharmacy
ADDENDUM M

ADOPTED AND FILED


AUGUST 30, 2017

Pursuant to Iowa Code section 17A.7(2), this rule making is the result of an overall review of administrative rules relating to controlled substances. The rule making rescinds current Chapter 10 and adopts a new, reorganized chapter in lieu thereof. Chapter 10 establishes the minimum standards for registration of entities involved in the handling and prescribing of controlled substances, accountability and security for and designation of controlled substances, and minimum standards for prescriptions issued and dispensed for controlled substances. The minimum standards are based, in large part, upon federal minimum standards for accountability, security, and designation of controlled substances.

The updated chapter is reorganized to provide clarity, removes rules that are no longer relevant or that are identified in other chapters, consolidates rules and subrules where appropriate, updates language to provide consistency and clarity where confusion has been noted, and identifies newly designated practitioners with authority to prescribe. To be consistent with recent rule making by the Board, the chapter expands the requirement for registration to include nonresident pharmacies shipping controlled substances into Iowa and emergency medical service programs located in Iowa or servicing Iowa with controlled substances. The rule making provides that a pharmacy technician can be involved in the sale of a pseudoephedrine-containing product.

The rule making provides consistency in the registration renewal process, identifying a grace period and terms for reactivation of a registration following the grace period. The requirement of pharmacists to initial each line of a DEA Form 222 upon receipt of Schedule II controlled substances is removed to be consistent with federal regulations. With respect to the handling and dispensing of controlled substances, the rule making requires all registrants to maintain policies and procedures to ensure security and accountability; requires all registrants to maintain a perpetual inventory log of Schedule II controlled substances (previously required only of pharmacies and service programs); requires all registrants to maintain records of dispensing controlled substances to patients or research subjects (previously only required of pharmacies and service programs); provides authority for pharmacists to add the name of the supervising physician on a Schedule II controlled substance prescription, after consultation with the physician assistant who issued the prescription; and requires documentation of each individual involved in the dispensing of a controlled substance prescription.

To provide consistency with federal regulations, the rule making authorizes a pharmacist to fill a Schedule II controlled substance in partial quantities as provided in the federal Comprehensive Addiction and Recovery Act of 2016 and temporarily places into controlled schedules several substances recently designated by the federal Drug Enforcement Administration (DEA) as controlled substances. The rule making also adds two new rules, as are being provided in all the Board’s licensing chapters, to provide clear direction on the responsibility of registrants to notify the Board when they have been subject to disciplinary sanctions or criminal convictions as well as to summarize the Board’s authority to sanction registrations. The amendments update references to provisions in Chapter 10 that are found in other chapters of the Board’s rules.

Notice of Intended Action was published in the Iowa Administrative Bulletin as ARC 3136C on June 21, 2017. No public comments were received for this rule making. Changes were made in rule 657—10.3(124) to provide that required registration of nonresident facilities and practitioners involved in the distributing, dispensing, or administering of controlled substances into Iowa is delayed until January 1, 2018.
Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy. After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

These amendments will become effective November 1, 2017.

The following amendments are adopted.

ITEM 1. Amend subparagraph 7.11(2)“c”(1) as follows:

(1) Schedule II controlled substance. An outpatient medication order for administration of a Schedule II controlled substance shall be written and, except as provided in rule 657—10.25(124) 657—10.29(124) regarding the issuance of multiple Schedule II prescriptions, may authorize the administration of an appropriate amount of the prescribed substance for a period not to exceed 90 days from the date ordered.

ITEM 2. Amend subparagraph 8.35(7)“f”(2) as follows:

(2) The inventory of controlled substances shall be completed pursuant to the requirements in 657—10.35(124,155A) 657—10.19(124,155A).

ITEM 3. Amend subparagraph 8.35(7)“f”(5) as follows:

(5) Controlled substances requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these substances as provided in rule 657—10.18(124) 657—10.22(124).

ITEM 4. Rescind 657—Chapter 10 and adopt the following new chapter in lieu thereof:

CHAPTER 10
CONTROLLED SUBSTANCES

657—10.1(124) Purpose and scope. This chapter establishes the minimum standards for any activity that involves controlled substances. Any person or business that manufactures, distributes, dispenses, prescribes; conducts instructional activities, research, or chemical analysis with; or imports or exports controlled substances listed in Schedules I through V of Iowa Code chapter 124 in or into the state of Iowa, or that proposes to engage in such activities, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.8(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business. A registration is not transferable to any person or business.

657—10.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply:

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

“Board” means the Iowa board of pharmacy.

“CSA” means the Iowa uniform controlled substances Act.

“CSA registration” or “registration” means the registration issued by the board pursuant to the CSA that signifies the registrant’s authorization to engage in registered activities with controlled substances.

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

“Individual practitioner” means a physician or surgeon (M.D.), osteopathic physician or surgeon (D.O.), dentist (D.D.S. or D.M.D.), doctor of veterinary medicine (D.V.M.), podiatric physician (D.P.M.), optometrist (O.D.), physician assistant (P.A.), resident physician, advanced registered nurse practitioner (A.R.N.P.), or prescribing psychologist.
657—10.3(124) Who shall register. The following persons or businesses shall register on forms provided by the board:

1. Manufacturers, distributors, importers, and exporters located in Iowa. Effective January 1, 2018, nonresident manufacturers, distributors, importers, and exporters distributing controlled substances into Iowa.

2. Reverse distributors located in Iowa. Effective January 1, 2018, nonresident reverse distributors engaging in the transfer of controlled substances with registrants located in Iowa.

3. Individual practitioners located in Iowa who are administering, dispensing, or prescribing controlled substances and individual practitioners located outside of Iowa who are dispensing or prescribing controlled substances via telehealth services to patients located in Iowa.

4. Pharmacies located in Iowa that are dispensing controlled substances. Effective January 1, 2018, pharmacies located outside of Iowa that are delivering controlled substances to patients located in Iowa.

5. Hospitals located in Iowa that are administering or dispensing controlled substances. Effective January 1, 2018, hospitals located outside of Iowa that are administering or dispensing controlled substances to patients located in Iowa.

6. Emergency medical service programs that are administering controlled substances to patients located in Iowa.

7. Care facilities that are located in Iowa.

8. Researchers, analytical laboratories, and teaching institutions that are located in Iowa.

9. Animal shelters and dog training facilities that are located in Iowa.

657—10.4 Reserved.

657—10.5(124) Application. Applicants for initial registration, registration renewal pursuant to rule 657—10.6(124), or modifications pursuant to rule 657—10.9(124) shall complete the appropriate application and shall include all required information and attachments. Each registration application shall require submission of a $90 registration fee except as provided in subrule 10.5(3).

10.5(1) Signature requirements. Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location.

10.5(2) Submission of multiple applications. Any person or business required to obtain more than one registration pursuant to rule 657—10.7(124) or 657—10.8(124) may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.

10.5(3) Registration fee exemptions. The registration fee is waived for federal, state, and local law enforcement agencies and for the following federal and state institutions: hospitals, health care or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties. In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall maintain a registration to conduct chemical analysis (analytical laboratory). Such laboratories shall be exempt from any registration fee. Exemption from payment of any fees as provided in this subrule does not relieve the entity of registration or of any other requirements or duties prescribed by law.

657—10.6(124) Registration renewal. Each registration shall be renewed prior to its biennial expiration. A registrant may renew its registration up to 60 days prior to the registration expiration. The fee for registration renewal shall be $90.
10.6(1) Delinquent registration grace period. A registration that is not renewed prior to the first day of the month following expiration shall be delinquent. A registrant may continue operations within the first 30 days following expiration while the license is delinquent if the registrant is in the process of renewing the registration. Failure to renew a registration prior to the first day of the month following expiration, but when submitting a completed renewal application within the 30 days following expiration, shall require payment of the renewal fee and a penalty fee of $90.

10.6(2) Delinquent registration reactivation beyond grace period. If a registration renewal application is not postmarked or hand-delivered to the board office within 30 days following its expiration date, the registrant may not conduct operations that involve controlled substances until the registrant reactivates the registration. A registrant may apply for reactivation by submitting a registration application for reactivation and a $360 fee. As part of the reactivation application, the registrant shall disclose the activities conducted with respect to controlled substances while the registration was expired. A registrant that continues to conduct activities with respect to controlled substances without an active registration may be subject to disciplinary sanctions.

657—10.7(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.7(1) Manufacturing controlled substances. A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.7(2) Distributing controlled substances. This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.7(3) Dispensing, administering, prescribing, or instructing with controlled substances. These independent activities include, but are not limited to, prescribing, administering, and dispensing by individual practitioners; dispensing by pharmacies and hospitals; and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for these independent activities may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law. If an entity that engages in the distribution, administration, dispensing, or storing of controlled substances maintains multiple licenses, such as a hospital that has both inpatient and outpatient pharmacies, a separate registration shall be maintained for each license.

10.7(4) Conducting research with controlled substances listed in Schedule I. A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal DEA registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.7(5) Conducting research with controlled substances listed in Schedules II through V. A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code section 124.302(3), and may conduct instructional activities with controlled substances.
10.7(6) Conducting chemical analysis with controlled substances. A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code section 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

10.7(7) Importing or exporting controlled substances. A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.

657—10.8(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, dispensed, stored, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code section 124.302(3), this rule, or federal regulations.

10.8(1) Warehouse. A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:
   a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.
   b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code section 124.302(3).

10.8(2) Sales office. An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.8(3) Prescriber’s office. An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber’s practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.8(4) Prescriber in hospital. A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber’s registered practice location shall not be required to obtain a separate registration at the location of the hospital.

10.8(5) Affiliated interns, residents, or foreign physicians. An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the practitioner is employed provided that:
   a. The hospital or other institution by which the individual practitioner is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the appropriate licensing board.
   b. Such individual practitioner is acting only in the scope of employment or practice in the hospital, institution, internship program, or residency program.
   c. The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number, letters, or combination thereof which shall be appended to the institution’s DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12).
d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.

657—10.9(124) Modification or termination of registration. A registered individual or business shall apply to modify a current registration as provided by this rule.

10.9(1) Change of substances authorized. Any registrant shall apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant’s name, address, telephone number, registration number, and the substances or schedules to be added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.9(2) Change of address of registered location.
   a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant’s name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.
   b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the address of the registered location by submitting a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(3) Change of registrant’s name.
   a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the registrant’s name by submitting a written request to the board. The request shall include the registrant’s current name, new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.
   b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the registrant name by submitting a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(4) Change of ownership of registered business entity. A change of immediate ownership of a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the submission of a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(5) Change of responsible individual. Any registrant, except an individual practitioner or researcher or a pharmacy or hospital, shall apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant’s name, address, and telephone number; the name and title of the current responsible individual and of the new responsible individual; the effective date of the change; and the registration number and shall be signed by the new responsible individual. No fee shall be required for the modification.
   a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed or transferred.
   b. Pharmacies and hospitals. The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital.
The power of attorney shall include the name, address, DEA registration number, and CSA registration number of the registrant. The power of attorney shall identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities. The responsible individual may be changed on the CSA registration by submission of a completed application and fee for registration as provided in rule 657—10.5(124).

10.9(6) Termination of registration. A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice. A registration issued to an individual shall terminate upon the death of the individual.

657—10.10(124) Denial, modification, suspension, or revocation of registration.

10.10(1) Grounds for suspension or revocation. The board may suspend or revoke any registration upon a finding that the registrant:

a. Has furnished false or fraudulent material information in any application filed under this chapter.

b. Has had the registrant’s federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked.

c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant’s appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation.

d. Has committed such acts as would render the registrant’s registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section.

e. Has been subject to discipline by the registrant’s respective professional licensing board and the discipline revokes or suspends the registrant’s professional license or otherwise disciplines the registrant’s professional license in a way that restricts the registrant’s authority to handle or prescribe controlled substances. A copy of the record of licensee discipline or a copy of the licensee’s surrender of the professional license shall be conclusive evidence.

10.10(2) Limited suspension or revocation. If the board finds grounds to suspend or revoke a registration, the board may limit revocation or suspension of the registration to the particular controlled substance, substances, or schedules with respect to which the grounds for revocation or suspension exist. If the revocation or suspension is limited to a particular controlled substance, substances, or schedules, the registrant shall be given a new certificate of registration reflecting the restrictions imposed by the revocation or suspension; no fee shall be required for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board.

10.10(3) Denial of registration or registration renewal. If, upon examination of an application for registration or registration renewal, including any other information the board has or receives regarding the applicant, the board determines that the issuance of the registration would be inconsistent with the public interest, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

10.10(4) Considerations in denial of registration. In determining the public interest, the board shall consider all of the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.

d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant’s establishment of effective controls against diversion.
e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant’s federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

10.10(5) Order to show cause. Before denying, modifying, suspending, or revoking a registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should not be denied, modified, revoked, or suspended. The order to show cause shall contain a statement of the basis therefore and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, suspension, or modification of registration and a summary of the matters of fact and law asserted. If the order to show cause involves the possible denial of registration renewal, the order shall be served not later than 30 days before the expiration of the registration. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension pursuant to subrule 10.10(9).

10.10(6) Hearing requested. If an applicant or registrant that has received an order to show cause desires a hearing on the matter, the applicant or registrant shall file a request for a hearing within 30 days after the date of service of the order to show cause. If a hearing is requested, the board shall hold a hearing pursuant to 657—Chapter 35 at the time and place stated in the order and without regard to any criminal prosecution or other proceeding. Unless otherwise ordered by the board, an administrative law judge employed by the department of inspections and appeals shall be assigned to preside over the case and to draft a proposed decision for the board’s consideration.

10.10(7) Waiver of hearing. If an applicant or registrant entitled to a hearing on an order to show cause fails to file a request for hearing, or if the applicant or registrant requests a hearing but fails to appear at the hearing, the applicant or registrant shall be deemed to have waived the opportunity for a hearing unless the applicant or registrant shows good cause for such failure.

10.10(8) Final board order when hearing waived. If an applicant or registrant entitled to a hearing waives or is deemed to have waived the opportunity for a hearing, the executive director of the board may cancel the hearing and issue, on behalf of the board, the board’s final order on the order to show cause.

10.10(9) Order of immediate suspension. The board may suspend any registration simultaneously with the service upon the registrant of an order to show cause why such registration should not be revoked or suspended if the board finds there is an imminent danger to the public health or safety that warrants such action. If the board suspends a registration simultaneously with the service of the order to show cause upon the registrant, it shall serve upon the registrant with the order to show cause an order of immediate suspension containing a statement of its findings regarding the danger to public health or safety. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, under the provisions of the Iowa administrative procedure Act, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

10.10(10) Disposition of controlled substances. If the board suspends or revokes a registration, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board suspending or revoking the registration, the registrant shall deliver all affected controlled substances in the registrant’s possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order’s becoming final, all such controlled substances may be forfeited to the state.
10.10(11) Notifications. The board shall promptly notify the DEA and the Iowa department of public safety of all orders suspending or revoking registration and all forfeitures of controlled substances.

657—10.11 Reserved.

657—10.12(124) Inspection. The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.

657—10.13(124) Security requirements. All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

10.13(1) Physical security. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet or safe.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet or safe. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

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

10.13(2) Factors in evaluating physical security systems. In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted.

b. The type, form, and quantity of controlled substances handled.

c. The location of the premises and the relationship such location bears to security needs.

d. The type of building construction comprising the facility and the general characteristics of the building or buildings.

e. The type of vault, safe, and secure enclosures available.

f. The type of closures on vaults, safes, and secure enclosures.

g. The adequacy of key control systems or combination lock control systems.

h. The adequacy of electronic detection and alarm systems, if any.

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas.

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any.

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel.

l. The availability of local police protection or of the registrant’s or applicant’s security personnel.

m. The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.
10.13(3) Manufacturing and compounding storage areas. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

657—10.14(124) Accountability of controlled substances. The registrant shall maintain ultimate accountability of controlled substances and records maintained at the registered location.

10.14(1) Records. Pursuant to rule 657—10.36(124,155A), records shall be available for inspection and copying by the board or its authorized agents for two years from the date of the record.

10.14(2) Policies and procedures. The registrant shall have policies and procedures that identify, at a minimum:

a. Adequate storage for all controlled substances to ensure security and proper conditions with respect to temperature and humidity.

b. Access to controlled substances and records of controlled substances by employees of the registrant.

c. Proper disposition of controlled substances.

657—10.15 Reserved.

657—10.16(124) Receipt and disbursement of controlled substances. Each transfer of a controlled substance between two registrants, to include a transfer between two separately registered locations regardless of any common ownership, except as provided in subrule 10.16(2), shall require a record of the transaction. Each registrant shall maintain a copy of the record for at least two years from the date of the transfer. Records of the transfer of Schedule II controlled substances shall be created and maintained separately from records of the transfer of Schedules III through V controlled substances pursuant to rule 657—10.36(124,155A). Upon receipt of a controlled substance, the individual responsible for receiving the controlled substance shall date and sign the receipt record.

10.16(1) Record. The record, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

a. The name of the substance.

b. The strength and dosage form of the substance.

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from which the substances were acquired.

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to which the substances were distributed.

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to which the substances were distributed for disposal, if appropriate.

10.16(2) Distribution of samples and other complimentary packages. Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items provides to the practitioner a record that contains the information found in this subrule. The individual responsible for receiving the controlled substances shall sign and date the record.

a. The name, address, and DEA registration number of the supplier.

b. The name, address, and DEA registration number of the practitioner.

c. The name, strength, dosage form, and quantity of the specific controlled substances delivered.

d. The date of delivery.

657—10.17(124) Ordering or distributing Schedule I or II controlled substances.

10.17(1) DEA Form 222. Except as otherwise provided by subrule 10.17(2) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form
may be executed only on behalf of the registrant named on the order form and only if the registrant’s DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filled pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity of each substance received and the date of receipt.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise void order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.17(2) Electronic ordering system. A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser’s agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedule I or II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant’s authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.
i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board’s agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

10.18(1) Record format. The perpetual inventory record may be maintained in a manual 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.

10.18(2) Information included. The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each receipt, disbursement, and current balance of each individual drug or NDC number. The record shall also include incident reports and reconciliation records pursuant to subrules 10.18(3) and 10.18(4).

10.18(3) Changes to a record. If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.18(4) Reconciliation. The registrant shall be responsible for reconciling or ensuring the completion of a reconciliation of the perpetual inventory balance with the physical inventory of all Schedule II controlled substances at least annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the registrant shall be notified immediately. The registrant shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 657—10.21(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or its authorized agents for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The individual responsible for a disbursement verifies that the physical inventory matches the perpetual inventory following each disbursement and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If any Schedule II controlled substances in the registrant’s current inventory have been disbursed and verified in this manner within the year and there are no discrepancies noted, no additional reconciliation action is required. A perpetual inventory record for a drug that has had no activity within the year shall be reconciled pursuant to paragraph 10.18(4)”b.”

b. A physical count of each Schedule II controlled substance stocked by the registrant shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record
the date, the time, the individual’s initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory.

657—10.19(124) Physical count and record of inventory. Each registrant shall be responsible for taking a complete and accurate inventory of all stocks of controlled substances under the control of the registrant pursuant to this rule. The responsible individual may delegate the actual taking of any inventory.

10.19(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

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

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

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

(1) The name of the substance.

(2) The strength and dosage form of the substance.

(3) The quantity of the substance.

(4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

(5) The signature of the person or persons responsible for taking the inventory.

(6) The date and time (opening or closing) of the inventory.

(7) For all substances listed in Schedule I or II, the quantity shall be an exact count or measure of the substance.

(8) For all substances listed in Schedule III, IV, or V, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.19(2) Initial inventory. A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, storage, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.19(3) Annual inventory. After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within 372 days after the date of the previous annual inventory.

10.19(4) Change of ownership, pharmacist in charge, or registered location. When there is a change in ownership, pharmacist in charge, or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following
the close of business the last day under terminating ownership, terminating pharmacist in charge’s employment, or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner, terminating pharmacist in charge, or location being vacated, as well as a record of the beginning inventory for the new owner, pharmacist in charge, or location.

