

State of Iowa
Board of Pharmacy

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BOARD MEMBERS

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Storm Lake

MINUTES

January 5-6, 2015

The Iowa Board of Pharmacy met on January 5-6, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa. Vice-Chair Miller called the meeting to order at 1:00 p.m.

MEMBERS PRESENT

Edward L. Maier, Chairperson
(joined at 2:15 p.m. on January 5)
James Miller, Vice-Chair
Susan M. Frey
LaDonna Gratias
Edward J. McKenna
Sharon K. Meyer

MEMBERS ABSENT

Judith M. Trumpy

SPEAKERS

Heather Rickertsen, Mercy Family Pharmacy
Josh Feldman, Mercy Family Pharmacy
Megan Myers, Iowa Pharmacy Association
Carl Olsen, Des Moines

STAFF PRESENT

Lloyd Jessen, Executive Director
Meghan Gavin, Esq., Assistant Attorney
General
Laura Steffensmeier, Esq., Assistant
Attorney General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary

Compliance Officers Present:

Andrew Funk
Curt Gerhold
Mark Mather
Sue Mears
Jean Rhodes
Jennifer Tiffany
Jennifer O'Toole
Jim Wolfe

I. Minutes.

The Minutes of the November 14, 2014, teleconference meeting; the November 18-19, 2014, meeting; and the December 10, 2014, teleconference meeting were read.

Motion (Gratias/Meyer) to approve the minutes of the November 14, 2014, teleconference meeting. Passed: 5-0-0-2. Absent: Maier, Trumpy.

Motion (Gratias/McKenna) to approve the minutes of the November 18-19, 2014, meeting. Passed: 5-0-0-2. Absent: Maier; Trumpy.

Motion (McKenna/Meyer) to approve the minutes of the December 10, 2014, teleconference meeting. Passed: 4-1-0-2. Abstain: Frey; Absent: Maier, Trumpy.

II. Requests.

- A. Request for Termination of Probation – Bill Poulos, Pharmacist License No. 20076, Dodge City, Kansas.

Motion (Frey/McKenna) to table request. Passed: 5-0-0-2. Absent: Maier, Trumpy.

Motion (Miller/Frey) to approve request for termination of probation. Passed: 6-0-0-1. Absent: Trumpy.

- B. Request for Waiver – 657 I.A.C. 8.34 Collaborative Drug Therapy Management – Heather Rickertsen, Pharmacist License No. 20196, Delmar.

Motion (Frey/Meyer) to table the request for waiver pending additional information and follow-up with the Board of Medicine and Board of Nursing. Passed: 4-0-1-2. Abstain: Miller; Absent: Maier, Trumpy.

- C. 2015 Pharmacy Summit Invitation – University of Iowa College of Pharmacy.

The University of Iowa College of Pharmacy will be hosting an Iowa Pharmacy Technician Education Summit on February 5, 2015, in Des Moines.

- D. Recommendations Regarding Licensure Preferences for Military Spouses.

Motion (Frey/McKenna) to send recommendation to the Legislature to include Military Spouses. Passed: 5-0-0-2. Absent: Maier, Trumpy.

- E. Petition to Request Reclassification of Marijuana – Carl Olsen, Des Moines.

Motion (Miller/Frey) to deny the petition. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order Denying Petition is attached as Addendum A.

Motion (Frey/Gratias) to recommend to the Legislature that Cannabidiol be classified as a Schedule II substance in the Controlled Substances Act (CSA). Passed: 6-0-0-1. Absent: Trumpy. A copy is attached as Addendum B.

Motion (Frey/Gratias) to recommend to the Legislature that they remove the phrase “pursuant to rules of the Board,” from Schedule I exemption for medical marijuana because the Board does not have the authority to establish such a program and I further recommend that the same

phrase be removed from Schedule II regarding medical marijuana for the same reason. Passed: 6-0-0-1. Absent: Trumpy. Addendum B addresses this motion.

III. Reports.

Executive Director's Report.

A. Financial.

FY15 as of 11/30/14 ((41.67% of FY completed)

Revenue Anticipated:	\$ 3,833,933
Revenue Y-T-D	\$ 1,586,494 (59%)
Carry-over from FY14	\$ 1,504,637
FY15 Fee Receipts	\$ 771,538
Budget Allocation	\$ 3,833,933
Obligations Y-T-D	\$ 1,275,116 (33.3%)
Cash Fund Balance	\$ 1,365,568
(\$ 850,000 reserved for database)	
Fines/Civil Penalties Collected	\$ 32,250

B. Meetings and Travel.

1. A public hearing on proposed administrative rules will be held on January, 15, 2015, at the Board office in Des Moines.
2. The next Rules Committee Meeting is scheduled for January 27, 2015, at the Board office in Des Moines.
3. An Administrative Hearing for PCM Venture, LLC, Sandy, Utah, is scheduled for January 28-29, 2015, at the Board office in Des Moines.
4. The IPA Legislative Day will be held on January 29, 2015, in Des Moines.
5. An Iowa Pharmacy Technician Education Summit will be held on February 5, 2015, at the Pappajohn Education Center in Des Moines. The summit is being hosted by the University of Iowa College of Pharmacy. The Iowa Board of Pharmacy will present information on pharmacy technician demographics in Iowa.
6. An Iowa Prescription Monitoring Program (PMP) Conference will be held on February 10, 2015, at Camp Dodge in Johnston. The conference is being hosted by the Iowa Board of Pharmacy, the Iowa PMP Advisory Council, and the Governor's Office of Drug Control Policy.
7. The 2015 Midwest Pharmacy Expo will be held in Des Moines, on February 13-15, 2015. The Iowa Board of Pharmacy will provide a pharmacy law presentation on February 15, 2015.

8. The March Board Meeting is scheduled for March 9-11, 2015, at the Board office in Des Moines. The meeting will begin at 1:00 p.m. on March 9.

9. The April Board Meeting is scheduled for April 28-29, 2015, at the Board office in Des Moines. A retirement dinner for Susan Frey will be held on the evening of April 28.

C. Prescription Drug Abuse: 2013- Strategies to Stop the Epidemic – Trust for America’s Health. Informational item.

D. Iowa Electronic Pseudoephedrine Tracking System Annual Report (National Precursor Log Exchange – NPLEx) – Office of Drug Control Policy.

The Iowa Electronic Pseudoephedrine Tracking System Annual Report was provided for review.

E. Carl Olsen vs. Iowa Board of Pharmacy – Ruling on Petition for Judicial Review.

Meghan Gavin advised the Board that this matter has now been appealed to the Iowa Supreme Court. She further indicated that a decision may be issued by the Iowa Court of Appeals as early as sometime in the Fall of 2015. A copy of Ruling on Petition for Judicial Review is attached as Addendum C.

F. Surescripts Second Update Regarding Industry Progress in Implementing Electronic Prescribing for Controlled Substances (EPCS).

Discussion was held regarding prescribers and pharmacies being in full compliance with the Drug Enforcement Administration’s (DEA) interim final rule (IFR) allowing electronic prescribing for controlled substances (EPCS) and that all application vendors connecting to the Surescripts network have met all the applicable DEA EPCS IFR requirements, ensuring that EPCS communications on Surescripts’ network are legal.

G. Pharmacy Opening and Closing Statistics.

Opening and closing statistics for Iowa Pharmacies were provided for review. In future reports, the Board requested geographical information regarding as to where the changes are occurring.

2012 New = 43 / Closed = 44

2013 New = 43 / Closed = 45

2014 New = 24 / Closed = 40

H. Patient Safety & Medication Error Prevention for Pharmacy.

The Oregon State University College of Pharmacy recently released their Patient Safety & Medication Error Prevention for Pharmacy Course. The course provides pharmacists the tools

to identify problems, reduce risks, and improve communications, resulting in improved patient safety within the pharmacy environment.

I. List of Those Indicted in NECC Case – John R. Ellement, Boston Globe.

Informational item.

J. New Practice Model Interim Report – Megan Myers, Iowa Pharmacy Association.

The Iowa Pharmacy Association and Drake University College of Pharmacy provided their Quarterly New Practice Model Report for review.