10.19(5) Discontinuing registered activity. A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to which the substances are transferred.

10.19(6) New or rescheduled controlled substances. On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances or the rescheduling of a previously controlled substance to another schedule, any registrant who possesses the newly scheduled or rescheduled controlled substance shall take an inventory of all stocks of the substance on hand. That inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the controlled substance shall be included in the appropriate schedule of each inventory made by the registrant.

657—10.20 Reserved.

657—10.21(124) Report of theft or loss. A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

10.21(1) Immediate notice to board. If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from which the controlled substances were stolen shall notify the board immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

10.21(2) Immediate notice to DEA. A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

10.21(3) Timely report submission. Within 14 calendar days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA Web site at http://www.deadiversion.usdoj.gov/. A copy of the report that was completed and submitted to the DEA shall be immediately submitted to the board via facsimile, e-mail attachment, or personal or commercial delivery.

10.21(4) Record maintained. A copy of the report shall be maintained in the registrant’s files for a minimum of two years following the date the report was completed.

657—10.22(124) Disposal of registrant stock. A registrant shall dispose of controlled substances pursuant to the requirements of this rule. Disposal records shall be maintained by the registrant for at least two years from the date of the record.

10.22(1) Registrant stock supply. Controlled substances shall be removed from current inventory and disposed of by one of the following procedures:

a. The registrant shall utilize the services of a DEA-registered and Iowa-licensed reverse distributor.

b. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:

(1) By delivery to an agent of the board or to the board office.

(2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual.

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.
10.22(2) Waste resulting from administration or compounding. 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 from a registrant’s stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the wastage. The record shall include the following:

a. The controlled substance wasted.
b. The date of wastage.
c. The quantity or estimated quantity of the wasted controlled substance.
d. The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance.
e. The reason for the waste.
f. The signatures of both individuals involved in the wastage.

657—10.23(124) Disposal of previously dispensed controlled substances. Except as provided in 657—Chapter 23 care facilities, a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.

657—10.24(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

10.24(1) Form of prescription. All prescriptions for controlled substances shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions for controlled substances issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber’s written or electronic signature.

a. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions.

b. A prescriber’s agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber, but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription.

c. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations.

d. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber’s electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual.

e. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.24(2) Verification by pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber’s agent in each case when a written or oral prescription
for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient’s agent is known to the pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber’s agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist’s name or unique identifier.

10.24(3) Intern, resident, foreign physician. An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.8(5) shall include on all prescriptions issued the hospital’s registration number and the special internal code number assigned by the hospital in lieu of the prescriber’s registration number required by this rule. Each prescription shall include the stamped or legibly printed name of the prescribing intern, resident, or foreign physician as well as the prescriber’s signature.

10.24(4) Valid prescriber/patient relationship. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient’s use of the controlled substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken when the prescriber dies, retires, or moves out of the local service area or when the prescriber’s authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.24(5) Facsimile transmission of a controlled substance prescription. With the exception of an authorization for emergency dispensing as provided in rule 657—10.26(124), a prescription for a controlled substance in Schedules II, III, IV and V may be transmitted via facsimile from a prescriber to a pharmacy only as provided in rule 657—21.9(124,155A).

657—10.25(124) Dispensing records. Each registrant shall create a record of controlled substances dispensed to a patient or research subject.

10.25(1) Record maintained and available. The record shall be maintained for two years from the date of dispensing and be available for inspection and copying by the board or its authorized agents.

10.25(2) Record contents. The record shall include the following information:
   a. The name and address of the person to whom dispensed.
   b. The date of dispensing.
   c. The name or NDC number, strength, dosage form, and quantity of the substance dispensed.
   d. The name of the prescriber, unless dispensed by the prescriber.
   e. The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber’s agent involved in dispensing.
   f. The serial number or unique identification number of the prescription.

657—10.26(124) Schedule II emergency prescriptions.

10.26(1) Emergency situation defined. For the purposes of authorizing an oral or facsimile transmission of a prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term “emergency situation” means those situations in which the prescribing practitioner determines that all of the following apply:
   a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.
   b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.
   c. It is not reasonably possible for the prescribing practitioner to provide a manually signed written prescription to be presented to the pharmacy before the pharmacy dispenses the controlled substance, or
the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

10.26(2) Requirements of emergency prescription. In the case of an emergency situation as defined in subrule 10.26(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to a facsimile transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner or a DEA-compliant electronic prescription.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist’s name or unique identification.

c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner’s agent, the record shall include the first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via facsimile transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the facsimile transmission shall not be obscured or rendered illegible due to such security features.

e. Within seven days after authorizing an emergency prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of rule 657—10.24(124,126,155A), the prescription shall have written on its face “Authorization for Emergency Dispensing” and the date of the emergency order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph 10.26(2)“c.”

f. The pharmacist shall notify the board and the DEA if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board and the DEA, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

g. Pursuant to federal law and subrule 10.27(3), the pharmacist may fill a partial quantity of an emergency prescription so long as the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and that the remaining portions are filled no later than 72 hours after the prescription is issued.

657—10.27(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule and federal regulations.

10.27(1) Insufficient supply on hand. If the pharmacist is unable to supply the full quantity authorized in a prescription and makes a notation of the quantity supplied on the prescription record, a partial fill of the prescription is permitted. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.27(2) Long-term care or terminally ill patient. A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical
diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” For each partial filling, the dispensing pharmacist shall record on the back of the prescription or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

d. Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—124.115A.

10.27(3) Patient or prescriber request. At the request of the patient or prescriber, a prescription for a Schedule II controlled substance may be partially filled pursuant to this subrule and federal law. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. Except as provided in paragraph 10.26(2) “g,” the remaining portion of a prescription partially filled pursuant to this subrule may be filled within 30 days of the date the prescription was issued.

657—10.28(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.18(124,155A), as applicable.

657—10.29(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.29(1) Refills prohibited. The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.29(2) Legitimate medical purpose. Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber’s professional practice.

10.29(3) Dates and instructions. Each prescription issued pursuant to this rule shall be dated as of and manually signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.29(4) Authorized fill date unalterable. Regardless of the provisions of rule 657—10.30(124), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.29(5) Number of prescriptions and authorized quantity. An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.
10.29(6) Prescriber’s discretion. Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber’s patients once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.

657—10.30(124) Schedule II—changes to a prescription. With appropriate verification, a pharmacist may add information provided by the patient or patient’s agent, such as the patient’s address, to a Schedule II controlled substance prescription.

10.30(1) Changes prohibited. A pharmacist shall never change the patient’s name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber.

10.30(2) Changes authorized. After consultation with the prescriber or the prescriber’s agent and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:

a. The drug strength.

b. The dosage form.

c. The drug quantity.

d. The directions for use.

e. The date the prescription was issued.

f. The prescriber’s address or DEA registration number.

g. The name of the supervising prescriber if the prescription was issued by a physician assistant.

657—10.31 Reserved.

657—10.32(124) Schedule III, IV, or V prescription. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times.

10.32(1) Record. Each filling and refilling of a prescription shall be entered in a uniformly maintained and readily retrievable record in accordance with rule 657—10.25(124). If the pharmacist merely initials or affixes the pharmacist’s unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.32(2) Oral refill authorization. The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to an authorized individual at the pharmacy provided the following conditions are met:

a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issuance of the original prescription.

b. The pharmacist, pharmacist-intern, or technician who obtains the oral authorization from the prescriber who issued the original prescription documents, on or with the original prescription, the date authorized, the quantity of each refill, the number of additional refills authorized, and the unique identification of the authorized individual.

c. The quantity of each additional refill is equal to or less than the quantity authorized for the initial filling of the original prescription.

d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

10.32(3) Partial fills. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill pursuant to subrule 10.32(1). The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed.
10.32(4) Medication order. A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

657—10.33(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.33(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. This subrule does not prohibit, after the pharmacist 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.

10.33(2) Frequency and quantity. Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:
   a. 240 cc (8 ounces) of any controlled substance containing opium.
   b. 120 cc (4 ounces) of any other controlled substance.
   c. 48 dosage units of any controlled substance containing opium.
   d. 24 dosage units of any other controlled substance.

10.33(3) Age of purchaser. The purchaser shall be at least 18 years of age.

10.33(4) Identification. The pharmacist shall require every purchaser under this rule who is not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.33(5) Record. A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.33(6) Prescription not required under other laws. No other federal or state law or regulation requires a prescription prior to distributing or dispensing the Schedule V controlled substance.

657—10.34(124) 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 certified pharmacy technician to a purchaser at retail pursuant to the conditions of this rule.

10.34(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist, by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, or by a registered certified 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 certified 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 another pharmacy employee.

10.34(2) Packaging of nonliquid forms. A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.34(3) Frequency and quantity. Dispensing without a prescription to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of
ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing without a prescription to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.34(4) **Age of purchaser.** The purchaser shall be at least 18 years of age.

10.34(5) **Identification.** The pharmacist, pharmacist-intern, or certified 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 certified 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.

10.34(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 PTS 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, pharmacist-intern, or certified pharmacy technician who approved the dispensing of the product.

b. **Alternate record format.** The record shall be maintained using one of the following options:

1. A hard-copy record.
2. A record in the pharmacy’s electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.
3. A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

b. **PTS records retrieval.** Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.34(7) **Notice required.** The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and visible to the public:

“Warning: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.”

657—10.35 **Reserved.**

657—10.36(124,155A) **Records.** Every record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited under federal law. If the secure storage area is not located within the same physical structure as the registrant, the records must be retrievable within 48 hours of a request by the board or its authorized agent.

10.36(1) **Schedule I and II records.** Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.
10.36(2) Schedule III, IV, and V records. Records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

10.36(3) Date of record. The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, distribution, exportation, disposal, or transfer.

657—10.37 Reserved.

657—10.38(124) Revision of controlled substances schedules.

10.38(1) Designation of new controlled substance. The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than 30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201(4).

10.38(2) Objection to designation of a new controlled substance. The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board’s decision on the new designation as provided in Iowa Code section 124.201(4).


10.39(1) Amend Iowa Code section 124.206(7) by adding the following new paragraph “c”:


10.39(2) Amend Iowa Code section 124.204(9) by adding the following new paragraphs:

   t. Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5F-ADB; 5F-MDMB-PINACA.

   u. Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: 5F-AMB.

   v. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5F-APINACA, 5F-AKB48.

   w. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: ADB-FUBINACA.

   x. Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: MDMB-CHMICA, MMB-CHMINACA.

   y. Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: MDMB-FUBINACA.

   z. N-(4-fluorophenyl)-N-[(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: 4-fluoroisobutyryl fentanyl, para-fluoroisobutyryl fentanyl.

657—10.40(124) Excluded and exempt substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of “Excluded Nonnarcotic Products” identified in Title 21, CFR Part 1308, Section 22, and the list of “Exempted Prescription Products” described in Title 21, CFR Part 1308, Section 32. Copies of such lists may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

657—10.41(124) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2(2), includes any substance identified as such in Iowa Code section 124.208(6) or 126.2(2).
657—10.42 Reserved.

657—10.43(124) Reporting discipline and criminal convictions. A registrant 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 registrant 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 registrant shall provide written notice to the board of any criminal conviction of the registrant or of any owner that is related to the operation of the registered location no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

657—10.44(124) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a registration for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act.
2. Any conviction of a crime related to controlled substances committed by the registrant, or if the registrant is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusing access to the registered location or registrant records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Failure to maintain registration pursuant to 657—Chapter 10.
5. Any violation of Iowa Code chapters 124, 124A, 124B, 126, 155A, or 205, or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

ITEM 5. Amend rule 657—21.9(124,155A) as follows:

657—21.9(124,155A) Facsimile transmission (fax) of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner’s agent. A pharmacist may dispense a Schedule II controlled substance to fill an emergency prescription authorization pursuant to the requirements of rule 657—10.22(124) 657—10.26(124). The means of transmission via facsimile shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber’s signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner’s agent, shall identify the transmitting agent by first and last names and title and shall include the prescriber’s signature or electronic signature. A prescription for a controlled substance shall include the prescriber’s manual signature. If the controlled substance prescription is not manually signed by the prescriber, the pharmacist shall orally verify the authenticity and the content of the prescription by contacting the prescriber or the prescriber’s agent via telephone. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). This rule shall not apply to a prescription drug order transmitted pursuant to 657—paragraph 8.15(1)“d.”

ITEM 6. Amend rule 657—21.13(124,155A) as follows:

657—21.13(124,155A) Facsimile transmission of a prescription for Schedule II controlled substances—emergency situations. A pharmacist may in an emergency situation as defined in 657—subrule 10.22(1) rule 657—10.26(124) dispense Schedule II controlled substances pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescribing practitioner.
or the practitioner’s agent pursuant to the requirements of 657—10.22(124) rule 657—10.26(124). The facsimile or a print of the facsimile transmission shall serve as the temporary written record required by 657—subrule 10.22(2) rule 657—10.26(124).

**ITEM 7.** Amend rule 657—23.18(124,155A) as follows:

657—23.18(124,155A) **Schedule II orders.** This rule shall not apply to Schedule II controlled substances orders in facilities that utilize a floor stock distribution system as provided in subrule 23.11(4). Schedule II controlled substances in all other facilities shall be dispensed only upon receipt of an electronic prescription prepared, transmitted, and received in compliance with DEA regulations for electronic prescriptions or an original written order signed by the prescribing individual practitioner or upon receipt of a facsimile transmission of an original written order signed by the prescribing individual practitioner pursuant to rule 657—21.15(124,155A). In emergency situations as defined in 657—subrule 10.22(4) rule 657—10.26(124), Schedule II controlled substances may be dispensed in compliance with the requirements of rule 657—10.22(124) 657—10.26(124) or rule 657—21.13(124,155A), as applicable. In all cases, any order for a Schedule II controlled substance shall specify the total quantity authorized by the prescriber.

**ITEM 8.** Amend subrule 100.3(4) as follows:

100.3(4) **Availability of electronic PTS.** If the electronic PTS is unavailable for use, the dispenser shall maintain a written record of each transaction pursuant to 657—subrule 10.32(6) 10.34(6). The dispenser shall enter the information from the written record into the PTS within 72 hours of the time the PTS is again available and shall include in the electronic record that the record is a delayed entry.

[Filed 9/8/17, effective 11/1/17]
[Published 9/27/17]

EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 9/27/17.
ADDENDUM N

ADOPTED AND FILED


AUGUST 30, 2017
PHARMACY BOARD[657]

Adopted and Filed


Pursuant to Iowa Code section 17A.7(2), this rule making is the result of an overall review of administrative rules. These amendments update language in Board rules to reflect the current name and contact information for the Board and, in some Items, correct inaccurate citations to rules and laws. Additionally, during the 2017 Legislative Session of the 87th General Assembly, 2017 Iowa Acts, Senate File 484, was signed into law, rescinding Iowa Code section 155A.13B regarding pharmacy Internet sites. As a result, Item 1 of this rule making rescinds 657—Chapter 24.

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 June 21, 2017, Iowa Administrative Bulletin as ARC 3133C. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

These amendments were approved during the August 30, 2017, meeting of the Board of Pharmacy. After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 17A.7(2) and 2017 Iowa Acts, Senate File 484.

These amendments will become effective on November 1, 2017.

The following amendments are adopted.

ITEM 1. Rescind and reserve 657—Chapter 24.

ITEM 2. Amend rule 657—25.1(252.I), definition of “Board,” as follows:

“Board” means the Iowa board of pharmacy examiners.

ITEM 3. Amend subrule 25.2(3) as follows:

25.2(3) Preparation and service of denial notice. The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee.

ITEM 4. Amend subrule 25.3(3) as follows:

25.3(3) Preparation and service of revocation or suspension notice. The executive secretary/director of the board is authorized to prepare and serve the revocation or suspension notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive secretary/director shall notify the licensee of the board’s intention to revoke the license.

ITEM 5. Amend subrule 25.3(5) as follows:

25.3(5) Reinstatement following license suspension, revocation, or denial of renewal. A licensee shall pay all board fees required for license renewal or license reinstatement, and all continuing education requirements shall be met, before a license will be reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) 657—2.1(147,155A) and shall pay all required examination fees pursuant to rule 657—2.2(147) 657—2.3(147,155A). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete the appropriate application and pay all board fees required for new registration.
ITEM 6. Amend rule 657—26.1(17A) as follows:

657—26.1(17A) Petition for rule making. Any person, association, agency, or political subdivision may file a petition for rule making with the board of pharmacy at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A petition is deemed filed when received by that office. The board shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten, machine printed, or legibly handwritten in ink and must substantially conform to the following form:

IOWA BOARD OF PHARMACY EXAMINERS

<table>
<thead>
<tr>
<th>Petition by (Name of Petitioner)</th>
<th>PETITION FOR RULE MAKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>for the (adoption, amendment, or repeal)</td>
<td>of rules relating to (state subject matter).</td>
</tr>
</tbody>
</table>

The petition shall include the following information:
1. to 5. No change.
6. Any request by petitioner for a meeting provided for by rule 657—26.4(17A).
7. No change.

ITEM 7. Amend rule 657—26.3(17A) as follows:

657—26.3(17A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or via electronic mail to lloyd.jessen@ibpe.state.ia.us andrew.funk@iowa.gov.

ITEM 8. Amend rule 657—27.1(17A) as follows:

657—27.1(17A) Petition for declaratory order. Any person may file a petition with the board of pharmacy examiners, hereinafter referred to as “the board,” for a declaratory order as to the applicability to specified circumstances of a statute, rule, or order within the primary jurisdiction of the Iowa Board of Pharmacy Examiners at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A petition is deemed filed when it is received by that office. The board shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition shall be typewritten or legibly handwritten in ink and shall substantially conform to the following form:

IOWA BOARD OF PHARMACY EXAMINERS

<table>
<thead>
<tr>
<th>Petition by (Name of Petitioner)</th>
<th>PETITION FOR DECLARATORY ORDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>for a Declaratory Order on (Cite provisions of law involved).</td>
<td></td>
</tr>
</tbody>
</table>

The petition shall provide the following information:
1. to 8. No change.

The petition shall be dated and signed by the petitioner or the petitioner’s representative. It shall also include the name, mailing address, and telephone number of the petitioner and petitioner’s representative and a statement indicating the person to whom communications concerning the petition should be directed.

ITEM 9. Amend subrule 27.3(3) as follows:

27.3(3) A petition for intervention shall be filed at the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Such a petition is deemed filed when it is received by that office. The board will provide the petitioner with a file-stamped copy of the petition for intervention if the
petitioner provides an extra copy for this purpose. A petition for intervention shall be typewritten or legibly handwritten in ink and shall substantially conform to the following form:

IOWA BOARD OF PHARMACY EXAMINERS

Petition by (Name of Original Petitioner)
for a Declaratory Order on
(Cite provisions of law cited in
original petition).

PETITION FOR INTERVENTION

The petition for intervention shall provide the following information:
1. to 6. No change.

The petition shall be dated and signed by the intervenor or the intervenor’s representative. It shall also include the name, mailing address, and telephone number of the intervenor and intervenor’s representative, and a statement indicating the person to whom communications should be directed.

ITEM 10. Amend rule 657—27.5(17A) as follows:

657—27.5(17A) Inquiries. Inquiries concerning the status of a declaratory order proceeding may be made to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

ITEM 11. Amend rule 657—27.6(17A) as follows:

657—27.6(17A) Service and filing of petitions and other papers.

27.6(1) No change.

27.6(2) Filing—when required. All petitions for declaratory orders, petitions for intervention, briefs, or other papers in a proceeding for a declaratory order shall be filed with the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. All petitions, briefs, or other papers that are required to be served upon a party shall be filed simultaneously with the board.

27.6(3) Method of service, time of filing, and proof of mailing. Method of service, time of filing, and proof of mailing shall be as provided by 657—35.11(17A,272C) 657—35.17(17A,272C).

ITEM 12. Amend rule 657—27.8(17A) as follows:

657—27.8(17A) Action on petition.

27.8(1) Within the time allowed by 1998 Iowa Acts, chapter 1202, section 13(5) Iowa Code section 17A.9(5), after receipt of a petition for a declaratory order, the executive secretary/director or designee board shall take action on the petition as required by 1998 Iowa Acts, chapter 1202, section 13(5) Iowa Code section 17A.9(5).

27.8(2) No change.

ITEM 13. Amend rule 657—27.9(17A) as follows:

657—27.9(17A) Refusal to issue order.

27.9(1) The board shall not issue a declaratory order where prohibited by 1998 Iowa Acts, chapter 1202, section 13(1), Iowa Code section 17A.9(1) and may refuse to issue a declaratory order on some or all questions raised for the following reasons:

1. to 10. No change.

27.9(2) and 27.9(3) No change.

ITEM 14. Amend 657—Chapter 27, implementation sentence, as follows:

These rules are intended to implement Iowa Code section 17A.9 as amended by 1998 Iowa Acts, chapter 1202, section 13.
Item 15. Amend rule 657—29.1(68B) as follows:

657—29.1(68B) Selling of goods or services by members of the board. The board members shall not sell, either directly or indirectly, any goods or services to individuals, associations, or corporations that are subject to the regulatory authority of the board of pharmacy examiners except as authorized by these rules.

Item 16. Amend subrules 29.3(1) and 29.3(2) as follows:

29.3(1) A member of the board may sell goods or services to any individual, association, or corporation regulated by any division within the department of public health, other than the board of pharmacy examiners. This consent is granted because the sale of such goods or services does not affect the board member’s duties or functions on the board.

29.3(2) A member of the board may sell goods or services to any individual, association, or corporation regulated by the board of pharmacy examiners if those goods or services are routinely provided to the public as part of that person’s regular professional practice. This consent is granted because the sale of such goods or services does not affect the board member’s duties or functions on the board. In the event an individual, association, or corporation to whom a board member sells goods or services is directly involved in any matter pending before the board, including a disciplinary matter, that board member shall not participate in any deliberation or decision concerning that matter. In the event a complaint is filed with the board concerning the services provided by the board member to a member of the public, that board member is otherwise prohibited by law from participating in any discussion or decision by the board in that case.

Item 17. Amend rule 657—29.4(68B) as follows:

657—29.4(68B) Application for consent. Prior to selling a good or service to an individual, association, or corporation subject to the regulatory authority of the board of pharmacy examiners, a board member must obtain prior written consent unless the sale is specifically allowed in rule 657—29.3(68B). The request for consent must be in writing, signed by the board member requesting consent. The application must provide a clear statement of all relevant facts concerning the sale. The application should identify the parties to the sale and the amount of compensation. The application should also explain why the sale should be allowed.

Item 18. Amend rule 657—31.1(261), definition of “Board,” as follows:

“Board” means the Iowa board of pharmacy examiners.

Item 19. Amend subrule 31.2(3) as follows:

31.2(3) Preparation and service of denial notice. The executive director of the board is authorized to prepare and serve the notice upon the licensee.

Item 20. Amend subrule 31.3(3) as follows:

31.3(3) Preparation and service of revocation or suspension notice. The executive director of the board is authorized to prepare and serve the notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive director shall notify the licensee of the board’s intention to revoke the license.

Item 21. Amend subrule 31.3(5) as follows:

31.3(5) Reinstatement following license suspension, revocation, or denial of renewal. All board fees required for license renewal or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) 657—2.1(147,155A) and shall pay all required examination fees pursuant to rule 657—2.2(147) 657—2.3(147,155A). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124
has been revoked shall complete the appropriate application and pay all board fees required for new registration.

[Filed 9/8/17, effective 11/1/17]
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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 9/27/17.
ADDENDUM O

ADOPTED AND FILED

AMENDING CHAPTER 34, “RULES FOR WAIVERS AND VARIANCES”

AUGUST 30, 2017
Pursuant to the authority of Iowa Code sections 17A.22 and 147.76, the Board of Pharmacy hereby amends Chapter 34, “Rules for Waivers and Variances,” Iowa Administrative Code.

These amendments eliminate duplicative information regarding filing deadlines and contested case procedures that are established in greater detail in 657—Chapter 35, “Contested Cases.” The required contents of the petition for waiver have also been simplified to eliminate information and requirements for information and documentation that have been deemed unnecessary or excessively burdensome, such as a signed release authorizing a person with information regarding a petition to provide the Board with such information.

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 June 21, 2017, Iowa Administrative Bulletin as ARC 3134C. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

These amendments were approved during the August 30, 2017, meeting of the Board of Pharmacy. After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 17A.9A, 17A.22, 22.2, 124.301, 126.17, 147.76, 155A.2, 205.11, 205.13, 272C.3, and 272C.4.

These amendments will become effective on November 1, 2017.

The following amendments are adopted.

ITEM 1. Amend rule 657—34.2(17A,124,126,147,155A,205,272C) as follows:

657—34.2(17A,124,126,147,155A,205,272C) Scope of chapter. This chapter outlines generally applicable standards and a uniform process for the granting of individual waivers from rules adopted by the board in situations when no other more specifically applicable law provides for waivers. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific provision shall supersede this chapter with respect to any waiver from that rule.

ITEM 2. Amend rule 657—34.4(17A) as follows:

657—34.4(17A) Criteria for waiver or variance. In response to a petition completed pursuant to rule 657—34.6(17A) for waiver, the board may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the board finds, based on clear and convincing evidence, all of the following:

1. to 4. No change.

ITEM 3. Amend rule 657—34.5(17A,124,126,147,155A,205,272C) as follows:

657—34.5(17A,124,126,147,155A,205,272C) Filing of petition. A petition for a waiver shall be submitted in writing to the board as follows:

34.5(1) License, registration, or permit application. If the petition relates to a license, registration, or permit application, the petition shall be made in accordance with the application requirements for the license, registration, or permit in question.

34.5(2) Contested cases. If the petition relates to a procedural rule governing a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case. A petition cannot be submitted to waive a substantive rule the respondent has been charged with violating in a pending contested case.

34.5(3) Other: If the petition does not relate to a license, registration, or permit application or to a pending contested case, the petition may be submitted to the board’s executive secretary/director.
ITEM 4. Amend rule 657—34.6(17A) as follows:

657—34.6(17A) Content of petition. A petition for waiver shall include the following information where applicable and known to the petitioner:

1. to 3. No change.

4. The relevant facts that the petitioner believes would justify a waiver under each of the four criteria described in rule 657—34.4(17A). This shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.

5. A history of any prior contacts between the board and the petitioner relating to the regulated activity, license, registration, or permit affected by the proposed waiver. This history shall include a description of each affected license, registration, or permit held by the petitioner and any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, registration, or permit within the last five years.

6. Any information known to the petitioner regarding the board’s treatment of similar cases.

7. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the granting of the waiver.

8. The name, address, and telephone number of any person who would be adversely affected by the granting of a petition for waiver.

9. The name, address, and telephone number of any person with knowledge of facts relevant to the proposed waiver.

10. Signed releases authorizing persons with knowledge of the request to furnish the board with information relevant to the proposed waiver.

ITEM 5. Amend rule 657—34.7(17A) as follows:

657—34.7(17A) Additional information and providing notice. Prior to issuing an order granting or denying a waiver, the board may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the board may, on its own motion or at the petitioner’s request, schedule a telephonic or in-person meeting between the petitioner and the board’s executive secretary/director, a committee of the board, or a quorum of the board. The board may provide notice of a petition for waiver to any person who might be affected by the waiver. The board shall provide public notice of any petitions for waiver by including any petitions for waiver on the agenda of the board meeting during which the petition for waiver will be discussed.

ITEM 6. Rescind and reserve rules 657—34.8(17A) and 657—34.9(17A).

ITEM 7. Rescind subrules 34.10(4), 34.10(7), 34.10(8) and 34.10(9).

ITEM 8. Renumber subrules 34.10(5) and 34.10(6) as 34.10(4) and 34.10(5).

[Filed 9/8/17, effective 11/1/17]
[Published 9/27/17]

EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 9/27/17.
ADDENDUM P

ADOPTED AND FILED


AUGUST 30, 2017
Pursuant to the authority of Iowa Code sections 17A.3, 17A.22, and 147.76, the Board of Pharmacy hereby rescinds Chapter 35, “Contested Cases,” and Chapter 36, “Discipline,” Iowa Administrative Code, and adopts new Chapters 35 and 36 with the same titles.

The amendments rescind current chapters regarding contested cases and discipline and adopt new chapters in lieu thereof. Many of the current rules are reorganized and moved from one chapter to another, and duplicative rules are eliminated. Because many of these rules are cross-referenced between the two chapters, and because disciplinary actions are governed by the procedures regarding contested cases, these two chapters have been reviewed and reorganized and are now proposed jointly.

Pursuant to the requirements of Iowa Code chapter 17A, the rules establish the procedures relating to contested cases, including required filings and timelines, requirements for notice of hearing and statements of charges, identification of the presiding officer, and the duties and authority of the presiding officer. The rules address the procedures for disciplinary hearings and nondisciplinary hearings, describe the circumstances under which a presiding Board member may need to withdraw from participation in a contested case hearing, identify and prohibit ex parte communications, establish the standards of evidence in a contested case, provide for default judgment, and define a final decision of the Board.

The rules identify the grounds for disciplinary action against a license, registration, or permit issued by the Board of Pharmacy, identify the disciplinary sanctions that may be imposed by the Board upon finding a violation of applicable Iowa Code or Iowa Administrative Code requirements, and identify minimum procedures for reinstatement of a license, registration, or permit that was previously suspended, revoked, or surrendered pursuant to these rules. The rules identify the Board’s authority to issue an administrative subpoena, the required basis for such a subpoena, and the procedures for the issuance and enforcement of a subpoena.

The rules establish the requirements for issuance of a confidential order for mental or physical examination of a licensee or registrant that is not a disciplinary action or order, provide for the utilization of a peer review committee when needed, and provide for the assessment of a hearing fee and authorized hearing costs on the subject of a disciplinary hearing that results in disciplinary action against a licensee.

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 June 21, 2017, Iowa Administrative Bulletin as ARC 3135C. The Board received no written comments regarding the proposed amendments. The adopted amendments differ from those published under Notice. Minor changes have been made as follows:

- In subrule 35.35(1), the Iowa Code reference is changed from section 17A.18 to section 17A.18A.
- Subrule 36.3(1) has been amended to include “that may violate the board’s rules or that are related to” and now reads as follows:

  “36.3(1) General. The board may, upon receipt of a written or verbal complaint or upon its own motion pursuant to other evidence received by the board, review and investigate alleged acts or omissions that may violate the board’s rules or that are related to the ethical or professional conduct of a licensee.”
- In subrule 36.10(2), the last word in the first sentence has been changed from “license” to “licensee.”

The amendments were approved during the August 30, 2017, meeting of the Board of Pharmacy. After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.55, 155A.6 to 155A.6B, 155A.12, 155A.13 to 155A.13C, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

These amendments will become effective on November 1, 2017.

The following amendments are adopted.
ITEM 1. Rescind 657—Chapter 35 and adopt the following new chapter in lieu thereof:

CHAPTER 35
CONTESTED CASES

657—35.1(17A,124,124B,126,147,155A,205,272C) Scope and applicability. This chapter applies to contested case proceedings conducted by the board of pharmacy.

657—35.2(17A,272C) Definitions. Except where otherwise specifically defined by law:

"Board" means the Iowa board of pharmacy.

"Contested case" means a proceeding defined by Iowa Code section 17A.2(5), including but not limited to licensee disciplinary proceedings, license denial proceedings, and license reinstatement proceedings.

"Issuance" means the date of mailing of a decision or order, or date of delivery if service is by other means, unless another date is specified in the order.

"License" means any license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

"Licensee" means any person or entity possessing a license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

"Party" means the state of Iowa, as represented by the office of the attorney general, and respondent or applicant.

"Probable cause" means a reasonable ground for belief in the existence of facts warranting the specified proceeding.

657—35.3(17A) Time requirements.

35.3(1) Computation. Time shall be computed as provided in Iowa Code section 4.1(34).

35.3(2) Changing time to take action. For good cause, the presiding officer may extend or shorten the time to take any action, except as precluded by statute or by rule. Except for good cause stated in the record, before extending or shortening the time to take any action, the presiding officer shall afford all parties an opportunity to be heard or to file written arguments.

657—35.4(17A) Applicability of Iowa Rules of Civil Procedure. Except as expressly provided in Iowa Code chapter 17A and these rules, the Iowa Rules of Civil Procedure do not apply to contested case proceedings. However, upon application by a party, the board may permit the use of procedures provided for in the Iowa Rules of Civil Procedure unless doing so would unreasonably complicate the proceedings or impose an undue hardship on a party.

657—35.5(17A,272C) Combined statement of charges and settlement agreement. Upon a determination by the board that probable cause exists to take public disciplinary action, the board and the licensee may enter into a combined statement of charges and settlement agreement.

35.5(1) No licensee is entitled to be offered a combined statement of charges and settlement agreement.

35.5(2) Entering into a combined statement of charges and settlement agreement is completely voluntary.

35.5(3) The combined statement of charges and settlement agreement shall include a brief statement of the charges, the circumstances that led to the charges, and the terms of settlement.

35.5(4) A combined statement of charges and settlement agreement shall constitute the commencement and resolution of a contested case proceeding. By entering into a combined statement of charges and settlement agreement, the licensee waives the right to a contested case hearing on the matter.

35.5(5) A combined statement of charges and settlement agreement is a permanent public record open for inspection under Iowa Code chapter 22.
657—35.6(17A,124B,126,147,155A,205,272C) Notice of hearing.
35.6(1) Delivery. Delivery of the notice of hearing constitutes the commencement of the contested case proceeding. Delivery may be executed by:
   a. Personal service, as provided in the Iowa Rules of Civil Procedure; or
   b. Certified restricted mail, return receipt requested; or
   c. Signed acknowledgment accepting service; or
   d. When service cannot be accomplished using the above methods:
      (1) An affidavit shall be prepared outlining the measures taken to attempt service; and
      (2) Notice of hearing shall be published once each week for three consecutive weeks in a newspaper of general circulation, published or circulated in the county of last-known residence of the respondent. The first notice of hearing shall be published at least 30 days prior to the scheduled hearing.
35.6(2) Contents. The notice of hearing shall contain the following information:
   a. A statement of the time, place, and nature of the hearing;
   b. A statement of the legal authority and jurisdiction under which the hearing is to be held;
   c. A reference to the particular sections of the statutes and rules involved;
   d. A short and plain statement of the matters asserted;
   e. Identification of all parties, including the name, address and telephone number of the assistant attorney general representing the state;
   f. Reference to the procedural rules governing conduct of the contested case proceeding;
   g. Reference to the procedural rules governing settlement;
   h. Identification of the presiding officer;
   i. Notification of the time period in which a party may request, pursuant to Iowa Code section 17A.11 and rule 657—35.10(17A,272C), that the presiding officer be an administrative law judge;
   j. Notification of the time period in which the respondent may file an answer; and
   k. Notification of the respondent’s right to request a closed hearing, if applicable.
35.6(3) Public record. A notice of hearing is a permanent public record open for inspection under Iowa Code chapter 22.

657—35.7(17A,272C) Statement of charges. In the event the board finds there is probable cause for taking public disciplinary action against a licensee, the board shall file a statement of charges. The statement of charges shall be incorporated within the notice of hearing. The statement of charges shall set forth the acts or omissions with which the respondent is charged, including the statute(s) and rule(s) which are alleged to have been violated, and shall be in sufficient detail to enable the preparation of the respondent’s defense. Every statement of charges prepared by the board shall be reviewed by the office of the attorney general before it is filed. A statement of charges is a permanent public record open for inspection under Iowa Code chapter 22.

657—35.8(13,272C) Legal representation. Following the issuance of a notice of hearing, the office of the attorney general shall be responsible for the legal representation of the public interest in the contested case. The assistant attorney general assigned to prosecute a contested case before the board shall not represent the board in that case but shall represent the public interest.

657—35.9(17A,272C) Presiding officer in a disciplinary contested case. The presiding officer in a disciplinary contested case shall be the board. When acting as presiding officer, the board may request that an administrative law judge perform certain functions as an aid to the board, such as ruling on prehearing motions, conducting the prehearing conference, ruling on evidentiary objections at hearing, assisting in deliberations, and drafting the written decision for review by the board.

657—35.10(17A,272C) Presiding officer for nondisciplinary hearings.
35.10(1) Request for administrative law judge. Any party in a nondisciplinary contested case who wishes to request that the presiding officer assigned to render a proposed decision be an administrative
law judge employed by the department of inspections and appeals must file a request within 20 days after service of a notice of hearing.

35.102 *Grounds for denial.* The board may deny the request only upon a finding that one or more of the following apply:

a. There is a compelling need to expedite issuance of a final decision in order to protect the public health, safety, or welfare.

b. An administrative law judge is unavailable to hear the case within a reasonable time.

c. The case involves significant policy issues of first impression that are inextricably intertwined with the factual issues presented.

d. The demeanor of the witnesses is likely to be dispositive in resolving the disputed factual issues.

e. Funds are unavailable to pay the costs of an administrative law judge and an interagency appeal.

f. The request was not timely filed.

g. The request is not consistent with a specified statute.

35.103 *Written ruling.* The board shall issue a written ruling specifying the grounds for its decision within 20 days after a request for an administrative law judge is filed. If the ruling is contingent upon the availability of an administrative law judge, the parties shall be notified at least 10 days prior to hearing if an administrative law judge will not be available.

657—35.11(17A,124B,147,155A,272C) *Waiver of procedures.* Unless otherwise precluded by law, the parties in a contested case proceeding may waive any provision of this chapter. However, the board in its discretion may refuse to give effect to such a waiver when it deems the waiver to be inconsistent with the public interest.

657—35.12(17A,272C) *Telephone or electronic proceedings.* The presiding officer may resolve prehearing matters by telephone conference in which all parties have an opportunity to participate. Contested case hearings will generally not be held by telephone or electronic means in the absence of consent by all parties under compelling circumstances. Nothing shall prohibit a witness from testifying by telephone or electronic means pursuant to subrule 35.26(3).

657—35.13(17A) *Disqualification.*

35.131 *Reasons for withdrawal from participation.* A presiding officer or other person shall withdraw from participation in the making of any proposed or final decision in a contested case if that person:

a. Has a personal bias or prejudice concerning a party or a representative of a party.

b. Has personally investigated, prosecuted or advocated in connection with that case, the specific controversy underlying that case, another pending factually related contested case, or a pending factually related controversy that may culminate in a contested case involving the same parties. If the licensee elects to appear before the board in the investigation process, the licensee waives this provision.

c. Is subject to the authority, direction or discretion of any person who has personally investigated, prosecuted or advocated in connection with that contested case, the specific controversy underlying that contested case, or a pending factually related contested case or controversy involving the same parties.

d. Has acted as counsel to any person who is a private party to that proceeding within the past two years.

e. Has a personal financial interest in the outcome of the case or any other significant personal interest that could be substantially affected by the outcome of the case.

f. Has a spouse or relative within the third degree of relationship that:

(1) Is a party to the case, or an officer, director or trustee of a party;

(2) Is a lawyer in the case;

(3) Is known to have an interest that could be substantially affected by the outcome of the case; or

(4) Is likely to be a material witness in the case.

g. Has any other legally sufficient cause to withdraw from participation in the decision making in that case.
35.13(2) “Personally investigated” defined. The term “personally investigated” means taking affirmative steps to interview witnesses directly or to obtain documents or other information directly. The term “personally investigated” does not include general direction and supervision of assigned investigators, unsolicited receipt of information which is relayed to assigned investigators, review of another person's investigative work product in the course of determining whether there is probable cause to initiate a proceeding, or exposure to factual information while performing other board functions, including fact gathering for purposes other than investigation of the matter which culminates in a contested case. Factual information relevant to the merits of a contested case received by a person who later serves as presiding officer in that case shall be disclosed if required by Iowa Code section 17A.17(3) and rule 657—35.28(17A,272C).