IV. Legislation.

A. Non-Resident Pharmacy Legislation Language: Karen Sisson, Walgreen Co., and Jeff Lindoo, Thrifty White Pharmacies.

Informational item.

B. Public Comment on Proposed Legislation.

Informational item.

V. Licensure/Registration.

A. Iowa Wholesale Drug License Application.

Motion (Frey/Miller) to approve renewal application and have compliance officer follow-up with the parent company in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

1. AR Scientific Inc., Wholesale Drug License No. 6310 of Philadelphia, Pennsylvania.
2. Mutual Pharmaceutical Company Inc., Wholesale Drug License No. 7480 of Philadelphia, Pennsylvania.
3. Mutual Pharmaceutical Company Inc., Wholesale Drug License No 7479 of Philadelphia, Pennsylvania.

B. Preliminary Notice of Intent to Deny License – Sun Pharmaceutical Industries, Inc., Cranbury, New Jersey.

Motion (Miller/Gratias) to approve Preliminary Notice of Intent to Deny License. Passed: 6-0-0-1. Absent: Trumpy. A copy is attached as Addendum D.

C. Preliminary Notice of Intent to Deny Registration.

Motion (Miller/McKenna) to approve Preliminary Notice of Intent to Deny Registration in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

1. Michelle Heidebrink, of Oskaloosa. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum E.
2. Rhonda Macy of Des Moines. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum F.
3. Stephanie Wadell of Orange City. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum G.

D. Pharmacy Support Person Application – Shaunetta L. McNeil, Iowa City.

Motion (Miller/McKenna) to approve Pharmacy Support Person Application. Passed: 4-1-0-1. No: Frey; Absent: Trumpy.

E. Zachary Monono - Licensure Transfer Candidate, Omaha, Nebraska.

Motion (Miller/McKenna) to approve Application for Transfer of Pharmacist License to the state of Iowa. Passed: 6-0-0-1. Absent: Trumpy.

VI. Complaints Against Non-Licensees.

A. 2014-193 Wellmark Blue Cross Blue Shield of Iowa.

Motion (Frey/Miller) to close with no action. Passed: 6-0-0-1. Absent: Trumpy.

VII. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; and 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Frey) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

VIII. Administrative Hearing.

A. Robert Osborn, Pharmacist License No. 19079 of Rock Island, Illinois.

On November 19, 2014, the Iowa Board of Pharmacy found probable cause to file Notice of Hearing and Statement of Charges against the above-named individual.

Margaret LaMarche, Administrative Law Judge for the State, presided. Assistant Attorney General Meghan Gavin represented the Board. Robert Osborn appeared without counsel.

The hearing was conducted in the presence of the Board. The hearing was closed to the public.

The Board heard testimony of witnesses and examined exhibits.

VIX. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Miller) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (Gratias/Frey) to direct Administrative Law Judge LaMarche to draft the decision of the Board in the Osborn case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

X. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; and 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (Frey/McKenna) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

In open session the following actions were taken.

A. Settlement Agreement and Final Order.

Motion (Miller/Frey) to approve the Settlement Agreement and Final Order in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

1. Matthew Sherrow, Pharmacist License No. 18612 of Springfield, Illinois. A copy of the Settlement Agreement and Final Order is attached as Addendum H.
2. James Kaufman, Pharmacist License No. 18228 of Sioux City. A copy of the Settlement Agreement and Final Order is attached as Addendum I.
3. OK Compounding LLC, Nonresident Pharmacy License No. 4204 of Skiatook, Oklahoma. A copy of the Settlement Agreement and Final Order is attached as Addendum J.

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

Motion (Miller/McKenna) to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the case of Richard Upton, Pharmacist License No. 19779 of

Sidney. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum K.

C. Combined Notice of Hearing and Statement of Charges.

Motion (Frey/McKenna) to approve Notice of Hearing and Statement of Charges in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

1. Amanda Knouse, Pharmacy Technician Registration No. 20304 of Des Moines. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum L.
2. Stacy Jahlas, Pharmacy Technician Registration No. 14928 of Belle Plaine. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum M.
3. Stephen Scott, Pharmacist License No. 18067 of Tipton. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.

D. Order to Show Cause.

Motion (Miller/Frey) to approve Order to Show Cause in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

1. Paula Curran, CSA Registration No. 5201077 of Burlington. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order to Show Cause is attached as Addendum O.
2. Timothy Smith, CSA Registration No. 1709957 of Marshalltown. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order to Show Cause is attached as Addendum P.

E. Confidential Order for Evaluation.

Motion (Miller/Meyer) to approve Confidential Order for Evaluation for C.S. and D.H. Passed: 6-0-0-1. Absent: Trumpy.

F. Draft Statement of Charges.

Motion (Miller/McKenna) to draft Statement of Charges against the stated individuals in the following complaints: pharmacy and pharmacist in charge in 2014-50; pharmacy in 2014-100; technician in 2014-137; technician in 2014-169; technician in 2014-173; pharmacy in 2014-182; technician in 2014-189; and pharmacy and pharmacist in charge in 2014-204. Passed: 6-0-0-1. Absent: Trumpy.

G. Administrative Warning.

Motion (Miller/McKenna) to send an Administrative Warning to the pharmacy in 2014-186. Passed: 6-0-0-1. Absent: Trumpy.

H. Letter of Education.

Motion (Miller/McKenna) to send a Letter of Education to the CSA Registrant in 2014-191. Passed: 6-0-0-1. Absent: Trumpy.

I. Close With No Action.

Motion (Miller/McKenna) to close with no further action the investigative file in complaint numbers: 2013-146, 2013-3435, 2013-3591, 2013-4095, 2013-9992, 2014-144, 2014-166, 2014-167, 2014-170, 2014-174, 2014-178, 2014-179, 2014-183, 2014-184, 2014-185, 2014-187, 2014-190, 2014-192, 2014-194, 2014-195, 2014-196, 2014-197, 2014-199, and 2014-206. Passed: 6-0-0-1. Absent: Trumpy.

J. Close and Refer to Another Agency.

Motion (Frey/Miller) to close 2014-16 and refer to another agency. Passed: 6-0-0-1. Absent: Trumpy.

K. Release Request from Consultant Requirement.

Motion (Miller/McKenna) to release Randy Moad from consultant requirement. Passed: 6-0-0-1. Absent: Trumpy.

L. Draft Order to Show Cause.

Motion (Miller/McKenna) to draft Order to Show Cause against the CSA registrant in 2014-171. Passed: 6-0-0-1. Absent: Trumpy.

XI. Closed Session.

Assistant Attorney Generals Meghan Gavin and Laura Steffensmeier left the room.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Gratias) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

In open session the following actions were taken.

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

Motion (Miller/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of James Nielcen, Pharmacist License No. 14579 of Waterloo. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Q.

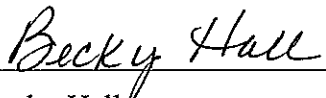
B. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Frey/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of Matthew Biggerstaff, CSA Registration No. 1306092 of Ankeny. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum R.

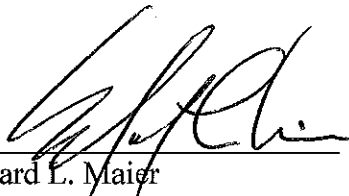
C. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Miller/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of Medicap Pharmacy, CSA Registration No. 1106533 of Oskaloosa. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum S.

Meeting adjourned at 1:15 p.m. on January 6, 2015.


Becky Hall
Recording Secretary


Lloyd K. Jessen
Executive Director


Edward L. Maier
Board Chair

APPROVED THIS 10th DAY OF March, 2015.

ADDENDUM A

**ORDER DENYING PETITION
FOR AGENCY ACTION
TO RESCHEDULE MARIJUANA**

JANUARY 5, 2015

BEFORE THE IOWA BOARD OF PHARMACY

PETITION FOR AGENCY ACTION TO RESCHEDULE MARIJUANA))))	ORDER DENYING PETITION
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PROCEDURAL BACKGROUND

On July 7, 2014, Carl Olsen filed a Petition for Agency Action requesting that the Iowa Board of Pharmacy ("Board") recommend to the Iowa General Assembly the removal of marijuana from Schedule I. The Petition does not request or suggest what schedule marijuana should be placed in, only that it be removed from Schedule I.

The Board first considered the Petition at its August 2014 meeting. The Board tabled consideration of the Petition at that time and appointed a committee to further study the request. The committee met on November 17, 2014, and invited public comment on the Petition. Several government agencies, advocacy groups, and private citizens provided both written and oral comments at the November meeting.

On November 19, 2014, the Board met in open session to deliberate the Petition. At that time, the Board voted to table the Petition until the January 2015 meeting. On January 5, 2015, the Board met in open session to deliberate and render a decision on the Petition. The Board voted to deny the Petition.

FACTUAL AND LEGAL BACKGROUND

Marijuana is currently listed in Schedule I under state law. *See* Iowa Code section 124.204(4)"m" (stating "Marijuana, except as otherwise provided by rules of the board for medicinal purposes."). Marijuana is also currently listed in Schedule II under state law. *See* Iowa Code section 124.206(7)"a" (stating "Marijuana when used for medicinal purposes pursuant to rules of the board."). In Iowa, marijuana is defined by Iowa law to include

all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

Iowa Code section 124.101(19). Marijuana is currently listed in Schedule I under federal law.

See 21 CFR § 1308.11(d)"23".

The Controlled Substances Act places some responsibilities on the Board as it relates to the scheduling of substances. In particular, Iowa Code section 124.203(2) provides:

1. The board shall recommend to the general assembly that the general assembly place a substance in schedule I if the substance is not already included therein and the board finds that the substance:
 - a. Has high potential for abuse; and
 - b. Has no accepted medicinal use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision.
2. If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate.

In 2014, the Iowa General Assembly passed the Medical Cannabidiol Act. *See* Iowa Code chapter 124D. The Act permits the use of cannabidiol by patients suffering from intractable epilepsy. The Iowa General Assembly granted the authority to administer the provisions of the Act to the Iowa Department of Public Health.

ANALYSIS

Typically, the Board makes recommendations regarding the scheduling of substances to the Iowa General Assembly when the federal Drug Enforcement Agency (1) adds a new substance to a schedule, (2) moves a scheduled substance to a different schedule, or (3) removes a substance from scheduling. Essentially, the Board notifies the Iowa General Assembly of

changes in the federal scheduling of controlled substances and recommends changes in the schedules under state law to be in accordance with federal scheduling.

Despite the passage of laws regarding marijuana in several states, it remains a Schedule I controlled substance under federal law. As a matter of policy, the federal government has allowed states, through non-enforcement of federal law, to serve as laboratories of democracy by experimenting with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government may change its policy at any time, thereby nullifying any laws or programs related to marijuana enacted by any state. The Board is hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law.

Regardless of federal law, Iowa Code section 124.203 requires that the Board recommend the removal of a substance from Schedule I if the Board finds that either (1) the substance does not have a high potential for abuse, or (2) the substance has some accepted medicinal use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, it also believes that the passage of the Medical Cannabidiol Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana, as it is defined by Iowa Code section 124.101(19). As a result of the Medical Cannabidiol Act, Schedule I is inappropriate for cannabidiol.

The Board is not inclined to make the broader recommendation requested by the Petition that marijuana be removed from Schedule I. Many substances can be derived from marijuana—some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to schedule each derivate after an individualized analysis. The Board points out that separately scheduling a substance that is a derivative of marijuana, such as cannabidiol, should be accompanied by an amendment to the definition of marijuana in Iowa Code section

124.101(19), explicitly excluding the derivative from the definition of marijuana, in order to avoid conflict.

The Board believes it has an obligation under the Controlled Substances Act to recommend the proper schedule for cannabidiol. Iowa Code section 124.205 establishes the criteria for including a substance in Schedule II. The criteria are: (1) the substance has a high potential for abuse, (2) the substance currently has accepted medical use with severe restrictions in the United States, and (3) abuse of the substance may lead to severe psychic or physical dependence. The Board feels that cannabidiol meets the criteria for Schedule II, and thus recommends to the Iowa General Assembly that cannabidiol, as defined by Iowa Code section 124D.2(1), be placed in Schedule II.

The Board believes that, if the Iowa General Assembly chooses to expand the Medical Cannabidiol Act or implement a medical marijuana program, a coalition of stakeholders should be established to further study the potential medicinal uses of marijuana or its derivatives in Iowa. These stakeholders should include, but not be limited to, the Office of Drug Control Policy, the Iowa Boards of Medicine and Pharmacy, law enforcement agencies, academia, addiction treatment specialists, and patients. It is incumbent that the establishment of a program involving marijuana or its derivatives for medicinal use includes the perspectives of all of these groups. No single entity can determine what conditions marijuana or its derivatives could be used to treat, what safety measures are needed to prevent unlawful use, and the myriad of other concerns raised by a program involving marijuana or its derivatives for medicinal use in Iowa. The Board is particularly concerned about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The dual scheduling of marijuana under state law is a holdover from experimental marijuana research programs authorized more than thirty years ago. The dual scheduling has understandably led to confusion as to the Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the Iowa General Assembly for the Board to unilaterally establish and implement a medical marijuana program in Iowa. This is evidenced by the fact that the Department of Public Health was vested with the authority to implement the Medical Cannabidiol Act. To avoid confusion, the Board recommends that the phrase "except as otherwise provided by rules of the board for medicinal purposes" be deleted from Iowa Code section 124.204(4)"m". In addition, the Board recommends that either the entirety of Iowa Code section 124.206(7)"a" be deleted, or, at a minimum, the phrase "pursuant to rules of the board" be deleted from Iowa Code section 124.206(7)"a".

ORDER

For the reasons stated herein, the Petition for Agency Action to Reschedule Marijuana is **DENIED.**



EDWARD MAIER
Chairperson, Iowa Board of Pharmacy

ADDENDUM B

**RECOMMENDATION TO THE
IOWA GENERAL ASSEMBLY
RE: CANNABIDIOL AND MARIJUANA**

JANUARY 5, 2015

BEFORE THE IOWA BOARD OF PHARMACY

RECOMMENDATION TO THE)	
IOWA GENERAL ASSEMBLY)	RE: CANNABIDIOL AND
)	MARIJUANA
)	

FACTUAL AND LEGAL BACKGROUND

Marijuana is currently listed in Schedule I under state law. *See* Iowa Code section 124.204(4)"m" (stating "Marijuana, except as otherwise provided by rules of the board for medicinal purposes."). Marijuana is also currently listed in Schedule II under state law. *See* Iowa Code section 124.206(7)"a" (stating "Marijuana when used for medicinal purposes pursuant to rules of the board."). In Iowa, marijuana is defined by Iowa law to include

all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

Iowa Code section 124.101(19). Marijuana is currently listed in Schedule I under federal law. *See* 21 CFR § 1308.11(d)"23".

The Controlled Substances Act places some responsibilities on the Board as it relates to the scheduling of substances. Iowa Code section 124.201 states, in part, "the board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems necessary or advisable." In addition, Iowa Code section 124.203(2) provides:

1. The board shall recommend to the general assembly that the general assembly place a substance in schedule I if the substance is not already included therein and the board finds that the substance:
 - a. Has high potential for abuse; and

- b. Has no accepted medicinal use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision.
2. If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate.

In 2014, the Iowa General Assembly passed the Medical Cannabidiol Act. *See* Iowa Code chapter 124D. The Act permits the use of cannabidiol by patients suffering from intractable epilepsy. The Iowa General Assembly granted the authority to administer the provisions of the Act to the Iowa Department of Public Health.

RECOMMENDATION

Typically, the Board makes recommendations regarding the scheduling of substances to the Iowa General Assembly when the federal Drug Enforcement Agency (1) adds a new substance to a schedule, (2) moves a scheduled substance to a different schedule, or (3) removes a substance from scheduling. Essentially, the Board notifies the Iowa General Assembly of changes in the federal scheduling of controlled substances and recommends changes in the schedules under state law to be in accordance with federal scheduling.