35.13(3) Determination that withdrawal is not necessary. In a situation where a presiding officer or other person knows of information which might reasonably be deemed to be a basis for disqualification and decides voluntary withdrawal is unnecessary, that person shall submit by affidavit for the record the relevant information and shall provide for the record a statement of the reasons for the determination that withdrawal is unnecessary.

35.13(4) Motion for disqualification. If a party asserts disqualification on any appropriate ground, including those listed in subrule 35.13(1), the party shall file a motion supported by an affidavit pursuant to Iowa Code section 17A.11(3). The motion shall be filed as soon as practicable after the reason alleged in the motion becomes known to the party. If, during the course of the hearing, a party first becomes aware of evidence of bias or other grounds for disqualification, the party may move for disqualification but must establish the grounds by the introduction of evidence into the record. The individual against whom disqualification is asserted shall make the initial determination as to whether disqualification is required. If the individual elects not to disqualify, the board shall make the final determination as to disqualification of that individual as part of the record in the case.


35.14(1) Consolidation. The presiding officer may consolidate any or all matters at issue in two or more contested case proceedings where:
   a. The matters at issue involve common parties or common questions of fact or law;
   b. Consolidation would expedite and simplify consideration of the issues involved; and
   c. Consolidation would not adversely affect the rights of any of the parties to those proceedings.

35.14(2) Severance. The presiding officer may, for good cause shown, order any contested case proceedings or portions thereof severed.

657—35.15(17A,272C) Appearance. The respondent or applicant may be represented by an attorney. The attorney must file an appearance in the contested case. If the attorney is not licensed to practice law in Iowa, the attorney must fully comply with Iowa Court Rule 31.14. If the respondent or applicant is an entity, the entity may designate a representative to appear on behalf of the entity.

657—35.16(17A,272C) Answer. An answer may be filed within 20 days of service of the notice of hearing and statement of charges. An answer shall specifically admit, deny, or otherwise answer all material allegations of the statement of charges to which it responds. It shall state any facts supporting any affirmative defenses and contain as many additional defenses as the respondent may claim. An answer shall state the name, address and telephone number of the person filing the answer. Any allegation in the statement of charges not denied in the answer is considered admitted. The presiding officer may refuse to consider any defense not raised in the answer which could have been raised on the basis of facts known when the answer was filed if any party would be prejudiced.

657—35.17(17A,272C) Service and filing of documents.

35.17(1) Filing—when required. After the notice of hearing, all documents in a contested case proceeding shall be filed with the board.
35.17(2) Filing—how made. Filing may be made by delivering or mailing the document to the board office located at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Filing may also be made by e-mailing the document to the e-mail addresses identified in the notice of hearing as the appropriate e-mail address for filing. A party electing to file a document via e-mail is responsible for ensuring the document was received.

35.17(3) Filing—when made. A document is deemed filed at the time it is delivered to the board, delivered to an established courier service for immediate delivery to the board office, mailed by first-class mail or state interoffice mail to the board office, so long as there is proof of mailing, or e-mailed.

35.17(4) Service—when required. Except where otherwise provided by law, every document filed in a contested case proceeding shall be simultaneously served upon each of the parties of record to the proceeding, including the assistant attorney general representing the state. Except for an application for rehearing as provided in Iowa Code section 17A.16(2), the party filing a document is responsible for service on all parties.

35.17(5) Service—how made. Service upon a party represented by an attorney shall be made upon the attorney unless otherwise ordered. Service is made by delivery or by mailing a copy to the person’s last-known address. Service by mail is complete upon mailing, except where otherwise specifically provided by statute, rule, or order, so long as there is proof of mailing.

35.17(6) Electronic service. Service may be made upon a party or attorney by e-mail if the person consents in writing that case to be served in that manner. The written consent shall specify the e-mail address for such service. The written consent may be withdrawn by written notice served on the parties or attorneys.

35.17(7) Proof of mailing/e-mailing. Proof of mailing/e-mailing includes one of the following:
   a. A legible United States Postal Service postmark on the envelope;
   b. A certificate of service;
   c. A notarized affidavit; or
   d. A certification in substantially the following form:

   I certify under penalty of perjury and pursuant to the laws of Iowa that, on (date of mailing), I mailed copies of (describe document) addressed to the Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, and to the names and addresses of the parties listed below by depositing the same in the United States mail, state interoffice mail, or e-mail when permitted by 657 IAC 35.17(6).

   ____________________________________________________________
   Date
   ____________________________________________________________
   Signature

657—35.18(272C) Investigative file. The board’s investigative file is available to the respondent or applicant upon request only after the commencement of a contested case and only prior to the resolution of the contested case. A licensee that elects to enter into a combined statement of charges and settlement agreement is not entitled to request the investigative file. In accordance with Iowa Code section 272C.6(4), information contained within an investigative file is confidential and may only be used in connection with the disciplinary proceedings before the board.

657—35.19(17A.272C) Discovery.
  35.19(1) Scope. The scope of discovery described in Iowa Rule of Civil Procedure 1.503 shall apply to contested case proceedings.

  35.19(2) Procedures available. The following discovery procedures available in the Iowa Rules of Civil Procedure are available to the parties in a contested case proceeding: depositions upon oral examination or written questions; written interrogatories; production of documents, electronically stored information, and things; and requests for admission. Unless lengthened or shortened by the presiding officer, the time frames for discovery in the specific Iowa Rules of Civil Procedure govern those specific procedures.
a. Iowa Rules of Civil Procedure 1.701 through 1.717 regarding depositions shall apply to any depositions taken in a contested case proceeding. Any party taking a deposition in a contested case shall be responsible for any deposition costs, unless otherwise specified or allocated in an order. Deposition costs include, but are not limited to, reimbursement for mileage of the deponent, costs of a certified shorthand reporter, and expert witness fees, as applicable.

b. Iowa Rule of Civil Procedure 1.509 shall apply to any interrogatories propounded in a contested case proceeding.

c. Iowa Rule of Civil Procedure 1.512 shall apply to any requests for production of documents, electronically stored information, and things in a contested case proceeding.

d. Iowa Rule of Civil Procedure 1.510 shall apply to any requests for admission in a contested case proceeding. Iowa Rule of Civil Procedure 1.511 regarding the effect of an admission shall apply in contested case proceedings.

35.19(3) Disclosure and discovery conference. The mandatory disclosure and discovery conference requirements in Iowa Rules of Civil Procedure 1.500 and 1.507 do not apply to contested case proceedings. However, upon application by a party, the board may order the parties to comply with these procedures unless doing so would unreasonably complicate the proceedings or impose an undue hardship.

35.19(4) Experts. Iowa Rule of Civil Procedure 1.508 shall apply to discovery of any experts identified by a party to a contested case proceeding.

35.19(5) Service. Discovery shall be served on all parties to the contested case proceeding but shall not be filed with the board.

35.19(6) Motions. A party may file a motion to compel or other motion related to discovery in accordance with this subrule. Any motion filed with the board relating to discovery shall allege that the moving party has previously made a good-faith attempt to resolve the discovery issues involved with the opposing party. Motions in regard to discovery shall be ruled upon by the presiding officer. Opposing parties shall be afforded the opportunity to respond within ten days of the filing of the motion unless the time is lengthened or shortened by the presiding officer. The presiding officer may rule on the basis of the written motion and any response or may order argument on the motion.

35.19(7) Use of evidence. Evidence obtained in discovery may be used in the contested case proceeding if that evidence would otherwise be admissible in that proceeding.

657—35.20(17A,272C) Issuance of subpoenas in a contested case.

35.20(1) Types of subpoenas. Subpoenas issued in a contested case may compel the attendance of witnesses at depositions or hearing and may compel the production of books, papers, records, and other real evidence. A command to produce evidence or to permit inspection may be joined with a command to appear at deposition or hearing or may be issued separately. Subpoenas shall be issued by the executive director or designee upon a written request that complies with the requirements of this rule. A request for a subpoena of mental health records must confirm that the conditions described in subrule 35.20(3) have been satisfied prior to the issuance of the subpoena. The executive director or designee may refuse to issue a subpoena if the request does not comply with the requirements of this rule.

35.20(2) Request for subpoena—contents. A request for a subpoena shall include the following information, as applicable, unless the subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes:

a. The name, address, and telephone number of the person requesting the subpoena;

b. The name and address of the person to whom the subpoena shall be directed;

c. The date, time, and location at which the person shall be commanded to attend and give testimony;

d. Whether the testimony is requested in connection with a deposition or hearing;

e. A description of the books, papers, records, or other real evidence requested;

f. The date, time, and location for production or inspection and copying; and

g. In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 35.20(3) have been satisfied.
35.20(3) Request for subpoena—mental health records. In the case of a request for a subpoena of mental health records, the request must confirm compliance with the following conditions prior to the issuance of the subpoena:

a. The nature of the issues in the case reasonably justifies the issuance of the requested subpoena;

b. Adequate safeguards have been established to prevent unauthorized disclosure;

c. An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and

d. An attempt was made to notify the patient and to secure an authorization from the patient for the release of the records at issue.

35.20(4) Content of subpoena. Each subpoena shall contain, as applicable:

a. The caption of the case;

b. The name, address, and telephone number of the person who requested the subpoena;

c. The name and address of the person to whom the subpoena is directed;

d. The date, time, and location at which the person is commanded to appear;

e. Whether the testimony is commanded in connection with a deposition or hearing;

f. A description of the books, papers, records or other real evidence the person is commanded to produce;

g. The date, time, and location for production or inspection and copying;

h. The time within which a motion to quash or modify the subpoena must be filed;

i. The signature, address, and telephone number of the executive director or designee;

j. The date of issuance;

k. A return of service.

35.20(5) Distribution of subpoena. Unless a subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes, the executive director or designee shall mail copies of all subpoenas to the parties. The person who requested the subpoena is responsible for serving the subpoena upon the subject of the subpoena.

35.20(6) Timely motion. Any person who is aggrieved or adversely affected by compliance with the subpoena, or any party to the contested case who desires to challenge the subpoena, shall, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified, and may be accompanied by legal briefs or factual affidavits.

35.20(7) Consideration of motion. Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to issue a decision, or the board may issue a decision. Oral argument may be scheduled at the discretion of the board or the administrative law judge. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

35.20(8) Appeal of ruling on motion. A person aggrieved by a ruling of an administrative law judge who desires to challenge the ruling shall appeal the ruling to the board by serving on the executive director in accordance with rule 657—35.17(17A,272C), a notice of appeal within ten days after service of the decision of the administrative law judge.

35.20(9) Judicial review. If the person contesting the subpoena is not a party to the contested case proceeding, the board’s decision is final for purposes of judicial review. If the person contesting the subpoena is a party to the contested case proceeding, the board’s decision is not final for purposes of judicial review until there is a final decision in the contested case.

35.20(10) Refusal to obey subpoena. In the event of a refusal to obey a subpoena, the board may petition the district court for its enforcement. Upon proper showing, the district court shall order the person to obey the subpoena and, if the person fails to obey the order of the court, the person may be found guilty of contempt of court.
657—35.21(17A.272C) Motions.

35.21(1) Form. No technical form for motions is required. Prehearing motions must be in writing, state the grounds for relief, and state the relief sought.

35.21(2) Timely response. Any party may file a written response to a motion within ten days after the motion is served, unless the time period is extended or shortened by rules of the board or the presiding officer. The presiding officer may consider a failure to respond within the required time period in ruling on a motion.

35.21(3) Oral argument. The presiding officer may schedule oral argument on any motion.

35.21(4) Timely filing. Motions pertaining to the hearing shall be filed and served at least ten days prior to the date of hearing unless there is good cause for permitting later action or the time for such action is lengthened or shortened by rule of the board or an order of the presiding officer.

35.21(5) Dispositive motions. Dispositive motions, such as motions for summary judgment or motions to dismiss, must be filed with the board and served on all parties to the contested case proceeding at least 30 days prior to the scheduled hearing date, unless otherwise ordered or permitted by the presiding officer. Any party may file a written response to a dispositive motion within 10 days after the motion is served, unless the time for response is otherwise lengthened or shortened by the presiding officer.

657—35.22(17A.272C) Prehearing conference.

35.22(1) Request or order for conference. Any party may request a prehearing conference. Prehearing conferences shall be conducted by the executive director, who may request that an administrative law judge conduct the prehearing conference. A written request for prehearing conference or an order for prehearing conference on the executive director’s own motion shall be filed not less than seven days prior to the hearing date, unless authorized by the person conducting the prehearing conference. A prehearing conference shall be scheduled not less than three business days prior to the hearing date.

35.22(2) Conference subjects. Each party shall be prepared to discuss the following subjects at the prehearing conference:

a. Submission of expert and other witness lists. Witness lists may be amended subsequent to the prehearing conference within the time limits established by the executive director or administrative law judge at the prehearing conference. Any such amendments must be served on all parties. Witnesses not listed on the final witness list may be excluded from testifying unless there was good cause for the failure to include their names.

b. Submission of exhibit lists. Exhibit lists may be amended subsequent to the prehearing conference within the time limits established by the executive director or administrative law judge at the prehearing conference. Other than rebuttal exhibits, exhibits that are not listed on the final exhibit list may be excluded from admission into evidence unless there was good cause for the failure to include them.

c. The entry of a scheduling order to include deadlines for completion of discovery.

d. Stipulations of law or fact.

e. Stipulations on the admissibility of exhibits.

f. Identification of matters which the parties intend to request be officially noticed.

g. Consideration of any additional matters which will expedite the hearing.

35.22(3) Conducted by telephone. Prehearing conferences shall be conducted by telephone unless otherwise ordered.

35.22(4) Intra-agency appeal. A party must seek intra-agency appeal to the board of prehearing rulings made by an administrative law judge in order to adequately exhaust administrative remedies. Such appeals must be filed within ten days of the date of the issuance of the challenged ruling but no later than the time for compliance with the order or the date of hearing, whichever is first.

657—35.23(17A.272C) Continuances. Unless otherwise provided, requests for continuances shall be filed with the board.
35.23(1) Requirements of request. A written request for a continuance shall:
   a. Be made at the earliest possible time and no less than seven days before the hearing except in case of unanticipated emergencies;
   b. State the specific reasons for the request; and
   c. Be signed by the requesting party or the party’s attorney.
35.23(2) Notice to parties. No request for continuance shall be made or granted without notice to all parties except in an emergency where notice is not feasible. The presiding officer may allow an oral application for continuance at the contested case hearing only in the event of an unanticipated emergency.
35.23(3) Authorized individuals. The presiding officer or the executive director has the authority to grant or deny a request for a continuance in accordance with this subrule. The executive director or an administrative law judge may enter an order granting an uncontested request for a continuance. Upon consultation with the board chair, the executive director or an administrative law judge may deny an uncontested request for a continuance or may rule on a contested request for continuance.
35.23(4) Consideration of request. In determining whether to grant a continuance, the presiding officer or the executive director may require documentation of any grounds for a continuance and may consider:
   a. Prior continuances;
   b. The interests of all parties;
   c. The public interest;
   d. The likelihood of settlement;
   e. The existence of an emergency;
   f. Any objection;
   g. Any applicable time requirements;
   h. The existence of a conflict in the schedules of counsel, parties, or witnesses;
   i. The timeliness of the request; and
   j. Other relevant factors.

657—35.24(17A.272C) Settlement agreements.

35.24(1) Initiation and participation. A contested case may be resolved by settlement agreement. Settlement negotiations may be initiated by any party at any stage of a contested case. No party is required to participate in the settlement process.
35.24(2) Assistant attorney general and board chair discussion of possible settlement. If the respondent initiates or consents to settlement negotiations, the assistant attorney general prosecuting the case may discuss settlement with the board chair without violating the prohibition against ex parte communications in Iowa Code section 17A.17 and without disqualifying the board chair from participating in the adjudication of the contested case. The full board shall not be involved in settlement negotiations until a proposed settlement agreement executed by the respondent is submitted to the board for approval.
35.24(3) Board consideration of proposed settlement. By signing the proposed settlement agreement, the respondent authorizes an assistant attorney general to have ex parte communications with the board related to the terms of the proposed settlement. If the board fails to approve the proposed settlement agreement, it shall be of no force or effect to either party and shall not be admissible at hearing. Upon rejecting a proposed settlement agreement, the board may suggest alternative terms of settlement, which the respondent is free to accept or reject.
35.24(4) Public record. A settlement agreement is a permanent public record open for inspection under Iowa Code chapter 22.

657—35.25(17A.124B,126,147,155A,205,272C) Hearing procedures in contested cases.

35.25(1) Presiding officer. The presiding officer shall be in control of the proceedings and shall have the authority to administer oaths and to admit or exclude testimony or evidence and shall rule on all motions and objections. The board may request that an administrative law judge assist the board by performing any of these functions.
35.25(2) *Panel of specialists.* When, in the opinion of the board, it is desirable to obtain specialists within an area of practice when holding disciplinary hearings, the board may appoint a panel of three specialists who are not board members to make findings of fact and to report to the board. Such findings shall not include any recommendation for or against licensee discipline.

35.25(3) *Right of participation or representation.* An applicant or respondent has the right to participate or to be represented in all hearings related to the party’s case. Partnerships, corporations, or associations may be represented by any member, officer, director, or duly authorized agent. Any applicant or respondent may be represented by an attorney at the party’s own expense.

35.25(4) *Objections.* All objections shall be timely made and stated on the record.

35.25(5) *Rights of all parties.* Subject to terms prescribed by the presiding officer, parties have the right to introduce evidence on issues of material fact, cross-examine witnesses at the hearing as necessary for a full and true disclosure of the facts, present evidence in rebuttal, submit briefs, and engage in oral argument.

35.25(6) *Disorderly conduct.* The presiding officer shall maintain the decorum of the hearing and may refuse to admit or may expel anyone whose conduct is disorderly.

35.25(7) *Sequestering witnesses.* Witnesses may be sequestered during the hearing.

35.25(8) *Appeal of administrative law judge rulings.* All rulings by an administrative law judge who acts either as presiding officer or as an aid to the board are subject to appeal to the board. While a party may seek immediate board review of rulings made by an administrative law judge when the administrative law judge is sitting with and acting as an aid to the board or panel of specialists during a hearing, such immediate review is not required to preserve error for judicial review.

35.25(9) *Conduct of hearing.* The presiding officer shall conduct the hearing in the following manner:

a. The presiding officer shall give an opening statement briefly describing the nature of the proceedings;

b. The parties shall be given an opportunity to present opening statements;

c. Parties shall present their cases in the sequence determined by the presiding officer;

d. Each witness shall be sworn or affirmed by the presiding officer or the court reporter and be subject to examination and cross-examination. The board members and administrative law judge have the right to question a witness. The presiding officer may limit questioning in a manner consistent with law;

e. When all parties and witnesses have been heard, parties may be given the opportunity to present final arguments.

35.25(10) *Open/closed hearing and protective order.* The hearing shall be open to the public unless the respondent requests that the hearing be closed, in accordance with Iowa Code section 272C.6(1). At the request of either party, or on the board’s own motion, the presiding officer may issue a protective order to protect documents which are privileged or confidential by law.

657—35.26(17A,272C) *Evidence.*

35.26(1) *General.*

a. Relevant evidence is admissible, subject to the discretion of the presiding officer. Irrelevant, immaterial and unduly repetitious evidence should be excluded. A finding will be based upon the kind of evidence on which reasonably prudent persons are accustomed to rely for the conduct of their serious affairs, and may be based on hearsay or other types of evidence which may or would be inadmissible in a jury trial.

b. The presiding officer shall rule on admissibility of evidence and may, where appropriate, take official notice of facts in accordance with all applicable requirements of law.

c. Stipulation of facts is encouraged. The presiding officer may make a decision based on stipulated facts.

d. Evidence in the proceeding shall be confined to the issues as to which the parties received notice prior to the hearing unless the parties waive their right to such notice or the presiding officer determines that good cause justifies expansion of the issues. If the presiding officer decides to admit evidence on
issues outside the scope of the notice over the objection of a party who did not have actual notice of those issues, that party, upon timely request, shall receive a continuance sufficient to amend pleadings and to prepare on the additional issue.

e. Any party may object to specific evidence or may request limits on the scope of any examination or cross-examination. A brief statement of the grounds upon which it is based shall accompany the objection. The objection, the ruling on the objection, and the reasons for the ruling shall be noted in the record. The presiding officer may rule on the objection at the time it is made or may reserve a ruling until the written decision.

f. Whenever evidence is ruled inadmissible, the party offering that evidence may submit an offer of proof on the record. The party making the offer of proof for excluded oral testimony shall briefly summarize the testimony or, with permission of the presiding officer, present the testimony. If the excluded evidence consists of a document or exhibit, it shall be marked as part of an offer of proof and inserted in the record.