Despite the passage of laws regarding marijuana in several states, it remains a Schedule I controlled substance under federal law. As a matter of policy, the federal government has allowed states, through non-enforcement of federal law, to serve as laboratories of democracy by experimenting with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government may change its policy at any time, thereby nullifying any laws or programs related to marijuana enacted by any state. The Board is hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law.

Regardless of federal law, Iowa Code section 124.203 requires that the Board recommend the removal of a substance from Schedule I if the Board finds that either (1) the substance does

not have a high potential for abuse, or (2) the substance has some accepted medicinal use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, it also believes that the passage of the Medical Cannabidiol Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana, as it is defined by Iowa Code section 124.101(19). As a result of the Medical Cannabidiol Act, Schedule I is inappropriate for cannabidiol.

The Board is not inclined to make the broader recommendation that marijuana be removed from Schedule I. Many substances can be derived from marijuana—some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to schedule each derivate after an individualized analysis. The Board points out that separately scheduling a substance that is a derivative of marijuana, such as cannabidiol, should be accompanied by an amendment to the definition of marijuana in Iowa Code section 124.101(19), explicitly excluding the derivative from the definition of marijuana, in order to avoid conflict.

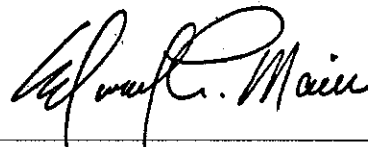
The Board believes it has an obligation under the Controlled Substances Act to recommend the proper schedule for cannabidiol. Iowa Code section 124.205 establishes the criteria for including a substance in Schedule II. The criteria are: (1) the substance has a high potential for abuse, (2) the substance currently has accepted medical use with severe restrictions in the United States, and (3) abuse of the substance may lead to severe psychic or physical dependence. The Board feels that cannabidiol meets the criteria for Schedule II, and thus recommends to the Iowa General Assembly that cannabidiol, as defined by Iowa Code section 124D.2(1), be placed in Schedule II.

The Board believes that, if the Iowa General Assembly chooses to expand the Medical Cannabidiol Act or implement a medical marijuana program, a coalition of stakeholders should

be established to further study the potential medicinal uses of marijuana or its derivatives in Iowa. These stakeholders should include, but not be limited to, the Office of Drug Control Policy, the Iowa Boards of Medicine and Pharmacy, law enforcement agencies, academia, addiction treatment specialists, and patients. It is incumbent that the establishment of a program involving marijuana or its derivatives for medicinal use includes the perspectives of all of these groups. No single entity can determine what conditions marijuana or its derivatives could be used to treat, what safety measures are needed to prevent unlawful use, and the myriad of other concerns raised by a program involving marijuana or its derivatives for medicinal use in Iowa. The Board is particularly concerned about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The dual scheduling of marijuana under state law is a holdover from experimental marijuana research programs authorized more than thirty years ago. The dual scheduling has understandably led to confusion as to the Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the Iowa General Assembly for the Board to unilaterally establish and implement a medical marijuana program in Iowa. This is evidenced by the fact that the Department of Public Health was vested with the authority to implement the Medical Cannabidiol Act. To avoid confusion, the Board recommends that the phrase "except as otherwise provided by rules of the board for medicinal purposes" be deleted from Iowa Code section 124.204(4)"m". In addition, the Board recommends that either the entirety of Iowa Code section 124.206(7)"a" be deleted, or, at a minimum, the phrase "pursuant to rules of the board" be deleted from Iowa Code section 124.206(7)"a". References to board rules in Iowa Code sections 124.204(4)"u" and 124.207 should also be deleted to ensure consistency.

Attached are proposed legislative changes reflecting the Board's recommendations described herein.

A handwritten signature in cursive script, appearing to read "Edward C. Maier".

EDWARD MAIER
Chairperson, Iowa Board of Pharmacy

Proposed Legislative Changes relating to Controlled Substances
January 14, 2015

An Act making changes to controlled substances schedules and making penalties applicable.

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

Section 1. Section 124.101, subsection 19, Iowa Code 2015, is amended to read as follows:

19. "*Marijuana*" means all parts of the plants of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination. It does not include cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 2. Section 124.204, subsection 4, paragraph "m," Iowa Code 2015, is amended to read as follows:

m. ~~Marijuana, except as otherwise provided by rules of the board for medicinal purposes.~~

Section 3. Section 124.204, subsection 4, paragraph "u," Iowa Code 2015, is amended to read as follows:

u. Tetrahydrocannabinols, ~~except as otherwise provided by rules of the board for medicinal purposes,~~ meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (Cannabis plant) as well as synthetic equivalents of the substances contained in the Cannabis plant, or in the resinous extractives of such plant, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

- (1) 1 cis or trans tetrahydrocannabinol, and their optical isomers.
- (2) 6 cis or trans tetrahydrocannabinol, and their optical isomers.
- (3) 3,4 cis or trans tetrahydrocannabinol, and their optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

Section 4. Section 124.204, subsection 7, Iowa Code 2015, is deleted in its entirety as follows:

~~7. *Exclusions.* This section does not apply to marijuana, tetrahydrocannabinols or chemical derivatives of tetrahydrocannabinol when utilized for medicinal purposes pursuant to rules of the board.~~

Section 5. Section 124.206, subsection 7, Iowa Code 2015, is amended by adding the following new paragraph:

NEW PARAGRAPH: xx. Cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 6. Section 124.206, subsection 7, paragraph "a," Iowa Code 2015, is deleted in its entirety as follows:

- a. ~~Marijuana when used for medicinal purposes pursuant to rules of the board.~~

ADDENDUM C

**RULING ON PETITION
FOR JUDICIAL REVIEW**

**CARL OLSEN
DES MOINES, IOWA**

IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

CARL OLSEN,

Petitioner,

vs.

IOWA BOARD OF PHARMACY,

Respondent

Case No.: CVCV047867

**RULING ON PETITION FOR
JUDICIAL REVIEW**

Hearing in this case was held October 24, 2014. Petitioner Carl Olsen appeared personally. Megan Gavin appeared for respondent, Iowa Board of Pharmacy.

Introduction

This is a judicial review action from a November 6, 2013 ruling of the Iowa Board of Pharmacy. Mr. Olsen petitioned the Board to recommend to the 2014 Iowa General Assembly that it remove marijuana from Schedule I of the Uniform Controlled Substances Act, Iowa Code Chapter 124. He wishes to clear the way for medical use of marijuana in Iowa. The Board denied Mr. Olsen's petition.

Olsen timely filed this judicial review action in Polk County District Court. He asserts that the Board erred because it has a duty under Iowa Code Chapter 124 to recommend reclassification of marijuana. He filed an amended petition June 17, 2014. Mr. Olsen asks that the court set aside the Board's November 6, 2013 ruling, enter a declaratory judgment that marijuana has accepted medical use in treatment in the United States, and issue a writ of mandamus requiring the Board to recommend removal of marijuana from Schedule I of the Iowa Controlled Substances Act. The Board resists.

The record consists of attachments filed with the Petition for Judicial Review, and the Proposed Agency Record filed by respondent on July 25, 2014.

Statement of Facts

In 2010, at the request of Mr. Olsen, the Iowa Board of Pharmacy recommended to the legislature that it reclassify marijuana from a Schedule I controlled substance to a Schedule II controlled substance, under Iowa Code Chapter 124. The legislature has never adopted this recommendation.

In general, Schedule I controlled substances are illegal to sell or possess in the State of Iowa, and include such substances as opium derivatives and hallucinogens. *See* Iowa Code § 124.204(2013).¹ The Board of Pharmacy may recommend to the legislature that it remove a controlled substance from Schedule I, or reclassify a substance to Schedule II, which would allow for its use for medicinal purposes. *See* Iowa Code §§ 124.203, 124.205.

In August 2012 Olsen again petitioned the Board of Pharmacy to recommend removal of marijuana from Schedule I. In November 2012, the Board denied that request, stating “that the supporting documentation did not contain sufficient, new scientific information to warrant recommending the reclassification of marijuana this year.” (Cited in Ruling and Order on Petition for Judicial Review, Polk County Case No. CVCV045505). Olsen sought judicial review of that ruling. In February 2014, the Polk County District Court denied Mr. Olsen’s petition for judicial review, holding that the Board’s ruling was not irrational or illogical on its face, and that the record before the District Court was insufficient to determine whether the Board’s decision was in error. (Case No. CVCV045505, February 18, 2014 Ruling and Order on Petition for Judicial Review.)

In July 2013, Olsen again petitioned the Pharmacy Board to recommend that the legislature remove marijuana from Schedule I. He cited a number of scientific studies, as well as statutes from other states which allow medical use of marijuana. In November 2014, the Board denied Olsen’s request. This ruling is attached to plaintiff’s petition. It states:

¹ References in this ruling are to the 2013 Code of Iowa in effect at the time the Board ruled on Olsen’s petition, unless otherwise noted.

The Board recommended the rescheduling of marijuana in 2010. The Board recognized at that time and continues to recognize that the scheduling of controlled substances is ultimately a decision for the Iowa Legislature. The General Assembly took no action on the Board's 2010 recommendation. During the 2013 session, the legislature considered but did not act upon two bills calling for the rescheduling of marijuana. On November 6, 2013, the Board concluded that it was not advisable or appropriate to recommend the rescheduling of marijuana in 2014.

Ex. 1.

Motions for Judicial Notice

Olsen asks the court to take judicial notice of: 1) a law enacted in North Carolina in July 2014, 2) a law enacted in New York in July 2014, and 3) a law enacted in Missouri in July 2014.

The Board resists.

The court may consider such evidence as it deems appropriate in judicial review of "other agency action", i.e. actions other than evidentiary hearings. Iowa Code § 17A.19(7). However, the court's discretion to hear additional evidence "is for the limited purpose of 'highlighting what actually occurred in the agency in order to facilitate the court's search for errors of law or unreasonable, arbitrary, or capricious action.'" *Office of Consumer Advocate v. Iowa Utilities Board*, 770 N.W.2d 334, 343 (Iowa 2009) (internal citations omitted). The additional evidence is not to be used to retry the factual issues in district court. *Id.*

Because the laws that petitioner asks the court to consider were enacted after the Board's ruling was issued in November 2013, they have no relevance to what actually happened before the Board. Therefore, the three motions to take judicial notice are overruled.

Petitioner also cites legislation that was passed by the Iowa legislature in 2014 allowing use of cannabinoid oil for treatment of epilepsy. 2014 Iowa Acts, SF 2360. This legislation was also enacted after the agency action at issue here, and is not directly relevant to the Board's 2013 decision.

On December 6, 2014, Mr. Olsen filed a motion asking the court to consider a section of the statute that he had not cited previously – Section 124.208(9)(b). This code section was in effect when the Board issued its decision in November 2013. The court will consider this statute in ruling on this matter.

Standard of Review

This is a proceeding for judicial review of administrative agency action under Iowa Code Chapter 17A. Petitioner may obtain relief from agency action if his substantial rights are prejudiced, and the agency has violated any of the subsections of Code Section 17A.19(10). Olsen asserts that the Board's decision is based upon an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency, in violation of Iowa Code Section 17A.19(10)(c).²

The Board argues that the decision to recommend rescheduling of marijuana is a decision that is vested by a provision of law in the Board's discretion, and thus its decision should be reversed only if it is irrational, illogical, or wholly unjustifiable, pursuant to Section 17A.19(10)(D). The court must not give any deference to the agency's view of whether it is vested with discretion to interpret the law. Iowa Code § 17A.19(11)(a).

The Iowa Supreme Court has stated:

Our review of authorities on this subject has confirmed our belief that each case requires a careful look at the specific language the agency has interpreted as well as the specific duties and authority given to the agency with respect to enforcing particular statutes. It is generally inappropriate, in the absence of any explicit guidance from the legislature, to determine whether an agency has the authority to interpret an entire statutory scheme. As we have seen, it is possible that an agency has the authority to interpret some portions of or certain specialized language in a statute, but does not have the authority to interpret other statutory provisions. Accordingly, broad articulations of an agency's authority, or lack of authority,

² Olsen's petition for judicial review alleges violations of additional provisions of Section 17A.19(10). *See Id.*, ¶ 31. However, he did not brief or argue these additional alleged violations. Therefore the court deems them waived.

should be avoided in the absence of an express grant of broad interpretive authority.

Renda v. Iowa Civil Rights Com'n, 784 N.W.2d 8, 13 -14 (Iowa 2010). The Court in *Renda* set forth guidelines for courts to follow, including 1) whether the statutory provision being interpreted is a substantive term within the special expertise of the agency; 2) whether the provisions to be interpreted are found in a statute other than the statute the agency has been tasked with enforcing; and 3) whether the term has an independent legal definition that is not uniquely within the subject matter expertise of the agency. *Renda*, 784 N.W.2d at 14.

The court has reviewed the specific authority granted to the Board to make annual recommendations for reclassification of controlled substances to the legislature (Sections 124.201(1) and (2)); the statutes listing marijuana as controlled substances (Iowa Code § 124.204(4)(m), 124.206(7)(a), and 124.208(9)(b)); and the statutes dealing with reclassification or deletions of controlled substances (Code Sections 124.203 and 124.205). In addition, Iowa Code Section 135.31 gives the Board of Pharmacy policymaking authority. Five of the seven members of the board must be licensed pharmacists. Iowa Code § 147.(1)(e). The statutory scheme for classification of controlled substances is highly technical and relies heavily on the expertise of the Board. Based upon these statutes, the court concludes the Board is given discretion to make recommendations for rescheduling controlled substances, and the decision of the Board is entitled to appropriate deference under Section 17A.19(10) and (11).

Therefore, the court will reverse the agency's decision only if it is irrational, illogical, or wholly unjustifiable. Iowa Code § 17A.19(10)(I). Review of agency action under the irrational, illogical, or wholly unjustifiable standard is highly deferential. *Iowa Dental Ass'n v. Iowa Ins. Div.*, 831 N.W.2d 138, 142-43 (Iowa 2013).

Discussion and Analysis

This case turns on interpretation of several provisions of Iowa Code Chapter 124, the Uniform Controlled Substances Act. *See* Iowa Code Section 124.601.

Chapter 124 creates five schedules for controlled substances. Schedule I substances are listed in Section 124.204, and are the most highly regulated substances. Schedule I substances include opiates and hallucinogenic substances. Marijuana is listed under Schedule I as follows: “Marijuana, except as otherwise provided by rules of the board [of pharmacy] for medicinal purposes.” Iowa Code § 124.204(4)(m). The Code section also states, “Exclusions. This section does not apply to marijuana, tetrahydrocannabinols or chemical derivatives tetrahydrocannabinol when utilized for medicinal purposes pursuant to rules of the board.” Iowa Code § 124.204(7).

Schedule II controlled substances are listed in Section 124.206, and include substances which are addictive, but frequently used for medical purposes such as opiates, codeine, hydrocodone, and morphine. *See* Iowa Code § 124.206(2). Marijuana is also listed in Schedule II as follows: “Marijuana when used for medicinal purposes pursuant to rules of the board.” Iowa Code § 124.206(7)(a).