35.26(2) Exhibits.

a. The party seeking admission of an exhibit must provide opposing parties with an opportunity to examine the exhibit prior to the ruling on its admissibility. Copies of documents should normally be provided to opposing parties. Copies of admitted documents should be distributed to individual board members and the administrative law judge. Unless prior arrangements have been made, the party seeking admission of a document should arrive at the hearing prepared with sufficient copies of the document to distribute to opposing parties, board members, the administrative law judge, and witnesses who are expected to examine the document. The state’s exhibits shall be marked numerically, and the applicant’s or respondent’s exhibits shall be marked alphabetically.

b. All exhibits admitted into evidence shall be appropriately marked and be made part of the record.

c. An original is not required to prove the content of a writing, recording, or photograph. Duplicates or photocopies are admissible. Any objection related to the authenticity of an exhibit shall go to the weight given to that exhibit and not preclude its admissibility.

35.26(3) Witnesses.

a. Witnesses may be sequestered during the hearing.

b. Subject to the terms prescribed by the presiding officer and the limitations in Iowa Rule of Civil Procedure 1.704, parties may present the testimony of witnesses in person, by telephone, by videoconference, by affidavit, or by written or video deposition. If a witness is providing testimony in person, by telephone, or by videoconference, use of any deposition is limited by Iowa Rule of Civil Procedure 1.704.

c. Witnesses are entitled to be represented by an attorney at their own expense. In a closed hearing, the attorney may be present only when the client testifies. The attorney may assert legal privileges personal to the client, but may not make other objections. The attorney may only ask questions of the client to prevent a misstatement from being entered into the record.

d. The parties in a contested case shall be responsible for any witness fees and expenses incurred by witnesses appearing at the contested case hearing, unless otherwise specified or allocated in an order. The costs for lay witnesses shall be determined in accordance with Iowa Code section 622.69. The costs for expert witnesses shall be determined in accordance with Iowa Code section 622.72. Witnesses are entitled to reimbursement for mileage and may be entitled to reimbursement for meals and lodging, as incurred.

657—35.27(17A.272C) Default.

35.27(1) Failure to appear. If a party fails to appear or participate in a contested case proceeding after proper service of notice, the presiding officer may, if no adjournment is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party.

35.27(2) Motion for default. Where appropriate and not contrary to law, any party may move for default against a party who has requested the contested case proceeding and has failed to file a required pleading or has failed to appear after proper service.
35.27(3) Motion to vacate. A default decision or a decision rendered on the merits after a party has failed to appear or participate in a contested case proceeding shall become final board action unless, within 15 days after the date of notification or mailing of the decision, a motion to vacate is filed and served on all parties or unless an appeal of a decision on the merits is timely initiated within the time provided by rule 657—35.30(17A,272C). A motion to vacate must state all facts relied upon by the moving party which establish that good cause existed for that party’s failure to appear or participate at the contested case proceeding. Each fact so stated must be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) must be attached to the motion.

35.27(4) Appeal. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate.

35.27(5) Proof of good cause. Properly substantiated and timely filed motions to vacate shall be granted only for good cause shown. The burden of proof as to good cause is on the moving party. Adverse parties shall have ten days to respond to a motion to vacate. Adverse parties shall be allowed to conduct discovery as to the issue of good cause and to present evidence on the issue prior to a decision on the motion if a request to do so is included in that party’s response.

35.27(6) “Good cause” defined. “Good cause,” for purposes of this rule, shall have the same meaning as “good cause” for setting aside a default judgment under Iowa Rule of Civil Procedure 1.971.

35.27(7) Appeal of decision on motion to vacate. A decision by an administrative law judge granting or denying a motion to vacate is subject to appeal to the board within 20 days.

35.27(8) Notice of hearing. If a motion to vacate is granted and no timely appeal to the board has been filed, the presiding officer shall issue a rescheduling order setting a new hearing date and the contested case shall proceed accordingly.

657—35.28(17A,272C) Ex parte communication.

35.28(1) Prohibited communications. Unless required for the disposition of ex parte matters specifically authorized by statute, following issuance of the notice of hearing there shall be no communication, directly or indirectly, between the presiding officer and any party or representative of any party or any other person with a direct or indirect interest in such case in connection with any issue of fact or law in the case except upon notice and opportunity for all parties to participate. This does not prohibit persons jointly assigned such tasks from communicating with each other. Nothing in this provision is intended to preclude the presiding officer from communicating with members of the board or seeking the advice or help of persons other than those with a personal interest in, or those engaged in personally investigating as defined in subrule 35.13(2), prosecuting, or advocating in, either the case under consideration or a pending factually related case involving the same parties as long as those persons do not directly or indirectly communicate to the presiding officer any ex parte communications they have received of a type that the presiding officer would be prohibited from receiving or that furnish, augment, diminish, or modify the evidence in the record.

35.28(2) Duration of prohibition. Prohibitions on ex parte communications commence with the issuance of the notice of hearing in a contested case and continue for as long as the case is pending.

35.28(3) “Ex parte” defined. Written, oral, or other forms of communication are “ex parte” if made without notice and opportunity for all parties to participate.

35.28(4) Authorized communications. To avoid prohibited ex parte communications, notice must be given in a manner reasonably calculated to give all parties a fair opportunity to participate. Notice of written communications shall be provided in compliance with rule 657—35.17(17A,272C) and may be supplemented by telephone, facsimile, electronic mail, or other means of notification. Where permitted, oral communications may be initiated through conference telephone call including all parties or their representatives.

35.28(5) Communications between presiding officers. Persons who jointly act as presiding officers in a pending contested case may communicate with each other without notice or opportunity for parties to participate.

35.28(6) Others authorized to communicate with presiding officer. The executive director or other persons may be present in deliberations or otherwise advise the presiding officer without notice or
opportunity for parties to participate as long as they are not disqualified from participating in the making of a proposed or final decision under any provision of law and they comply with subrule 35.28(1).

35.28(7) Communications not prohibited. Communications with the presiding officer involving uncontested scheduling or procedural matters do not require notice or opportunity for parties to participate. Parties should notify other parties prior to initiating such contact with the presiding officer when feasible and shall notify other parties when seeking to continue hearings or other deadlines pursuant to rule 657—35.23(17A,272C).

35.28(8) Disclosure of prohibited communications received during pendency of case. A presiding officer who receives a prohibited ex parte communication during the pendency of a contested case must initially determine if the effect of the communication is so prejudicial that the presiding officer should be disqualified.

a. If the presiding officer determines that disqualification is warranted, a copy of any prohibited written communication, all written responses to the communication, a written summary stating the substance of any prohibited oral or other communication not available in written form for disclosure, all responses made, and the identity of each person from whom the presiding officer received a prohibited ex parte communication shall be submitted for inclusion in the record under seal by protective order.

b. If the presiding officer determines that disqualification is not warranted, such documents shall be submitted for inclusion in the record and served on all parties.

c. Any party desiring to rebut the prohibited communication must be allowed the opportunity to do so upon written request filed within ten days after notice of the communication.

35.28(9) Disclosure of prohibited communications received prior to assignment as presiding officer. Promptly after being assigned to serve as presiding officer at any stage in a contested case proceeding, a presiding officer shall disclose to all parties material factual information received through ex parte communication prior to such assignment unless the factual information has already been or shortly will be disclosed pursuant to Iowa Code section 17A.13(2) or through discovery. Factual information contained in an investigative report or similar document need not be separately disclosed by the presiding officer as long as such documents have been or will shortly be provided to the parties.

35.28(10) Sanctions for violation. The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule, including default, a decision against the offending party, censure, or suspension or revocation of the privilege to practice before the board. Violation of ex parte communication prohibitions by board personnel shall be reported to the executive director for possible sanctions including censure, suspension, dismissal, or other disciplinary action.

657—35.29(17A,272C) Recording costs. Contested case hearings shall be recorded by electronic means or by a certified shorthand reporter. The board may assess the costs of the certified shorthand reporter to the licensee in a disciplinary hearing which results in disciplinary action taken against the licensee by the board in accordance with 657—subrule 36.10(2). Upon request, the board shall provide a copy of the whole or any portion of the record at cost. The requesting party shall pay the cost of preparing a copy of the record or of transcribing the hearing record. If the request for the hearing record is made as a result of a petition for judicial review, the party who filed the petition shall be considered the requesting party.

657—35.30(17A,272C) Proposed decisions. Decisions issued by an administrative law judge in nondisciplinary cases are proposed decisions. A proposed decision issued by an administrative law judge becomes a final decision if not timely appealed or reviewed in accordance with this rule.

35.30(1) Appeal by party. Any adversely affected party may appeal a proposed decision to the board within 30 days after issuance of the proposed decision.

35.30(2) Review. The board may initiate review of a proposed decision on its own motion at any time within 30 days following the issuance of such a decision.

35.30(3) Exhaustion. A party must timely seek intra-agency appeal of a proposed decision in order to adequately exhaust administrative remedies.
35.30(4) Notice of appeal. An appeal of a proposed decision is initiated by filing a timely notice of appeal with the board. The notice of appeal must be signed by the appealing party or an attorney for that party and contain a certificate of service. The notice shall specify:
   a. The parties initiating the appeal;
   b. The proposed decision or order which is being appealed;
   c. The specific findings or conclusions to which exception is taken and any other exceptions to the decision or order;
   d. The relief sought;
   e. The grounds for relief.

35.30(5) Requests to present additional evidence. A party may request the taking of additional evidence only by establishing that the evidence is material, that good cause existed for the failure to present the evidence at the hearing, and that the party has not waived the right to present the evidence. A written request to present additional evidence must be filed with the notice of appeal or, by a nonappealing party, within 14 days of service of the notice of appeal. The board may remand a case to the presiding officer for further hearing or may itself preside at the taking of additional evidence.

35.30(6) Scheduling. The board shall issue a schedule for consideration of the appeal.

35.30(7) Briefs and arguments. Unless otherwise ordered, within 20 days of the notice of appeal or order for review, each appealing party may file exceptions and briefs. Within 20 days thereafter, any party may file a responsive brief. Briefs shall cite any applicable legal authority and specify relevant portions of the record in that proceeding. Written requests to present oral argument shall be filed with the briefs. The board may resolve the appeal on the briefs or provide an opportunity for oral argument. The board may shorten or extend the briefing period as appropriate.

35.30(8) Record. The record on appeal or review shall be the entire record made before the administrative law judge.

657—35.31(17A) Final decision.

35.31(1) Contents. A final decision of the board shall include findings of fact and conclusions of law. When the board presides over the reception of the evidence at the hearing, its decision is a final decision.

35.31(2) Hearing fee and costs. The board may charge a hearing fee and assess other costs to the licensee for conducting a disciplinary hearing which results in disciplinary action taken against the licensee by the board in accordance with 657—subrule 36.10(2).

35.31(3) Method of service. Final decisions shall be served on the respondent or applicant using one of the following methods:
   a. Personal service, as provided in the Iowa Rules of Civil Procedure.
   b. Certified mail, return receipt requested.
   c. Signed acknowledgment accepting service.
   d. When service cannot be accomplished using the above methods:
      (1) An affidavit shall be prepared outlining the measures taken to attempt service; and
      (2) The final decision shall be published once each week for three consecutive weeks in a newspaper of general circulation, published or circulated in the county of last-known residence of the respondent.
   e. If the respondent or applicant is represented by an attorney, the final decision shall be mailed to the attorney. The attorney may waive the requirement to serve the respondent or applicant through a written acknowledgment that the attorney is accepting service on behalf of the client. The state shall be served by first-class mail or state interoffice mail.

35.31(4) Public record. A final decision is a permanent public record open for inspection under Iowa Code chapter 22, in accordance with Iowa Code section 272C.6(4).

657—35.32(17A,124B,126,147,155A,205,272C) Applications for rehearing.

35.32(1) By whom filed. Any party to a contested case proceeding may file an application for rehearing from a final order.
35.32(2) Content of application. The application for rehearing shall state on whose behalf it is filed, the specific grounds for rehearing, and the relief sought. In addition, the application shall state whether the applicant desires reconsideration of all or part of the board decision on the existing record and whether, upon showing good cause, the applicant requests an opportunity to submit additional evidence. A party may request the taking of additional evidence after the issuance of a final order only by establishing that:
   a. The evidence is material; and
   b. The evidence arose after the completion of the original hearing; or
   c. Good cause exists for failure to present the evidence at the original hearing; and
   d. The party has not waived the right to present additional evidence.

35.32(3) Time of filing. The application shall be filed with the board within 20 days after issuance of the final decision.

35.32(4) Notice to other parties. A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein. If the application does not contain a certificate of service, the board shall serve copies on all parties.

35.32(5) Disposition. Any application for a rehearing shall be deemed denied unless the board grants the application within 20 days after its filing.

35.32(6) Only remedy. Application for rehearing is the only procedure by which a party may request that the board reconsider a final board decision.

657—35.33(17A,272C) Stays of board actions.

35.33(1) When available. Any party to a contested case proceeding may petition the board for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board or pending judicial review. The petition shall state the reasons justifying a stay or other temporary remedy. The petition must be filed within 30 days of the issuance of the final order, or if a party filed a request for rehearing that was denied, the petition must be filed within 30 days after the request for rehearing was denied or deemed denied.

35.33(2) When granted. The board shall not grant a stay in any case in which the district court would be expressly prohibited by statute from granting a stay. In determining whether to grant a stay, the presiding officer or board shall consider the following factors:
   a. The extent to which the applicant is likely to prevail when the court finally disposes of the matter;
   b. The extent to which the applicant will suffer irreparable injury if relief is not granted;
   c. The extent to which the grant of relief to the applicant will substantially harm other parties to the proceedings;
   d. The extent to which the public interest relied on by the board is sufficient to justify the board’s action in the circumstances.

35.33(3) Exhaustion required. A party must petition the board for a stay pursuant to this rule prior to requesting a stay from the district court in a judicial review proceeding.

657—35.34(17A,272C) No factual dispute contested cases. If the parties agree that no dispute of material fact exists as to a matter that would be a contested case if such a dispute of fact existed, the parties may present all relevant admissible evidence either by stipulation or otherwise as agreed by the parties, without necessity for the production of evidence at an evidentiary hearing. If such agreement is reached, a jointly submitted schedule detailing the method and timetable for submission of the record, briefs and oral argument should be submitted to the presiding officer for approval as soon as practicable.

657—35.35(17A,124B,126,147,155A,205,272C) Emergency adjudicative proceedings.

35.35(1) Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, the board may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the board by emergency
adjudicative order. Before issuing an emergency adjudicative order, the board shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the board is proceeding on the basis of reliable information;
b. Whether the specific circumstances that pose immediate danger to the public health, safety, or welfare have been identified and determined to be continuing;
c. Whether the person required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety, or welfare;
d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and
e. Whether the specific action contemplated by the board is necessary to avoid the immediate danger.

35.35(2) Issuance of order.

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the agency’s decision to take immediate action.

b. The written emergency adjudicative order shall be immediately served on persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal service, as provided in the Iowa Rules of Civil Procedure; or
(2) Certified restricted mail, return receipt requested; or
(3) Signed acknowledgment accepting service.

c. To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

35.35(3) Notice. Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the board shall make reasonable immediate efforts to contact by telephone and electronic mail the persons who are required to comply with the order.

35.35(4) Completion of proceedings. Issuance of a written emergency adjudicative order shall include notification of the date on which board proceedings are scheduled for hearing. After issuance of an emergency adjudicative order, the licensee subject to the emergency adjudicative order may request a continuance of the hearing at any time by filing a request with the board. The state may only file a request for a continuance in compelling circumstances. Nothing in this subrule shall be construed to eliminate the opportunity to resolve the matter with a settlement agreement.

35.35(5) Public record. An emergency adjudicative order is a permanent public record open for inspection under Iowa Code chapter 22.

657—35.36(17A,147,272C) Application for reinstatement. Any person whose license has been revoked or has been voluntarily surrendered may apply for reinstatement. An application for reinstatement must be made in accordance with the terms specified in the board’s order of revocation or order accepting the voluntary surrender. Any person whose license has been suspended and the board order imposing the suspension indicates that the respondent must apply for and receive reinstatement may apply for reinstatement in accordance with the terms specified in the board’s order. All applications for reinstatement must be filed in accordance with this rule.

35.36(1) Timing of application. If the order for revocation, suspension, or acceptance of surrender of a license did not establish terms for reinstatement, an initial application for reinstatement may not be filed until at least one year has elapsed from the date of issuance of the order. Persons who have failed to satisfy the terms imposed by the board order revoking, suspending, or accepting surrender of a license shall not be entitled to apply for reinstatement.

35.36(2) Initiated by respondent. Reinstatement proceedings shall be initiated by the respondent, who shall file with the board an application for reinstatement of the respondent’s license. Such application shall be docketed in the original contested case in which the license was revoked, suspended, or surrendered. The person filing the application for reinstatement shall immediately serve a copy upon
the office of the attorney general and shall serve any additional documents filed in connection with the application.

35.36(3) Contents. The application shall allege facts and circumstances which, if established, will be sufficient to enable the board to determine that the basis for the revocation, suspension, or surrender no longer exists and that it shall be in the public interest for the license to be reinstated. The application shall include written evidence supporting the respondent’s assertion that the basis for the revocation, suspension, or surrender no longer exists and that it shall be in the public interest for the license to be reinstated. Such evidence may include, but is not limited to, medical and mental health records establishing successful completion of any necessary medical or mental health treatment and aftercare recommendations; documentation verifying successful completion of any court-imposed terms of probation; statements from support group sponsors verifying active participation in a support group; verified statements from current and past employers attesting to employability; and evidence establishing that prior professional competency or unethical conduct issues have been resolved. The burden of proof to establish such facts shall be on the respondent.

35.36(4) Review for conformity. The executive director or designee shall review the application for reinstatement and determine if it conforms to the terms established in the board order that revoked, suspended, or accepted surrender of the license and the requirements imposed by this rule. Applications failing to comply with the specified terms or with the requirements in this rule will be denied. Such denial shall be in writing, stating the grounds, and may be appealed by requesting a hearing before the board.

35.36(5) Hearing and order. Applications not denied for failure to conform to the terms established in the board order that revoked, suspended, or accepted surrender of the license or requirements imposed by this rule may be set for hearing before the board. The hearing shall be a contested case hearing within the meaning of Iowa Code section 17A.12, and the order to grant or deny reinstatement shall incorporate findings of fact and conclusions of law. If reinstatement is granted, terms may be imposed. Such terms may include, but are not limited to, requiring the licensee to retake and pass an examination required for initial licensure, requiring the licensee to complete continuing education, restricting the licensee from engaging in a particular practice, and imposing a probationary term with monitoring requirements. Nothing shall prohibit the board from issuing an order granting reinstatement without terms, or from entering into a stipulated order granting reinstatement with terms, in the absence of a hearing.

35.36(6) License reactivation. A licensee whose license is reinstated must complete the requirements for license reactivation in order to receive an active license.

35.36(7) Public record. An order granting or denying reinstatement is a permanent public record open for inspection under Iowa Code chapter 22.

657—35.37(17A,22,272C) Dissemination of public records. All documents identified in this chapter as permanent public records open for inspection under Iowa Code chapter 22 are reported to national databanks in accordance with applicable reporting requirements. In addition, these documents may be posted on the board’s Web site, published in the board’s newsletter, distributed to national or state associations, transmitted to mailing lists or news media, issued in conjunction with a press release, or otherwise disseminated.