Schedule III controlled substances are listed in Code Section 124.208. They include stimulants, depressants, and narcotic drugs. *See* Iowa Code § 124.208(2). Dronabinol, a derivative of the cannabis plant, is listed in Schedule III. Iowa Code § 124.208(9)(b). This Code section states that the referenced drug – ANDA – has been approved the U.S. Food and Drug Administration. *Id.*

Thus the legislature has recognized that the Board may enact rules for medical use of marijuana under both Schedule I and Schedule II. To date the Board of Pharmacy has not enacted rules relating to the medical use of marijuana. The history of these enactments

concerning marijuana's listing in Schedule I and Schedule II of Chapter 124 is set forth in a dissenting opinion in *State v. Bonjour*, 694 N.W.2d 511, 516-17 (Iowa 2005) (Wiggins, J. and Lavorato, C.J. dissenting). In that case the court considered a different issue than is presented here, but the discussion of the statutory history concerning inclusion of marijuana under Schedules I and II is instructive. This is an issue which has been raised, studied, and considered in the past in Iowa. *See Id.*

The Board is given the duty to make recommendations to the legislature for deletions and revisions to the schedules of controlled substances "which it deems necessary or advisable." Iowa Code Section 124.201(1). That section states:

1. The board shall administer the regulatory provisions of this chapter. Annually, within thirty days after the convening of each regular session of the general assembly, the board ***shall recommend to the general assembly any deletions from, or revisions in the schedules of substances***, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, ***which it deems necessary or advisable***. In making a recommendation to the general assembly regarding a substance, the board shall consider the following:

.....

2. After considering the above factors, the board shall make a recommendation to the general assembly, specifying the change which should be made in existing schedules, if it finds that the potential for abuse or lack thereof of the substance is not properly reflected by the existing schedules.

Iowa Code § 124.201(1)(emphasis added).

In addition, Iowa Code Section 124.203 states that the Board shall recommend to the legislature that it place a substance in Schedule I if it has a high potential for abuse, and has no accepted medical use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision. Iowa Code § 124.203(1) (2013). The statute also states: "If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or

remove the substance from the list of controlled substances, as appropriate.” Iowa Code § 124.203(2).

Iowa Code Section 124.205 states that the Board shall recommend to the legislature that is place a substance in Schedule II if it has 1) a high potential for abuse, 2) currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions, and 3) abuse of the substance may lead to severe psychic or physical dependence. Iowa Code § 124.205(1).

Petitioner argues that, based on the record presented to the Board with his petition, the Board is required to conclude that marijuana has “currently accepted medical use in treatment in the United States,” within the meaning of Iowa Code Section 124.203(1). His petition to the Board includes citations to the record made before the Board in 2010 when it voted to recommend rescheduling marijuana from Schedule I to Schedule II. He also cited 19 states which accepted medical use of marijuana in treatment and a CD of scientific literature on this topic. (Petition for Agency Action, pp. 7-8.) He then argues that, under subsection (2) of Section 124.205, the Board must recommend removal of marijuana from the list of Schedule I controlled substances.

In construing statutes, the court must ascertain legislative intent. *Mall Real Estate, L.L.C. v. City of Hamburg*, 818 N.W.2d 190, 194 (Iowa 2012). In doing so, the court is to consider the language used in the statute, the object the legislature sought to accomplish, and the wrong the general assembly sought to remedy. *Id.* The court searches for legislative intent as shown by what the legislature said, rather than what it should or might have said. *Auen V. Alcoholic Beverages Div., Iowa Dept. of Commerce*. 679 N.W.2d 586, 590 (Iowa 2004). If a term is not defined in a statute, the term is given its ordinary and common meaning by considering the

context within which it is used. *Id.* If possible, a statute must be construed so as to give effect to all its provisions. *State v. Harrison*, 325 N.W.2d 770, (Iowa Ct. App. 1982); *see also State v. Netzer*, 579 S.W.2d 170 (Mo. Ct. App. S.D. 1979) (stating provisions of Uniform Controlled Substances Act must be construed together).

Chapter 124 is based on the Uniform Controlled Substances Act, and is to be construed to carry out its general purpose of making uniform the law of those states which enact it. Iowa Code §§ 124.601, 124.602. “The Uniform Controlled Substances Act was drafted to maintain uniformity between the laws of the several states and those of the federal government and is designed to complement the federal law and provide an interlocking trellis of federal and state law to enable government at all levels to control more effectively the drug abuse problem.” Prefatory Note to Uniform Controlled Substances Act (1990). One of the major purposes of the federal Controlled Substances Act is to prevent illegal manufacture, distribution, and possession of controlled substances that have a substantial and detrimental effect on the health and welfare of the American people. 21 U.S.C. § 801.

Petitioner focuses on the language of Section 124.203(2), which states that the legislature “shall” recommend deletion of a controlled substance from Schedule I if it does not meet the criteria concerning medical use in treatment in the United States. However, this narrow reading of the statute ignores the broad language of Section 124.201, which states that the Board shall annually recommend revisions to the schedules of substances “which it deems necessary or advisable.” Sections 124.201, .203, and .205 must be read to give effect to all of them. In doing so, the court concludes the legislature intended that the Board have discretion to recommend whether a controlled substance should be removed from Schedule I, or reclassified from Schedule I to Schedule II. This authority is clearly stated in subsection (201). The criteria for

reclassification or deletion are set forth in subsections (203) and (205). Petitioner's interpretation would nullify the language in Section 124.201.

Because the Board has discretion, petitioner must show that the Board abused its discretion in denying his petition for agency action. The Board made a finding that it did not deem it "advisable or appropriate to recommend the rescheduling of marijuana in 2014." This is within the discretion of the Board, and petitioner has not shown that this decision is irrational, illogical, or wholly unjustifiable. While a previous iteration of the Board did make such a recommendation to the legislature in 2010, in subsequent years the Board has declined to do so. This is within its discretion.

The court has also considered Section 124.208(9) and its listing of dronabinol, derived from the cannabis plant, as a Schedule III controlled substance. However, this does not cause the court to change its opinion that it is within the discretion of the Board whether to recommend marijuana be removed from Schedule I, for the reasons set forth above.

For the reasons stated above, the petition for judicial review should be dismissed.

IT IS ORDERED that the petition for judicial review is dismissed, with costs taxed to petitioner.

Dated this 10th day of December, 2014.



State of Iowa Courts

Type: OTHER ORDER

Case Number **Case Title**
CVCV047867 CARL OLSEN VS IOWA BOARD OF PHARMACY

So Ordered

A handwritten signature in cursive script, appearing to read "Eliza Ostrom".

Eliza Ostrom, District Court Judge,
Fifth Judicial District of Iowa

ADDENDUM D

**PRELIMINARY NOTICE OF
INTENT TO DENY LICENSE**

**SUN PHARMACEUTICAL INDUSTRIES, INC.
CRANBURY, NEW JERSEY**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
The Application for Wholesale Drug)	
License of)	PRELIMINARY NOTICE OF
)	INTENT TO DENY LICENSE
SUN PHARMACEUTICAL)	
INDUSTRIES, INC.)	
Applicant.)	

TO: Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd.
Cranbury, NJ 08512

YOU ARE HEREBY NOTIFIED that on November 19, 2014, the Iowa Board of Pharmacy ("Board") voted to deny your application for a wholesale drug license. The intent to deny licensure is based upon the following:

LEGAL GROUNDS

1. Applicants for an Iowa wholesale drug license must apply in accordance with Iowa Code section 155A.17 and 657 IAC 17.3.
2. The Board has the authority to deny an application for licensure for violations of Iowa Code chapters 126 and 155A and rules of the Board. *See* Iowa Code section 155A.17(2) and 657 IAC 17.18.
3. It is a violation of 657 IAC 36.1(4)"ad" to violate the pharmacy or drug laws or rules of another state while under the jurisdiction of that state.
4. It is a violation of Iowa Code section 155A.17(2) and 657 IAC 17.17, 17.18, and 36.1(4)"j" to fail to comply with the federal Food and Drug Administration's drug laws and regulations.

FACTUAL CIRCUMSTANCES

5. The Board received an Iowa Wholesale Drug License Application from Sun Pharmaceutical Industries on October 16, 2014.
6. On its application, Applicant indicated that it was formerly "Caraco Pharmaceutical Laboratories, Ltd".
7. On its application, Applicant disclosed the following disciplinary and adverse actions regarding Caraco Pharmaceutical Laboratories from licensing authorities in other states:
 - a. June 10, 2014—citation from the Georgia Board of Pharmacy for the Wixom, Michigan, facility for shipping without a valid permit.

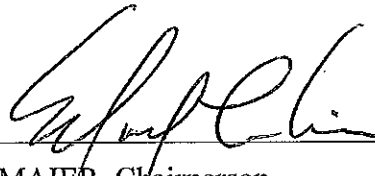
- b. August 28, 2012—fined \$10,000 by the Florida Department of Business & Professional Regulation for failing to provide a complete audit trail of all transactions regarding the receipt and distribution of prescription drugs.
- c. June 3, 2010—Maine Board of Pharmacy issued a preliminary denial of Applicant's wholesale distribution license based on a restricted FDA permit.

8. On its application, Applicant disclosed that Caraco Pharmaceutical Laboratories entered into a Voluntary Consent Degree with the FDA on September 29, 2009, regarding a Detroit, Michigan, facility where products were allegedly adulterated due to being manufactured under conditions not meeting cGMPs.

NOTICE OF APPEAL RIGHTS

9. Pursuant to the provisions of 657 IAC 36.16, you may appeal the Board's preliminary notice of denial of licensure by serving a written notice of appeal and request for hearing upon the Board not more than thirty (30) days following the date of service of this notice. The request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be held pursuant to the process outlined at 657 IAC 35.19 and 36.8. If an appeal is not filed within this time period, this preliminary notice of intent to deny licensure will become final.

DATED this 6th day of January, 2015.



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

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

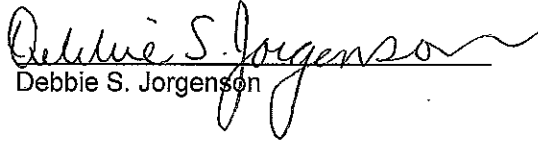
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755880</u> | <input type="checkbox"/> other _____ |

on the 7th day of January, 2015.

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


Debbie S. Jorgenson

ADDENDUM E

**PRELIMINARY NOTICE OF
INTENT TO DENY REGISTRATION**

**MICHELLE HEIDEBRINK
OSKALOOSA, IOWA**

**BEFORE THE BOARD OF PHARMACY
OF THE STATE OF IOWA**

IN THE MATTER OF)	
)	
THE APPLICATION)	PRELIMINARY NOTICE OF
FOR REGISTRATION OF)	INTENT TO DENY
)	REGISTRATION
Michelle Heidebrink)	
APPLICANT.)	

TO: Michelle D. Heidebrink
2402 Newport Ave
Oskaloosa, IA 52577

YOU ARE HEREBY NOTIFIED that on November 19, 2014, the Iowa Board of Pharmacy voted to deny your application for registration as a certified pharmacy technician trainee. The intent to deny registration is based upon the following:

LEGAL GROUNDS

The applicant applied for an Iowa pharmacist registration in accordance with Iowa Administrative Code rule 657-3.8. The Board has authority to deny an application for registration in accordance to rule 657-3.29.

FACTUAL CIRCUMSTANCES

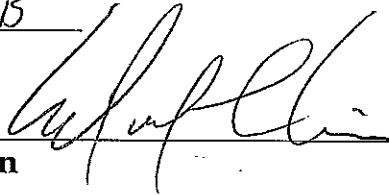
Michelle D. Heidebrink submitted an application for registration as a certified pharmacy technician trainee to the Iowa Board of Pharmacy. On that application Ms. Heidebrink answered "yes" to question 9 that stated: "9. Have you ever had a health profession license or registration (*pharmacy technician, pharmacist, nurse, physician, etc.*) issued in Iowa or another state suspended, revoked, or disciplined?"

On June 20, 2012, Ms. Heidebrink's Iowa pharmacist license was placed on probation for two years. On December 3, 2013, this Board issued an emergency order, immediately suspending Ms. Heidebrink's Iowa pharmacist license. On January 14, 2014, Ms. Heidebrink and the Board entered into a settlement agreement. Under the settlement agreement, Ms. Heidebrink's Iowa pharmacist license was indefinitely suspended. On September 11, 2014, this Board ordered that Ms. Heidebrink have no involvement in the ownership, management, direction, of control of any business engaged in the practice of pharmacy during the time that her license is suspended. Ms. Heidebrink's pharmacist license remains suspended.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of Iowa Administrative Code rule 657—36.16 you may appeal the Board's preliminary notice of denial of registration by serving a notice of appeal and request for hearing upon the board not more than thirty days following the date of mailing of this notice. The request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be held pursuant to the process outlined at Iowa Administrative Code rules 657—35.19 and 657—36.8. If an appeal is not filed within this time period, this preliminary notice of intent to deny licensure will become final.

Dated: January 6, 2015



**Edward Maier, Chairperson
Iowa Board of Pharmacy**

ADDENDUM F

**PRELIMINARY NOTICE OF
INTENT TO DENY REGISTRATION**

**RHONDA MACY
DES MOINES, IOWA**

**BEFORE THE BOARD OF PHARMACY
OF THE STATE OF IOWA**

IN THE MATTER OF)	
)	
THE APPLICATION)	PRELIMINARY NOTICE OF
FOR REGISTRATION OF)	INTENT TO DENY
)	REGISTRATION
Rhonda Macy)	
APPLICANT.)	

TO: Rhonda Macy
3103 SE 19th Street
Des Moines, IA 50320

YOU ARE HEREBY NOTIFIED that on November 19, 2014, the Iowa Board of Pharmacy voted to deny your application for registration as a pharmacist support person. The intent to deny registration is based upon the following:

LEGAL GROUNDS

The applicant applied for an Iowa pharmacist registration in accordance with Iowa Administrative Code rule 657—5.7. The Board has authority to deny an application for registration in accordance to rule 657—5.24.

FACTUAL CIRCUMSTANCES

Rhonda Macy submitted an application for registration as a pharmacist support person to the Iowa Board of Pharmacy. On that application Ms. Macy answered “yes” to question 8 that stated: “8. 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*)?”

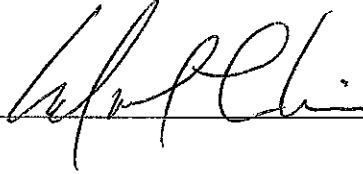
On June 27, 2014, Ms. Macy was convicted of a controlled substance violation and possession of ephedrine. Ms. Macy was sentenced to ten years imprisonment, which was suspended, and placed on probation for a period of three years.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of Iowa Administrative Code rule 657—36.16 you may appeal the Board's preliminary notice of denial of registration by serving a notice of appeal and request for hearing upon the board not more than thirty

days following the date of mailing of this notice. The request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be held pursuant to the process outlined at Iowa Administrative Code rules 657-35.19 and 657-36.8. If an appeal is not filed within this time period, this preliminary notice of intent to deny licensure will become final.

Dated: January 6, 2015



Edward Maier, Chairperson
Iowa Board of Pharmacy

ADDENDUM G

**PRELIMINARY NOTICE OF
INTENT TO DENY REGISTRATION**

**STEPHANIE WADELL
ORANGE CITY, IOWA**

**BEFORE THE BOARD OF PHARMACY
OF THE STATE OF IOWA**

IN THE MATTER OF)	
)	
THE APPLICATION)	PRELIMINARY NOTICE OF
FOR REGISTRATION OF)	INTENT TO DENY
)	REGISTRATION
Stephanie Wadell)	
APPLICANT.)	

TO: Stephanie Wadell
403 2nd St SE
Orange City, IA 51041

YOU ARE HEREBY NOTIFIED that on November 19, 2014, the Iowa Board of Pharmacy voted to deny your application for registration as pharmacist support person. The intent to deny registration is based upon the following:

LEGAL GROUNDS

The applicant applied for an Iowa pharmacist registration in accordance with Iowa Administrative Code rule 657-5.7. The Board has authority to deny an application for registration in accordance to rule 657-3.29.