657—35.38(17A) Judicial review. Judicial review of a final order of the board may be sought in accordance with the terms of Iowa Code chapter 17A.

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.55, 155A.6 to 155A.6B, 155A.12, 155A.13 to 155A.13C, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

ITEM 2. Rescind 657—Chapter 36 and adopt the following new chapter in lieu thereof:

CHAPTER 36
DISCIPLINE

18
657—36.1(147,155A,272C) Authority. The board has the authority to impose discipline for any violations of Iowa Code chapters 124, 124B, 126, 147, 155A, 205, and 272C or the rules promulgated thereunder.

657—36.2(147,155A,272C) Definitions. For purposes of this chapter:
   “Board” means the Iowa board of pharmacy.
   “License” means any license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.
   “Licensee” means any person or entity possessing a license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

657—36.3(147,155A,272C) Complaints, investigations, and board action.
   36.3(1) General. The board may, upon receipt of a written or verbal complaint or upon its own motion pursuant to other evidence received by the board, review and investigate alleged acts or omissions that may violate the board’s rules or that are related to the ethical or professional conduct of a licensee.
   36.3(2) Confidentiality of investigative files. Complaint files, investigation files, and all other investigation reports and investigative information in the possession of the board or its employees or agents that relate to licensee discipline shall be confidential pursuant to Iowa Code section 272C.6(4).
   36.3(3) Investigation of allegations. In order to determine if probable cause exists for a disciplinary hearing, the board, the executive director, or someone designated by the executive director shall cause an investigation to be made into the allegations of the complaint. The licensee that is the subject of the complaint shall be given a reasonable opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of a contested case.
   36.3(4) Investigatory subpoena powers. The board is authorized by law to subpoena books, papers, records, and any other real evidence, whether or not privileged or confidential under law, which are necessary for the board to decide whether to institute a contested case proceeding. The issuance of investigative subpoenas is governed by rule 657—36.4(17A,147,152,272C).
   36.3(5) Investigative report. Upon completion of the investigation, the investigator(s) shall prepare a report for the board’s consideration. The report may contain evidence gathered by the investigator, findings made by the investigator, the licensee’s response to the allegations, and the applicable laws or rules alleged to have been violated.
   36.3(6) Board consideration. The board shall review all investigations. Participation in the review of investigative materials shall not bar any board member from participating in any subsequent disciplinary proceeding.
      a. Board action. After reviewing an investigation, the board may institute a disciplinary proceeding by filing one or more statements of charges, approve a combined statement of charges and settlement agreement, send a confidential letter of education or administrative warning to the licensee, request additional investigation, including peer review, refer the case to another regulatory authority with jurisdiction over the issue, or close the case without further investigation.
      b. Confidential action. If the board determines that formal disciplinary action is not warranted, the board may send a confidential letter of education or administrative warning to the licensee. The purpose of a confidential letter of education or administrative warning is to alert the licensee to possible violations of Iowa law or board rules so that the licensee may address the issues. Confidential letters of education and administrative warnings do not constitute formal disciplinary action and are not open for inspection under Iowa Code chapter 22. The board shall maintain a copy of the confidential letter of education or administrative warning in the confidential investigative file regarding the licensee. Confidential letters of education and administrative warnings may be used as evidence against a licensee in future administrative hearings.

657—36.4(17A,147,152,272C) Issuance of investigatory subpoenas. The board shall have the authority to issue an investigatory subpoena in accordance with the provisions of Iowa Code section 17A.13.
36.4(1) Justification. The executive director or designee may, upon the written request of a board investigator or on the executive director’s own initiative, subpoena books, papers, records and other real evidence which are necessary for the board to decide whether to institute a contested case proceeding. In the case of a subpoena for mental health records, each of the following conditions shall be satisfied prior to the issuance of the subpoena:

a. The nature of the complaint reasonably justifies the issuance of a subpoena;

b. Adequate safeguards have been established to prevent unauthorized disclosure;

c. An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and

d. An attempt was made to notify the patient and to secure an authorization from the patient for release of the records at issue.

36.4(2) Contents of request. A written request for a subpoena or the executive director’s written memorandum in support of the issuance of a subpoena shall contain the following:

a. The name and address of the person to whom the subpoena will be directed;

b. A specific description of the books, papers, records or other real evidence requested;

c. An explanation of why the documents sought to be subpoenaed are necessary for the board to determine whether it should institute a contested case proceeding; and

d. In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 36.4(1) have been satisfied.

36.4(3) Contents of subpoena. Each subpoena shall contain the following:

a. The name and address of the person to whom the subpoena is directed;

b. A description of the books, papers, records or other real evidence requested;

c. The date, time and location for production or inspection and copying;

d. The time within which a motion to quash or modify the subpoena must be filed;

e. The signature, address and telephone number of the executive director or designee;

f. The date of issuance;

g. A return of service.

36.4(4) Motion to quash or modify. Any person who is aggrieved or adversely affected by compliance with the subpoena and who desires to challenge the subpoena must, within 14 days after service of the subpoena, or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified and may be accompanied by legal briefs or factual affidavits.

36.4(5) Timely filing of motion. Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to issue a decision or the board may issue a decision. Oral argument may be scheduled at the discretion of the board or the administrative law judge. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

36.4(6) Appeal of administrative law judge ruling. A person aggrieved by a ruling of an administrative law judge who desires to challenge that ruling must appeal the ruling to the board by filing a notice of appeal with the board within ten days after service of the decision of the administrative law judge in accordance with rule 657—35.17(17A,272C).

36.4(7) Judicial review. If the person contesting the subpoena is not the person under investigation, the board’s decision is final for purposes of judicial review. If the person contesting the subpoena is the person under investigation, the board’s decision is not final for purposes of judicial review until either (1) the person is notified that the investigation has been concluded with no formal action, or (2) there is a final decision in the contested case.

657—36.5(147,272C) Peer review committee. Any case may be referred to peer review for evaluation of the professional services rendered by the licensee.
36.5(1) Contract and case referral. The board shall enter into a contract with peer reviewers to provide peer review services. The board or board staff shall determine which peer reviewer(s) will review a case and what investigative information shall be referred to a peer reviewer.

36.5(2) Written opinion. Peer reviewers shall review the information provided by the board and provide a written report to the board. The written report shall contain an opinion of the peer reviewer regarding whether the licensee conformed to minimum standards of acceptable and prevailing practice of pharmacy and the rationale supporting the opinion.

36.5(3) Confidentiality. Peer reviewers shall observe the confidentiality requirements imposed by Iowa Code section 272C.6(4).

36.5(4) Board review and action. The board shall review the committee’s findings and proceed with action available under subrule 36.3(6).

657—36.6(147,155A,272C) Grounds for discipline. The board may impose any of the disciplinary sanctions set forth in rule 657—36.7(147,155A,272C) when the board determines that the licensee has committed any of the following acts or omissions:

36.6(1) 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. Fraud in procuring a license 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.

36.6(2) Professional incompetency. Professional incompetency includes but is not limited to:

a. A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist’s practice.

b. A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

c. A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

d. A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

36.6(3) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

36.6(4) Habitual intoxication or addiction to the use of drugs. Habitual intoxication or addiction to the use of drugs includes, but is not limited to:

a. The inability of a licensee to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

b. The excessive use of drugs which may impair a licensee’s ability to practice with reasonable skill or safety.

36.6(5) Conviction of a felony related to the profession or occupation of the licensee, or a conviction of a felony that would affect the licensee’s ability to practice within the licensee’s profession. A copy of the record of conviction or a plea of guilty shall be conclusive evidence.

36.6(6) Fraud in representations as to skill or ability. Fraud in representations as to skill or ability includes, but is not limited to, a pharmacist having made deceptive or untrue representations as to competency to perform professional services which the pharmacist is not qualified to perform by virtue of training or experience.

36.6(7) Use of untrue or improbable statements in advertisements.
36.6(8) Distribution of drugs for other than lawful purposes. The distribution of drugs for other than lawful purposes includes, but is not limited to, the disposition of drugs in violation of Iowa Code chapters 124, 126, and 155A.

36.6(9) Willful or repeated violations of the provisions of Iowa Code chapter 147 or 272C. Willful or repeated violations of these Acts include, but are not limited to, a licensee’s intentionally or repeatedly violating a lawful rule or regulation promulgated by the board of pharmacy or the Iowa department of public health, violating a lawful order of the board in a disciplinary hearing, or violating the provisions of title IV (public health) of the Iowa Code.

36.6(10) Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy or the distribution of controlled substances, prescription drugs, or nonprescription drugs.

36.6(11) Failure 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 revocation, suspension, or other disciplinary sanction.

36.6(12) Knowingly aiding, assisting, procuring, or advising another person to unlawfully practice pharmacy or to unlawfully perform the functions of a pharmacist-intern, a pharmacy technician, or a pharmacy support person.

36.6(13) Inability of a licensee to practice with reasonable skill and safety by reason of mental or physical impairment or chemical abuse.

36.6(14) Being adjudged mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a license for the duration of the license or registration unless the board otherwise orders.

36.6(15) Submission of a false report of continuing education, submission of a false certification of completion of continuing education, or failure to submit biennial reports of continuing education as directed by the board.

36.6(16) Failure to notify the board within 30 days after occurrence of any judgment or settlement of a malpractice court claim or action.

36.6(17) Failure to file reports concerning acts or omissions committed by another licensee.

36.6(18) Willful or repeated malpractice.

36.6(19) Willful or gross negligence.

36.6(20) Obtaining any fee by fraud or misrepresentation.

36.6(21) Violating any of the grounds for revocation or suspension of a license or registration listed in Iowa Code section 147.55, Iowa Code chapter 155A, or any of the rules of the board.

36.6(22) Practicing pharmacy without an active and current Iowa pharmacist license, operating a pharmacy without a current pharmacy license, operating a prescription drug wholesale facility without a current wholesale drug license, operating an outsourcing facility without a current outsourcing facility license, practicing as a pharmacist-intern without a current pharmacist-intern registration, assisting a pharmacist with technical functions associated with the practice of pharmacy without a current pharmacy technician registration except as provided in the introductory paragraph of rule 657—3.3(155A), or assisting a pharmacist with nontechnical functions associated with the practice of pharmacy without a current pharmacy support person registration.

36.6(23) Attempting to circumvent the patient counseling requirements or discouraging patients from receiving patient counseling concerning their prescription drug orders.

36.6(24) Noncompliance with a child support order or with a written agreement for payment of child support as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 252J.

36.6(25) Student loan default or noncompliance with the terms of an agreement for payment of a student loan obligation as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 261 or default on a repayment or service obligation under any federal or state educational loan or service-conditional scholarship program upon certification by the program of such a default.

36.6(26) Engaging in any conduct that subverts or attempts to subvert a board investigation.

36.6(27) Employing or continuing to employ as a practicing pharmacist any person whose Iowa pharmacist license is not current and active, employing or continuing to employ a person to
assist a pharmacist with technical functions associated with the practice of pharmacy who is not currently registered as a pharmacy technician except as provided in the introductory paragraph of rule 657—3.3(155A), or employing or continuing to employ a person to assist a pharmacist with nontechnical functions associated with the practice of pharmacy who is not currently registered as a pharmacy support person.

36.6(28) Retaliating against a pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person for making allegations of illegal or unethical activities, making required reports to the board, or cooperating with a board investigation or survey.

36.6(29) Failing to create and maintain complete and accurate records as required by state or federal law or regulation or rule of the board.

36.6(30) Violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state.

36.6(31) Having a license revoked or suspended or having other disciplinary action taken by a licensing authority of this state or of another state, territory, or country for conduct substantially equivalent to any of the grounds for disciplinary action in Iowa. A copy of the record from the licensing authority taking the disciplinary action shall be conclusive evidence of the action.

36.6(32) Failure to comply with mandatory child or dependent adult abuse reporter training requirements.

36.6(33) Failure to timely provide to the board or a representative of the board prescription fill data or other required pharmacy or controlled substances records.

36.6(34) Nonpayment of a state debt as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 272D.

36.6(35) Failure to notify the board of a criminal conviction relating to the practice of pharmacy or to the distribution of drugs within 30 days of the action, regardless of the jurisdiction where it occurred.

36.6(36) Obtaining, possessing, or attempting to obtain or possess prescription drugs without lawful authority.

36.6(37) Diverting prescription drugs from a pharmacy for personal use or for distribution.

36.6(38) Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of alcohol or illicit substances.

36.6(39) Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of prescription drugs or substances for which the licensee does not have a lawful prescription or while impaired by the use of legitimately prescribed pharmacological agents, drugs, or substances.

36.6(40) Forging or altering a prescription.

36.6(41) Practicing outside the scope of the profession.

36.6(42) Dispensing, or contributing to the dispensing of, an incorrect prescription, which includes, but is not limited to, the incorrect drug, the incorrect strength, the incorrect patient or prescriber, or the incorrect or incomplete directions.

36.6(43) Failing to comply with a confidential order for evaluation.

36.6(44) Failing to comply with the terms of an initial agreement or contract with the Iowa monitoring program for pharmacy professionals committee.

657—36.7(147,155A,272C) Disciplinary sanctions.

36.7(1) Possible sanctions. The board has the authority to impose the following disciplinary sanctions:

a. Revocation of a license issued by the board.

b. Suspension of a license issued by the board until further order of the board or for a specified period.

c. Nonrenewal of a license issued by the board.

d. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods or acts.

e. Probation.

f. Require a licensee to complete additional education or training.
g. Require a pharmacist to successfully complete any reexamination for licensure.

h. Order a licensee to undergo a physical or mental examination.

i. Impose civil penalties not to exceed $25,000.

j. Issue citation and warning.

k. Such other sanctions allowed by law as may be appropriate.

36.7(2) Considerations in determining sanctions. The board may consider the following factors in determining the nature and severity of the disciplinary sanction to be imposed:

a. The relative seriousness of the violation as it relates to assuring the citizens of this state a high standard of professional care.

b. The facts of the particular violation.

c. Any extenuating circumstances or other countervailing considerations.

d. Number of prior violations or complaints.

e. Seriousness of prior violations or complaints.

f. Whether remedial action has been taken.

g. Any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee.

657—36.8(147,272C) Voluntary surrender. A voluntary surrender of a license may be submitted to the board as resolution of a contested case or in lieu of continued compliance with a disciplinary order of the board. A voluntary surrender, when accepted by the board, has the same force and effect as an order of revocation. The voluntary surrender of a license during the pendency of a complaint or investigation shall be considered discipline and shall have the same force and effect as an order of revocation. A request for reinstatement of a license that has been surrendered shall be handled under the terms established by rule 657—35.36(17A,147,272C).

657—36.9(155A,272C) Order for mental or physical examination. A licensee is, as a condition of licensure, under a duty to submit to a mental or physical examination within a time period specified by order of the board. Such examination may be ordered upon a showing of probable cause and shall be at the expense of the licensee.

36.9(1) Content of order. A board order for mental or physical examination shall include the following items:

a. A description of the type of examination to which the licensee must submit.

b. The name and address of the examiner or treatment facility that the board has identified as having the potential to perform the examination.

c. The time period in which the licensee must schedule the required examination.

d. The amount of time in which the licensee is required to complete the examination.

e. A requirement that the licensee cause a report of the examination results to be provided to the board within a specified period of time.

f. A requirement that the licensee communicate with the board regarding the status of the examination.

g. A provision allowing the licensee to request additional time to schedule or complete the examination or to request that the board approve an alternative examiner or treatment facility. The board shall, in its sole discretion, determine whether to grant such a request.

36.9(2) Objection to order. A licensee who is the subject of a board order and who objects to the order may file a request for hearing. The request for hearing shall specifically identify the factual and legal issues upon which the licensee bases the objection. The hearing shall be considered a contested case proceeding and shall be governed by the provisions of 657—Chapter 35. A contested case involving an objection to an examination order will be captioned in the name of Jane or John Doe in order to maintain the licensee’s confidentiality.

36.9(3) Closed hearing. Any hearing on an objection to the board order shall be closed pursuant to Iowa Code section 272C.6(4).
36.9(4) Order and reports—confidential. An examination order and any subsequent examination reports issued in the course of a board investigation are confidential investigative information pursuant to Iowa Code section 272C.6(4).

657—36.10(272C) Disciplinary hearings—fees and costs.

36.10(1) Definitions. As used in this chapter in relation to a formal disciplinary action filed by the board against a licensee:

“Deposition” means the testimony of a person pursuant to subpoena or at the request of the state of Iowa taken in a setting other than a hearing.

“Expenses” means costs incurred by persons appearing pursuant to subpoena or at the request of the state of Iowa for purposes of providing testimony on the part of the state of Iowa in a hearing or other official proceeding and shall include mileage reimbursement at the rate specified in Iowa Code section 70A.9 or, if commercial air or ground transportation is used, the actual cost of transportation to and from the proceeding. Also included are actual costs incurred for meals and necessary lodging.

“Medical examination fees” means actual costs incurred by the board in a physical, mental, chemical abuse, or other impairment-related examination or evaluation of a licensee when the examination or evaluation is conducted pursuant to an order of the board.

“Transcript” means a printed verbatim reproduction of everything said on the record during a hearing or other official proceeding.

“Witness fees” means compensation paid by the board to persons appearing pursuant to subpoena or at the request of the state of Iowa, for purposes of providing testimony on the part of the state of Iowa. For the purposes of this rule, compensation shall be the same as outlined in Iowa Code section 622.69 or 622.72 as the case may be.

36.10(2) Hearing fee and recoverable costs. The board may charge a fee not to exceed $75 for conducting a disciplinary hearing that results in disciplinary action taken by the board against the licensee. In addition to the fee, the board may recover from the licensee costs for the following procedures and personnel:

a. Recording fees of a certified shorthand reporter.

b. Transcript.

c. Witness fees and expenses.

d. Depositions.

36.10(3) Fees, costs as part of disciplinary order. Fees and costs assessed by the board shall be described as part of the board’s final disciplinary order. Fees and costs that can be calculated at the time of the issuance of the board’s final disciplinary order shall be itemized in the order. Fees and costs that cannot be calculated at the time of the issuance of the board’s final disciplinary order may be invoiced to the licensee at a later time, provided that the board’s final disciplinary order states that the particular fees and costs will be invoiced at a later date. The board’s final disciplinary order and any invoices shall specify the time period in which the licensee shall pay the assessed fees and costs.

36.10(4) Board treatment of collected fees, costs. Fees and costs collected by the board shall be allocated to the expenditure category of the board in which the hearing costs were incurred. The fees and costs shall be considered repayment receipts as defined in Iowa Code section 8.2.

36.10(5) Failure to pay assessed fees, costs. Failure of a licensee to pay the fees and costs assessed herein within the time period specified in the board’s final disciplinary order or subsequent invoice shall constitute a violation of a lawful order of the board.

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.55, 155A.6 to 155A.6B, 155A.12, 155A.13 to 155A.13C, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 9/27/17.
ADDENDUM Q

NOTICE OF INTENDED ACTION

AMENDING CHAPTER 2, “PHARMACIST LICENSES”

AUGUST 30, 2017
PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 2, “Pharmacist Licenses,” Iowa Administrative Code.

This amendment was approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

The proposed amendment permits an applicant who is not eligible for a social security number but who has an individual tax identification number (ITIN) to provide that ITIN on the application for pharmacist licensure by examination. Such applicant shall also be required to provide proof of presence such as a permanent resident card, an employment authorization document issued by the federal government, or certain types of visas.

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 October 31, 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 measurable impact on jobs has been found. Amending the application requirements in this manner may make it a bit easier for foreign applicants who do not yet qualify for a social security number to obtain employment in their profession in a more timely manner, but the amendment is not expected to impact many individuals.

This amendment is intended to implement Iowa Code sections 147.2, 147.36, and 155A.7 through 155A.9.

The following amendment is proposed.

Amend subrule 2.2(1) as follows:

2.2(1) Required information. The application for examination shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number or individual tax identification number (ITIN); name and location of college of pharmacy and date of graduation; one current photograph of a quality at least similar to a passport photograph; and internship experience. If the applicant provides an ITIN in lieu of a social security number, the applicant shall also provide acceptable proof of lawful presence. Each applicant shall also declare the following: history of prior pharmacist licensure examinations and record of offenses including but not limited to charges, convictions, and fines which relate to the profession or that may affect the licensee’s ability to practice pharmacy.
ADDENDUM R

NOTICE OF INTENDED ACTION

AMENDING CHAPTER 8, “UNIVERSAL PRACTICE STANDARDS”

AUGUST 30, 2017
PHARMACY BOARD[657]
Notice of Intended Action

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

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

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

This amendment was approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

The proposed amendment seeks to provide clarification for a pharmacist in dispensing remaining refills of prescriptions after the prescriber has ended a relationship with a patient, such as with discontinuation of practice or relocation to another state, so that the pharmacist is authorized to provide adequate and appropriate care to a patient while the patient is seeking the care of a new provider.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on October 31, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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

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.27.

The following amendment is proposed.

Amend rule 657—8.20(155A) as follows:

657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient’s use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining prescription refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber. The pharmacist may be dispensing, if the pharmacist reasonably determines that continuing the patient’s treatment is necessary and that the patient can reasonably obtain the service of another prescriber, the pharmacist shall consider the patient’s health care status and access to health care services.
ADDENDUM S

NOTICE OF INTENDED ACTION

AMENDING CHAPTER 5, “PHARMACY SUPPORT PERSON,” AND CHAPTER 11, “DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAM”

AUGUST 30, 2017
PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 5, “Pharmacy Support Persons,” and Chapter 11, “Drugs in Emergency Medical Service Programs,” Iowa Administrative Code.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

The proposed amendments provide clarification for registration of service programs that are owned by and based at the same physical address of a hospital that is already registered with the Board for controlled substances. Also, the amendments provide updated references to and consistency with 657—Chapter 10 as a result of recent rule making by the Board.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 17, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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

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 sections 124.301 and 124.302.

The following amendments are proposed:

ITEM 1. Amend rule 657—5.17(155A) as follows:

657—5.17(155A) Tasks a pharmacy support person shall not perform. A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:

1. to 13. No change.
14. Assist with or witness the destruction or wastage of controlled substances pursuant to 657—subrule 10.18(2) 657—subrule 10.22(2).
15. No change.

ITEM 2. Amend rule 657—11.3(124,147A,155A) as follows:

657—11.3(124,147A,155A) Registration required. In any service program which intends to provide services in or into Iowa that include the administration of controlled substances, the responsible individual shall ensure that 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 any other authorized individual.

11.3(1) No change.

11.3(2) Pharmacy-based service program. In a pharmacy-based service program, the CSA registration shall be issued in the name of the service program and shall secondarily name the provider pharmacy. The CSA 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.
that is owned by and physically located at the same address as an Iowa-licensed and -registered hospital may, but is not required to, obtain a separate registration.

11.3(3) No change.

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 completed application and fee as provided in 657—10.11(2) 657—subrule 10.9(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) No change.

ITEM 3. Amend subrule 11.26(2) as follows:

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 record of the disbursement pursuant to rule 657—10.34(124,155A) 657—10.16(124). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record shall include the following:
   a. to e. No change.

ITEM 4. 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) 657—subrule 10.17(2) 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, its representative, or any other authorized individual for a period of two years from the date of the record.

ITEM 5. 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 provide notice and reporting as required in rule 657—10.16(124) 657—10.21(124).
ADDENDUM T

NOTICE OF INTENDED ACTION

RESCINDING CHAPTER 28, “AGENCY PROCEDURE FOR RULE MAKING”

AUGUST 30, 2017
PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code sections 17A.3 and 17A.22, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 28, “Agency Procedure for Rule Making,” Iowa Administrative Code, and to adopt a new Chapter 28 with the same title.

This amendment was approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current Chapter 28 and adopts new rules regarding the procedures for rule making in line with the requirements of Iowa Code chapter 17A and current practices. The new rules address recent changes regarding rule-making actions and activities including emergency adoption of rules, regulatory analyses, fiscal impact statements, jobs impact statement, five-year review, and electronic filing, recording, and tracking of agency rule-making actions.

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 October 31, 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 impact on jobs has been found.

The amendment is intended to implement Iowa Code sections 17A.1 through 17A.9A.

The following amendment is proposed.

Rescind 657—Chapter 28 and adopt the following new chapter in lieu thereof:

CHAPTER 28

AGENCY PROCEDURE FOR RULE MAKING

657—28.1(17A) Applicability. Except to the extent otherwise expressly provided by statute, all rules adopted by the board of pharmacy, hereinafter referred to as “board,” are subject to the provisions of Iowa Code chapter 17A, the Iowa administrative procedure Act, and the provisions of this chapter.

657—28.2(17A) Definitions.

“Administrative rules review committee” or “ARRC” means a bipartisan standing committee composed of five senators and five representatives that meets on a regular basis for the purpose of selectively reviewing rules whether proposed or in effect.

“ARC” means the governor’s administrative rules coordinator.

“ARC number” means the identification number assigned by the ARC to each rule making document.

“Iowa Administrative Bulletin” or “IAB” is the official biweekly publication that contains the text or texts of notices of intended action and of all adopted rules.

“Notice of Intended Action” means a published notice of the board’s intent to adopt, amend, or rescind one or more rules pursuant to Iowa Code section 17A.4(1).

657—28.3(17A) Solicitation of comments before notice. In addition to seeking information by other methods, the board may, before publication of a Notice of Intended Action, solicit comments from the public on a subject matter of possible rule making by causing notice to be published in the
Iowa Administrative Bulletin of the subject matter and indicating where, when, and how persons may comment.

657—28.4(17A) Public rule-making docket. Proposed rule making is made available for inspection and comment by the public through the Web sites identified in this rule.

28.4(1) Proposed rule making. Each proposed rule making is published in the Iowa Administrative Bulletin and can be found on the state’s administrative rules Web site at https://rules.iowa.gov. Each proposed rule making is identified by agency and by ARC number and shall include information on the opportunity to directly submit public comments, suggestions, and objections regarding the proposed rule making, including the deadline for submission of such comments.


28.4(4) Public participation—written comments. For at least 20 days after publication of the Notice of Intended Action, persons may submit written comments on the proposed rule. Such written submissions shall identify the proposed rule to which they relate and shall be submitted to the Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or to the person designated in the Notice of Intended Action.

28.4(5) Public participation—public hearings. The board may, at any time, schedule a public hearing in accordance with rule 657—28.4(17A) on a proposed rule. The board shall schedule a public hearing on a proposed rule if, within 20 days after the published Notice of Intended Action, a written request for an opportunity to make oral presentations is submitted to the board by the ARRC, a governmental subdivision, an agency, an association having not less than 25 members, or at least 25 persons. The request shall contain the following information:
   a. A request by one or more individual persons shall include the printed name, signature, address, telephone number, and e-mail address of each person.
   b. A request by an association shall contain a statement that the association has at least 25 members and include the printed name, signature, address, telephone number, and e-mail address of an officer or designee of the association.
   c. A request by an agency or governmental subdivision shall contain the printed name, signature, address, telephone number, and e-mail address of an official having authority to act on behalf of the entity.

657—28.5(17A) Public hearing proceedings.

28.5(1) Applicability. This rule applies only to those public hearings in which an opportunity to make oral presentations is authorized or required by Iowa Code section 17A.4(1) “b.”

28.5(2) Scheduling and notice. A public hearing on a proposed rule may be held in one or more locations and shall not be held earlier than 20 days after notice of its location and time is published in the IAB. That notice shall also identify the proposed rule by ARC number and citation to the IAB.

28.5(3) Presiding officer. The board, a member of the board, or another person designated by the board who will be familiar with the substance of the proposed rule, shall preside at the oral proceeding on a proposed rule. If the board does not preside, the presiding officer shall prepare a memorandum for consideration by the board summarizing the contents of the presentations made at the oral proceeding unless the board determines that such a memorandum is unnecessary because the board will personally listen to or read the entire transcript of the oral proceeding.

28.5(4) Conduct of hearing. At a public hearing on a proposed rule, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed rule. Persons wishing to make oral presentations at such a proceeding are encouraged to notify the board at least one business day prior to the hearing and indicate the general subject of their presentations. At the hearing, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other
information relating to their participation deemed appropriate by the presiding officer. Hearings shall be open to the public and shall be recorded by stenographic or electronic means.

a. At the beginning of the public hearing, the presiding officer shall give a brief synopsis of the proposed rule, a statement of the statutory authority for the proposed rule, and the reasons for the board decision to propose the rule. The presiding officer may place time limitations on individual oral presentations when necessary to ensure the orderly and expeditious conduct of the hearing. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.

b. Persons making oral presentations are encouraged to avoid restating matters which have already been submitted in writing.

c. To facilitate the exchange of information, the presiding officer may, where time permits, open the floor to questions or general discussion.

d. The presiding officer shall have the authority to take any reasonable action necessary for the orderly conduct of the meeting.

e. Physical and documentary submissions presented by participants in the hearing shall be submitted to the presiding officer. Such submissions become the property of the board.

f. The hearing may be continued by the presiding officer to a later time without notice other than by announcement at the hearing.

g. Participants in a public hearing shall not be required to take an oath or to submit to cross-examination. However, the presiding officer in a hearing may question participants and permit the questioning of participants by other participants about any matter relating to that rule-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

h. The presiding officer in a hearing may permit rebuttal statements and request the filing of written statements subsequent to the adjournment of the oral presentations.

28.5(5) Additional information. In addition to receiving written comments and oral presentations on a proposed rule according to the provisions of this rule, the board may obtain information concerning a proposed rule through any other lawful means deemed appropriate under the circumstances.

28.5(6) Accessibility. The board shall schedule public hearings in rooms accessible to and functional for persons with physical disabilities. Persons who have special requirements should contact the board, telephone (515)281-5944, in advance to arrange access or other needed services.

657—28.6(17A) Regulatory analyses.

28.6(1) Definition of small business. A “small business” is defined in Iowa Code section 17A.4A(8) “a.”

28.6(2) Regulatory analysis—economic impact. The board shall issue a regulatory analysis of a proposed board rule in response to a written request from the ARC or the ARRC. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

28.6(3) Regulatory analysis—business impact. The board shall issue a regulatory analysis of a proposed board rule in response to a written request from one of the following. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

a. The administrative rules review committee;

b. The administrative rules coordinator;

c. At least 25 or more persons who sign the request provided that each represents a different small business;

d. An organization representing at least 25 small businesses. That organization shall list the name, address, and telephone number of not less than 25 small businesses it represents.

28.6(4) Time period for analysis. Upon receipt of a timely request for a regulatory analysis, the board shall adhere to the time lines described in Iowa Code section 17A.4A.

28.6(5) Contents of request. A request for a regulatory analysis is made when it is mailed or delivered to the board. The request shall be in writing and satisfy the requirements of Iowa Code section 17A.4A.
28.6(6) **Contents of concise summary.** The contents of the concise summary shall conform to the requirements of Iowa Code section 17A.4A.

28.6(7) **Publication of a concise summary.** The board shall make available, to the maximum extent feasible, copies of the published summary in conformance with Iowa Code section 17A.4A.

28.6(8) **Jobs impact statement.** Pursuant to 2017 Iowa Acts, Senate File 1, the board shall include in the preamble of each rule making a jobs impact statement, unless such statement is waived by the ARC. The board may seek and shall accept public comments and information from stakeholders relating to a jobs impact statement.

657—28.7(17A,25B) **Fiscal impact statement.**

28.7(1) A proposed rule that mandates additional combined expenditures exceeding $100,000 by all affected political subdivisions or agencies and entities which contract with political subdivisions to provide services shall be accompanied by a fiscal impact statement outlining the costs associated with the rule. A fiscal impact statement shall satisfy the requirements of Iowa Code section 25B.6.

28.7(2) If the board determines at the time it adopts a rule that the fiscal impact statement upon which the rule is based contains errors, the board shall, at the same time, issue a corrected fiscal impact statement and publish the corrected fiscal impact statement in the Iowa Administrative Bulletin.

657—28.8(17A) **Time and manner of rule adoption.**

28.8(1) **Time of adoption.** At least 35 days following publication of a Notice of Intended Action, the board may adopt a rule or terminate the rule making. Within 180 days after the date of publication of the notice or the deadline for public comments, whichever is later, the board shall adopt a rule or terminate the proceeding. Subsequent actions shall be published in the Iowa Administrative Bulletin.

28.8(2) **Consideration of public comment.** Before the adoption of a rule, the board shall consider fully all of the written submissions and oral submissions received in that rule-making proceeding, or any memorandum summarizing such oral submissions, and any regulatory analysis, jobs impact statement, or fiscal impact statement issued in that rule-making proceeding.

28.8(3) **Reliance on board expertise.** Except as otherwise provided by law, the board may use its own experience, technical competence, specialized knowledge, and judgment in the adoption of a rule.

657—28.9(17A) **Variance between adopted rule and published notice of proposed rule adoption.**

28.9(1) The board shall not adopt a rule that differs from the rule proposed in the Notice of Intended Action on which the rule is based unless:

a. The differences are within the scope of the subject matter announced in the Notice of Intended Action and are in character with the issues raised in that notice; and

b. The differences are a logical outgrowth of the contents of that Notice of Intended Action and the comments submitted in response thereto; and

c. The Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question.

28.9(2) In determining whether the Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question, the board shall consider the following factors:

a. The extent to which persons who will be affected by the rule should have understood that the rule-making proceeding on which it is based could affect their interests;

b. The extent to which the subject matter of the rule or the issues determined by the rule are different from the subject matter or issues contained in the Notice of Intended Action; and

c. The extent to which the effects of the rule differ from the effects of the proposed rule contained in the Notice of Intended Action.

28.9(3) **Concurrent rule-making proceedings.** Nothing in this rule disturbs the discretion of the board to initiate, concurrently, several different rule-making proceedings on the same subject with several different published Notices of Intended Action.
657—28.10(17A) Exemptions from public rule-making procedures.

28.10(1) Emergency-adopted rule. To the extent the board for good cause finds that public notice and participation are unnecessary, impracticable, or contrary to the public interest in the process of adopting a particular rule, and with the prior approval of the ARRC and ARC, or if a statute so provides, the board may adopt that rule without publishing advance Notice of Intended Action in the Iowa Administrative Bulletin and without providing for written or oral public submissions prior to its adoption. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.10(2) Notice of emergency-adopted rule. The board may, at any time, begin a standard rule-making proceeding for the adoption of a rule that is emergency-adopted without notice pursuant to subrule 28.10(1) and that is identical or similar to a rule it adopts in reliance upon subrule 28.10(1). After notice commenced pursuant to this subrule, the board may either readopt the rule it emergency-adopted without benefit of all usual procedures on the basis of subrule 28.10(1) or may take any other lawful action, including the amendment or repeal of the rule in question, with whatever further proceedings are appropriate.

657—28.11(17A) Concise statement of reasons. When requested by a person, either prior to the adoption of a rule or within 30 days after its publication in the Iowa Administrative Bulletin as an adopted rule, the board shall issue a concise statement of reasons for the rule pursuant to Iowa Code section 17A.4(2). Requests for such a statement shall be in writing and be delivered to the Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The request shall indicate whether the statement is sought for all or only a specified part of the rule. Requests will be considered made on the date received.

657—28.12(17A) Style and form. In preparing its rules, the board shall follow the uniform numbering system, form, and style prescribed by the administrative rules coordinator.

657—28.13(17A) Board rule-making record.

28.13(1) Requirement. The board shall maintain an official rule-making record for each rule it proposes by publication in the Iowa Administrative Bulletin of a Notice of Intended Action or adopts. The rule making record and materials incorporated by reference shall be available for public inspection.

28.13(2) Contents. The board rule-making record shall contain:

a. Copies of all publications in the Iowa Administrative Bulletin with respect to the rule or the proceeding upon which the rule is based;

b. All written petitions, requests, and submissions received by the board, and all other written materials of a factual nature as distinguished from opinion that are relevant to the merits of the rule and that were created or compiled by the board and considered by the board, in connection with the formulation, proposal, or adoption of the rule or the proceeding upon which the rule is based, except to the extent the board is authorized by law to keep them confidential; provided, however, that when any such materials are deleted because they are authorized by law to be kept confidential, the board shall identify in the record the particular materials deleted and state the reasons for such deletion;

c. Any official transcript of oral presentations made in the proceeding upon which the rule is based or, if not transcribed, the stenographic record or electronic recording of those presentations, and any memorandum prepared by a presiding officer summarizing the contents of those presentations;

d. A copy of any regulatory analysis or fiscal impact statement;

e. A copy of the rule and any concise statement of reasons prepared for that rule;

f. All petitions for amendment of, or repeal or suspension of, the rule;

g. A copy of any objection to the rule filed by the administrative rules review committee, the governor, or the attorney general pursuant to Iowa Code section 17A.4(6), and any board response to that objection;

h. A copy of any significant written criticism of the rule, including a summary of any petitions for waiver of the rule; and
1. A copy of any executive order concerning the rule.

28.13(3) **Effect of record.** Except as otherwise required by a provision of law, the board rule-making record required by this rule need not constitute the exclusive basis for board action on that rule.

28.13(4) **Maintenance of record.** The board shall maintain the rule-making record for a period of not less than five years from the later of the date the rule to which it pertains became effective or the date of the Notice of Intended Action. The board shall maintain a record of significant written criticism as described in paragraph 28.13(2) “g,” “h,” or “i,” for a period of not less than five years from the date of the written criticism.

657—28.14(17A) **Filing of rules.** The board shall file each rule the board adopts with the office of the administrative rules coordinator. The filing shall be executed as soon after adoption of the rule as is practicable. In filing a rule, the board shall use the standard form prescribed by the administrative rules coordinator.

657—28.15(17A) **Effectiveness of rules prior to publication.**

28.15(1) **Grounds.** The board may make a rule effective after its filing at any stated time prior to 35 days after its indexing and publication in the Iowa Administrative Bulletin if it finds that a statute so provides, the rule confers a benefit or removes a restriction on some segment of the public, or that the effective date of the rule is necessary to avoid imminent peril to the public health, safety, or welfare. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.15(2) **Special notice.** When the board makes a rule effective prior to its indexing and publication in reliance upon the provisions of Iowa Code section 17A.5(2) “b,” the board shall employ all reasonable efforts to make its contents known to the persons who may be affected by that rule prior to the rule’s indexing and publication. The term “all reasonable efforts” requires the board to employ the most effective and prompt means of notice rationally calculated to inform potentially affected parties of the effectiveness of the rule that is justified and practical under the circumstances considering the various alternatives available for this purpose, the comparative costs to the board of utilizing each of those alternatives, and the harm suffered by affected persons from any lack of notice concerning the contents of the rule prior to its indexing and publication.

657—28.16(17A) **Review by board of rules.** Over each five-year period of time beginning July 1, 2012, the board shall conduct an ongoing and comprehensive review of all the board’s rules pursuant to Iowa Code section 17A.7(2). The purpose of the review is to identify and eliminate all rules that are outdated, redundant, or inconsistent or incompatible with statute, other board rules, or rules of other agencies. When the board’s five-year review of its rules is completed, the board shall summarize the results and provide the summary to the ARC and the ARRC.

These rules are intended to implement Iowa Code sections 17A.1 through 17A.9A.
ADDENDUM U

NOTICE OF INTENDED ACTION

AMENDING CHAPTER 6, GENERAL PHARMACY PRACTICE”

AUGUST 30, 2017
PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, “General Pharmacy Practice,” Iowa Administrative Code.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), this proposed rule making is, in part, the result of an overall review of administrative rules. The proposed amendments clarify and rearrange content of rules in a more efficient manner, incorporate language from 2017 Iowa Acts, House File 305, signed into law during the 2017 Legislative Session of the 87th General Assembly, and provide for remote storage of records in certain circumstances.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 17, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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

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

These amendments are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36 and 2017 Iowa Acts, House File 305.

The following amendments are proposed.

ITEM 1. Amend subrule 6.7(2) as follows:

6.7(2) Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours.

a. No change.

b. A pharmacy technician or a pharmacy support person who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the pharmacy technician or pharmacy support person worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be signed by the pharmacy technician or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge, and documentation of such review shall be maintained for two years from the date of entry.

ITEM 2. Amend rule 657—6.8(124,155A) as follows:

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription, except as provided in 657—subrule 21.5(1). The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. Refill Dispensing documentation shall include date of fill
or refill and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program. The name, strength, and either the manufacturer’s name or the National Drug Code (NDC) of the actual drug product dispensed shall be maintained and be readily retrievable.

ITEM 3. Amend rule 657—6.9(124,155A) as follows:

6.9(124,155A) Transfer of prescription. The transmission of a prescription drug order from a pharmacy to a pharmacy engaged in centralized prescription filling or processing on behalf of the originating pharmacy pursuant to the requirements of 657—Chapter 18 shall not constitute the transfer of a prescription. Upon the request of a patient or the patient’s caregiver, a pharmacy shall transfer original prescription drug order information and prescription refill information to a pharmacy designated by the patient or the patient’s caregiver, central fill or processing pharmacies excepted, subject to the following requirements:

6.9(1) Schedule III, IV, or V prescriptions. The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis except as provided in subrule 6.9(9) 6.9(8).

6.9(2) No change.

6.9(3) Communication. The transfer is communicated directly between pharmacists, directly between pharmacist-interns under the direct supervision of pharmacists at the respective pharmacies, directly between a pharmacist and a pharmacist-intern under the direct supervision of a pharmacist, or as authorized in subrule 6.9(9) 6.9(8). Following direct communication between authorized individuals as provided herein, the transferring pharmacist or pharmacist-intern may transmit the prescription and transfer information required under subrule 6.9(5) from the transferring pharmacy via facsimile. The receiving pharmacist or pharmacist-intern shall ensure the prescription transfer record maintained in the receiving pharmacy contains all of the information required under subrule 6.9(8) 6.9(7).

6.9(4) Prescriptions maintained. Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill activity.

6.9(5) and 6.9(6) No change.

6.9(7) Controlled substance prescription status. The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

6.9(8) 6.9(7) Record of transfer received. The pharmacist or pharmacist-intern receiving the transferred prescription drug order information shall:

a. No change.

b. Record on or with the transferred prescription drug order the following information:
   (1) to (7) No change.
   (8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule 6.9(9) 6.9(8) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled.

6.9(9) 6.9(8) Electronic transfer between pharmacies. Pharmacies electronically accessing the same prescription drug order records via a real-time, on-line database may electronically transfer prescription information, including controlled substance prescription information, up to the maximum refills permitted by law and the prescriber’s authorization, if the following requirements are met.

a. and b. No change.

c. For transfers of controlled substance prescriptions, all information requirements included in subrules 6.9(1) and 6.9(3) through 6.9(8) 6.9(7) shall be satisfied in the electronic system. Transfers of controlled substance prescriptions shall also identify the pharmacy name, address, DEA registration number, and prescription number from which the prescription was originally filled.

2
ITEM 4. Amend subrule 6.10(1) as follows:

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

a. and b. No change.

b. Except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors or 657—subrule 8.19(8) for opioid antagonists, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

c. to f. No change.

d. Unless otherwise directed by the prescriber, the label shall bear the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as “(generic name) Generic for (brand name product).”;

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as “(brand name product) for (generic name)”;

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as “(interchangeable biological product) for (biological product)”;

e. No change.

ITEM 5. Amend subrule 6.13(1) as follows:

6.13(1) Information required. A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist patient record system shall be responsible for obtaining, recording, and maintaining contain, at a minimum, the following information:

a. Full name of the patient for whom the drug is intended;

b. Address and telephone number of the patient;

c. Patient’s age or date of birth;

d. Patient’s gender;

e. Known allergies;

f. Significant patient information including a list of all prescription drug orders dispensed by the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received dispensed, and the name of the prescriber; and

g. Pharmacist comments relevant to the individual’s drug therapy patient’s health care, including:

(1) Known drug reactions,

(2) Identified idiosyncrasies,

(3) Known chronic conditions or disease states of the patient,

(4) The identity of any other drugs, over-the-counter drugs, herbals, supplements, other alternative medications, or devices currently being used by the patient that may relate to prospective drug review.

ITEM 6. Amend rule 657—6.14(155A) as follows:

657—6.14(155A) Patient counseling and instruction. Every general pharmacy that is open to the public and located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, 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 that are new or a change in drug therapy. The board shall provide a general pharmacy with the required signage.
pharmacy that provides no direct patient access to the pharmacy department, commonly referred to as a “closed-door pharmacy,” shall not be required to post the counseling notice.

6.14(1) Counseling required. Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to rule 657—8.21(155A), a pharmacist or pharmacist-intern shall counsel each patient or patient’s caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist’s professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. to f. No change.

6.14(2) and 6.14(3) No change.

6.14(4) Oral counseling not practicable. If in the pharmacist’s professional judgment oral counseling is not practicable, the pharmacist may select and use alternative forms of patient information which shall include information for the patient or patient’s caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. “Not practicable” refers to patient variables including, but not limited to, the absence of the patient or patient’s caregiver, the patient’s or caregiver’s hearing impairment, or a language barrier. “Not practicable” does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) No change.

6.14(6) Refusal of consultation. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient’s or caregiver’s refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist’s attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

ITEM 7. Amend rule 657—6.15(124,126) as follows:

657—6.15(124,126) Return of drugs and other items devices. For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact nature may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) Integrity maintained. Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug or device has not in any way been compromised.

6.15(2) and 6.15(3) No change.

6.15(4) Personal contact items. Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.

ITEM 8. Amend rule 657—6.16(124,155A) as follows:

657—6.16(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 pharmacy 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 or last activity 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. Original hard copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage
is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.

6.16(1) No change.

6.16(2) Prescriptions maintained Storage of records. The original prescription drug order shall be maintained for a period of two years following the date of last activity on the prescription. Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

6.16(3) Number imprinted. The original hard-copy prescription shall be imprinted with the prescription or control number assigned to the prescription drug order, except as provided in 657—subrule 21.5(1).

6.16(4) Alternative data retention system. Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. and b. No change.

c. The information maintained in the alternative system is not obscured or rendered illegible due to security features of the original hard-copy record.
ADDENDUM V

NOTICE OF INTENDED ACTION

RESCINDING CHAPTER 9, “AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES,” RESCINDING CHAPTER 21, ELECTRONIC DATA IN PHARMACY PRACTICE,” AND ADOPTING NEW CHAPTER 21, “ELECTRONIC DATA AND AUTOMATED SYSTEMS IN PHARMACY PRACTICE”

AUGUST 30, 2017
PHARMACY BOARD[657]

Notice of Intended Action

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

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

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 9, “Automated Medication Distribution Systems and Telepharmacy Services,” and Chapter 21, “Electronic Data in Pharmacy Practice,” and to adopt new Chapter 21, “Electronic Data and Automated Systems in Pharmacy Practice,” Iowa Administrative Code.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy. Pursuant to Iowa Code section 17A.7(2), this proposed rule making is the result of an overall review of administrative rules relating to automated medication distribution systems and electronic data in pharmacy practice. Chapter 9 is proposed to be rescinded to remove any overlap or inconsistencies of rules for telepharmacy practice found in 657—Chapter 13, “Telepharmacy Practice,” recently adopted by the Board. Further, automated systems are increasingly commonplace in pharmacy practice, with safety and security measures well established, and the Board wishes to pare down the rules to identify the core minimum standards for pharmacies utilizing such systems. Minimum standards for automated systems are proposed to be added to Chapter 21. Several rules relating to notice and reports to the Board are not continued in the proposed rule making to lessen the burden on pharmacies using such automated systems.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 17, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail at terry.witkowski@iowa.gov. Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

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

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, and 155A.35.

The following amendments are proposed.

ITEM 1. Rescind and reserve 657—Chapter 9.

ITEM 2. Rescind 657—Chapter 21 and adopt the following new chapter in lieu thereof:

CHAPTER 21
ELECTRONIC DATA AND AUTOMATED SYSTEMS IN PHARMACY PRACTICE

657—21.1(124,155A) Purpose and scope. The purpose of this chapter is to provide the minimum standards for the utilization of electronic data and automated systems in the practice of pharmacy and shall apply to all pharmacies located in Iowa.

657—21.2(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

“Automated data processing system” means an application that is used for prescription, patient, drug, and prescriber information; installed on a pharmacy’s computer or server; and controlled by the pharmacy.

“Automated medication distribution system” or “AMDS” includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or

...
dispensing. “AMDS” does not include electronic storage devices that do not have an electronic interface with one or more computers of the pharmacy.

“DEA” means the U.S. Department of Justice, Drug Enforcement Administration.

“Electronically prepared prescription” means a prescription that is generated utilizing an electronic prescription application.

“Electronic device” means an electronic, mechanical, or other device which is used to intercept communications and includes but is not limited to network, file and print servers; desktop workstations; laptop computers; tablets; mini-computers; smart phones; and similar devices.

“Electronic prescription” means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

“Electronic prescription application” means software that is used to create electronic prescriptions and that is intended to be installed on a prescriber’s computers and servers where access and records are controlled by the prescriber.

“Electronic signature” means a confidential personalized digital key, code, number, or other method used for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message, and indicates the person’s approval of the information contained in the transmission.

“Electronic transmission” means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber’s electronic prescription application to a pharmacy’s computer, where the data file is imported into the pharmacy prescription application.

“Facsimile transmission” or “fax transmission” means the transmission of a digital image of a prescription from the prescriber or the prescriber’s agent to the pharmacy. “Facsimile transmission” includes but is not limited to transmission of a written prescription between the prescriber’s fax machine and the pharmacy’s fax machine; transmission of an electronically prepared prescription from the prescriber’s electronic prescription application to the pharmacy’s fax machine or printer; or transmission of an electronically prepared prescription from the prescriber’s fax machine to the pharmacy’s fax machine, computer, or printer.

“Intermediary” means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

“Pharmacist verification” or “verified by a pharmacist” means the accuracy of a prescription drug is verified by a pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program.

“Prescription drug order” or “prescription” means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy, regardless of whether the communication is oral, electronic, via facsimile, or in printed form.

“Readily retrievable” means that hard copy or electronic records can be separated out from all other records within 48 hours of a request from the board or other authorized agent.

“Written prescription” means a prescription that is created on paper, a prescription that is electronically prepared and printed, or a prescription that is electronically prepared and transmitted from the prescriber’s electronic device to a pharmacy via facsimile. A written prescription for a controlled substance shall be manually signed by the prescriber in compliance with federal and state laws, rules, and regulations.

657—21.3(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system, computer, or electronic device utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual. Once a drug or device has been dispensed, any alterations in either the prescription drug order data or the patient record shall be documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist. An automated data processing system used for the receipt and processing of
electronic transmissions from a prescriber’s electronic prescription application shall comply with DEA requirements relating to electronic prescriptions and shall be certified compliant with DEA regulations.

657—21.4 Reserved.

657—21.5(124,155A) Automated data processing systems. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of prescription, patient, prescriber and drug data as well as data relating to the pharmacy staff utilization of the system.

21.5(1) Electronic storage of hard-copy prescriptions. A pharmacy that maintains an electronic copy of an original hard-copy prescription for a noncontrolled substance shall retain, in a readily retrievable format, the original hard-copy prescription as required in rule 657—6.8(155A) but shall be exempt from the requirement to record on the original hard-copy prescription the date and unique identification number of the prescription.

21.5(2) Data retrievable and printable. Any automated data processing system shall be capable of immediate retrieval (via computer monitor or hard-copy printout) of, at a minimum, any prescription, patient, prescriber, and drug data as well as data relating to pharmacy staff utilization of the system.

21.5(3) Auxiliary procedure for system downtime. A pharmacy utilizing an automated data processing system shall have a procedure that will maintain security and confidentiality of all data as well as ensure the legal dispensing of any prescription drug order in the event the system experiences downtime.

657—21.6(124,155A) Electronic prescription applications. A prescriber may initiate and authorize a prescription drug order utilizing an electronic prescription application that has been determined to maintain security and confidentiality of patient information and records and, if prescribing controlled substances via an electronic prescribing system, certified compliant with DEA regulations for electronic prescribing of controlled substances. The prescription drug order shall contain all information required by Iowa Code sections 155A.27 and 147.107(5). The receiving pharmacist shall be responsible for verifying the authenticity of an electronically prescribed prescription pursuant to rule 657—8.19(124,126,155A). A prescription that is electronically generated may be transmitted to a pharmacy via electronic or facsimile transmission or printed in hard-copy format for delivery to the pharmacy. A prescription that is transmitted by a prescriber’s agent via electronic or facsimile transmission shall include the first and last names and title of the agent responsible for the transmission.

21.6(1) Electronic transmission. A prescription prepared pursuant to this rule may be transmitted to a pharmacy via electronic transmission. A pharmacy shall be certified compliant with DEA regulations relating to electronic prescriptions prior to electronically receiving prescriptions for controlled substances. The electronic record shall serve as the original record and shall be maintained for two years from the date of last activity on the prescription. Any annotations shall be made and retained on the electronic record.

a. An electronically prepared and transmitted prescription that is printed following transmission shall be clearly labeled as a copy, not valid for dispensing.

b. The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic automated data processing system shall be deemed verified by virtue of the security processes included in those applications.

c. A pharmacy shall ensure that no intermediary has the ability to change the content of the prescription drug order or compromise its confidentiality during the transmission process. The electronic format of the prescription drug order may be changed by the intermediary to facilitate the transmission between electronic applications as long as the content of the prescription drug order remains unchanged.

d. In addition to the information requirements for a prescription, an electronically transmitted prescription shall identify the transmitter’s telephone number for verbal confirmation, the time and date
of transmission, and the pharmacy intended to receive the transmission as well as any other information
required by federal or state laws, rules, or regulations.

c. If the transmission of an electronic prescription fails, the prescriber may print the prescription,
manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile
transmission in accordance with subrule 21.6(2).

21.6(2) Printed (hard-copy) prescriptions. An electronically generated prescription may be printed
in hard-copy format for facsimile transmission or delivery to the pharmacy.

a. A prescription for a controlled substance shall include the prescriber’s manual signature.
Printed or hard-copy prescriptions for Schedule II controlled substances shall not be transmitted to a
pharmacy via facsimile transmission, except as authorized in rule 657—21.7(124,155A).

b. If the prescriber authenticates a prescription for a noncontrolled prescription drug utilizing an
electronic signature, the printed prescription shall be printed on security paper. Security features of the
paper shall ensure that prescription information is not obscured or rendered illegible when transmitted
via facsimile or when scanned into an electronic record system.

c. If the facsimile transmission of a printed prescription is a result of a failed electronic
transmission, the facsimile shall indicate that it was originally transmitted to the named pharmacy, the
date and time of the original electronic transmission, and the fact that the original transmission failed.

657—21.7(124,155A) Facsimile transmission of a prescription. A pharmacist may dispense
noncontrolled and controlled drugs, including Schedule II controlled substances only as provided
in this rule, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the
practitioner’s agent. The means of transmission via facsimile shall ensure that prescription information
is not obscured or rendered illegible due to security features of the paper utilized by the prescriber
to prepare a written prescription. The faxed prescription shall serve as the original record, except as
provided in subrule 21.7(1), shall be maintained for a minimum of two years from the date of the last
activity on the prescription, and shall contain all information required by Iowa Code sections 155A.27
and 147.107(5), including the prescriber’s signature. If the prescription is transmitted by an agent of
the prescriber, the facsimile transmission shall include the first and last names and title of the agent
responsible for the transmission. The pharmacist shall be responsible for verifying the authenticity of
the prescription as to the source of the facsimile transmission.

21.7(1) Schedule II controlled substances—emergency situations. A pharmacist may, in an
emergency situation as defined in 657—subrule 10.26(1), dispense a Schedule II controlled substance
pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescriber
or the prescriber’s agent pursuant to the requirements of rule 657—10.26(124). The facsimile shall
serve as the temporary written record required by 657—subrule 10.26(2).

21.7(2) Schedule II controlled substances—compounded injectable. A prescription for a Schedule II
narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous,
intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a prescriber or the prescriber’s
agent to a pharmacy via facsimile.

21.7(3) Schedule II controlled substances—long-term care facility patients. A prescription for any
Schedule II controlled substance for a resident of a long-term care facility, as “long-term care facility”
is defined in rule 657—23.1(155A), may be transmitted by the prescriber or the prescriber’s agent to a
pharmacy via facsimile. The prescription shall identify that the patient is a resident of a long-term care
facility.

21.7(4) Schedule II controlled substances—hospice patients. A prescription for any Schedule II
controlled substance for a patient in a hospice program licensed pursuant to Iowa Code chapter 135J or
a program certified or paid for by Medicare under Title XVIII may be transmitted via facsimile by the
prescriber or the prescriber’s agent to the pharmacy. The prescription shall identify that the patient is a
hospice patient.

657—21.8 and 21.9 Reserved.
657—21.10(124,155A) Automated medication distribution system (AMDS). Any pharmacy that utilizes an AMDS shall comply with these rules in addition to all applicable federal and state laws, rules, and regulations.

21.10(1) Policies and procedures. Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:

a. Access to drugs and patient information,
b. Pharmacy personnel training in the proper operation of the AMDS,
c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),
d. Confidentiality of patient information,
e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,
f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and

g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:

(1) Drug loading, storage, and records.
(2) Drugs removed from system components but not used.
(3) Inventory.
(4) Cross contamination.
(5) Lot number control.
(6) Wasted or discarded drugs.
(7) Controlled substances.

21.10(2) Stocking the AMDS. The pharmacy shall have adequate procedures in place to ensure the accurate stocking of drugs into an AMDS using barcode scanning technology. Only a pharmacy technician, pharmacist-intern, or pharmacist shall be allowed to participate in the stocking of the AMDS.

21.10(3) Pharmacist verification of drugs dispensed from AMDS.

a. When an AMDS only dispenses drugs that were prepackaged and verified by a pharmacist prior to being stocked in the AMDS and there was no further manipulation of the drug or package other than affixing a patient-specific label, such drugs shall not require additional pharmacist verification prior to administration or dispensing to the patient or authorized representative.

b. When a drug is stocked in an AMDS and undergoes further manipulation, such as counting and packaging, such drugs shall require pharmacist verification prior to dispensing to the patient. Such verification shall be documented.

21.10(4) Placement of AMDS.

a. An AMDS placed outside a pharmacist’s direct supervision shall only dispense pharmacist-verified packages in compliance with paragraph 21.10(3)“a.”

b. An AMDS that manipulates, including but not limited to counting, packaging, or labeling, prescription drugs for subsequent patient dispensing shall only be utilized in a pharmacy under the direct supervision of a pharmacist, except in an approved telepharmacy pursuant to 657—Chapter 13.

657—21.11(124,155A) Pharmacist verification of controlled substance fills—daily printout or logbook. The individual pharmacist who makes use of the pharmacy prescription application shall provide documentation of the fact that the fill information entered into the pharmacy prescription application each time the pharmacist fills a prescription order for a controlled substance is correct. If the pharmacy prescription application provides a hard-copy printout of each day’s controlled substance prescription order fill data, that printout shall be verified, dated, and signed by each individual pharmacist who filled a controlled substance prescription order. Each individual pharmacist must verify that the data indicated is correct and sign this document in the same manner as the pharmacist would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day’s controlled substance prescription order fill data shall be generated by and available at each pharmacy using a computerized pharmacy prescription application within 48 hours of the date on
which the prescription was dispensed. The printout shall be verified and signed by each pharmacist involved with such dispensing. In lieu of preparing and maintaining printouts as provided above, the pharmacy may maintain a bound logbook or separate file. The logbook or file shall include a statement signed each day by each individual pharmacist involved in each day’s dispensing that attests to the fact that the prescription information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The logbook or file shall be maintained at the pharmacy for a period of two years after the date of dispensing.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, and 155A.35.