FACTUAL CIRCUMSTANCES

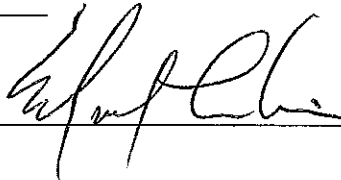
Stephanie Wadell submitted an application for registration as a pharmacy support person to the Iowa Board of Pharmacy. On that application Ms. Wadell answered "yes" to question 7: "7. Do you currently have any physical or mental condition that in any way impairs or limits your ability to perform the duties of a pharmacy support person with reasonable skill and safety or have you ever used any drugs, alcohol, or other chemical substances that in any way impair or limit your ability to perform the duties of a pharmacy support person with reasonable skill and safety?" On that application Ms. Wadell also answered "yes" to question 8 that stated: "8. 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*)?"

Ms. Wadell admitted that she was convicted of a "crime involving methamphetamine" in 2012. The conviction occurred out of state and Ms. Wadell did not provide the Board with the relevant court documents. Ms. Wadell, however, admitted that she is currently on probation and will be for several years. Ms. Wadell further failed to reveal several misdemeanor charges and convictions in Iowa, including an operating while intoxicated conviction from 2010, a theft conviction from 2003, and an assault conviction from 2000.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of Iowa Administrative Code rule 657-36.16 you may appeal the Board's preliminary notice of denial of registration by serving a notice of appeal and request for hearing upon the board not more than thirty days following the date of mailing of this notice. The request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be held pursuant to the process outlined at Iowa Administrative Code rules 657-35.19 and 657-36.8. If an appeal is not filed within this time period, this preliminary notice of intent to deny licensure will become final.

Dated: January 6, 2015



**Edward Maier, Chairperson
Iowa Board of Pharmacy**

ADDENDUM H
SETTLEMENT AGREEMENT
AND
FINAL ORDER

MATTHEW SHERROW
PHARMACIST LICENSE NO. 18612
SPRINGFIELD, ILLINOIS

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2010-133
Pharmacist License of)	
MATTHEW SHERROW)	SETTLEMENT AGREEMENT AND
License No. 18612)	FINAL ORDER
Respondent.)	

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Matthew Sherrow ("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 a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:


1. Respondent holds Iowa pharmacist license no. 18612, which is currently active and expires on June 30, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. A Statement of Charges was filed against Respondent on November 19, 2014. A contested case hearing in this matter is scheduled for January 6, 2015.
4. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
5. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent is freely and voluntarily entering into this Order.
7. Respondent acknowledges that he has the right to be represented by counsel on this matter.
8. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
9. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

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

IT IS THEREFORE ORDERED:

14. Respondent is hereby **CITED** for violating a board order and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.
15. Respondent agrees to pay a civil penalty in the amount of one-thousand dollars (\$1000). This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the Iowa Board of Pharmacy, Attn: Lloyd Jessen, 400 SW Eighth Street, Suite E, Des Moines, IA 50309, within sixty (60) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.
16. In the event Respondent fails to pay the civil penalty within the time period specified above, the Board will issue a notice to Respondent that his license will be suspended within thirty (30) days of the date the notice is served on Respondent. That suspension will occur automatically and without further Board action, unless Respondent files with the Board a request for hearing on the notice within twenty (20) days of the date the notice is served. Paying the civil penalty will immediately terminate the suspension and return Respondent's license to its appropriate status.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 16 day of December, 2014.



MATTHEW SHERROW
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the
6th day of January, 2015.



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

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

ADDENDUM I
SETTLEMENT AGREEMENT
AND
FINAL ORDER

JAMES KAUFMAN
PHARMACIST LICENSE NO. 18228
SIOUX CITY, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-28
Pharmacist License of)	
)	
JAMES KAUFMAN,)	SETTLEMENT AGREEMENT
License No. 18228,)	AND FINAL ORDER
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and James Kaufman ("Respondent"), and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2013).

1. Respondent holds Iowa pharmacist license number 18228, which is currently active.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. The Board issued a Notice of Hearing and Statement of Charges concerning the Respondent's license on July 2, 2014.
4. Execution of this Settlement Agreement and Final Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent is freely and voluntarily entering into this Agreement. Respondent agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.
6. Respondent agrees to **VOLUNTARILY SURRENDER** his Iowa pharmacist license to resolve this matter.
7. Respondent shall surrender his Iowa pharmacist license to the Board within ten (10) days of the Board's approval of this Agreement.
8. This voluntary surrender is considered a revocation under 657 Iowa Administrative Code rule 36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least one year from the date of Board approval of this Settlement Agreement. Reinstatement requests are governed by 657 Iowa Administrative Code rule 36.13.
9. Prior to seeking reinstatement, Respondent must be found safe to practice pharmacy by a mental health evaluator, including a substance abuse evaluation which concludes that Respondent is safe to practice as a certified pharmacist technician. Respondent shall cause the records from the evaluation to be provided to the Board in conjunction with any request for

reinstatement. The Board shall not schedule a reinstatement hearing until the Board has received the appropriate mental health and substance abuse evaluation records.

10. Respondent agrees not to perform any activities that would require an Iowa pharmacist license until such time as his license is reinstated.

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

12. Should Respondent violate the terms of this Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.


13. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

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

15. This Agreement shall not be binding as to any new complaints received by the Board.

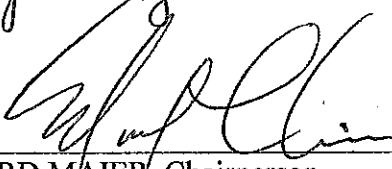
16. The Board's approval of this Agreement shall constitute a FINAL ORDER of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the ___ day of _____, 2014.



JAMES KAUFMAN
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the 6th day of January, 2014⁵.



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

Copies to:

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

ADDENDUM J

**SETTLEMENT AGREEMENT
AND
FINAL ORDER**

**OK COMPOUNDING LLC
NONRESIDENT PHARMACY LICENSE NO. 4204
SKIATOOK, OKLAHOMA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-121
Nonresident Pharmacy License of)	
OK COMPOUNDING LLC)	SETTLEMENT AGREEMENT AND
License No. 4204)	FINAL ORDER
Respondent.)	

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and OK Compounding LLC ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a disciplinary proceeding currently pending before the Board.

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

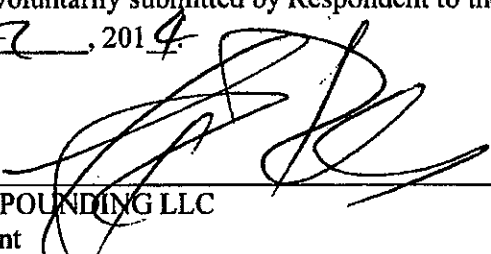
1. Respondent was issued Iowa nonresident pharmacy license number 4204, which is currently active and expires on December 31, 2014.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent pharmacy has closed. Respondent acknowledges that it is not entitled to a nonresident pharmacy license due to the pharmacy's closure.
4. A Statement of Charges was filed against Respondent on November 19, 2014.
5. 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 discipline.
6. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to a hearing on the charges, but waives its right to hearing and all attendant rights, including the right to appeal, by freely and voluntarily agreeing to this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
7. Respondent is freely and voluntarily entering into this Order.
8. Respondent acknowledges that it has a right to be represented by counsel on this matter.
9. The State's legal counsel may present this Order to the Board *ex parte*.
10. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

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

IT IS THEREFORE ORDERED:

15. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license to resolve this matter.
16. This voluntary surrender, when accepted by the Board, has the same force and effect as an order of revocation under 657 Iowa Administrative Code rule 36.15 for purposes of reinstatement. Reinstatement requests are governed by 657 Iowa Administrative Code rule 36.13.
17. Respondent shall surrender its Iowa nonresident pharmacy license to the Board within ten (10) days of the Board's approval of this Order.
18. Respondent agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.
19. Should Respondent violate the terms of this Settlement Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.

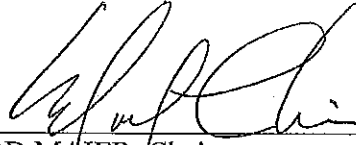
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 29 day of DEC, 2014.



OK COMPOUNDING LLC
Respondent

By this signature, Christopher Parks acknowledges s/he is the Manager of OK Compounding LLC and is authorized to sign this Settlement Agreement and Final Order on behalf of OK Compounding LLC.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the
6th day of January, 2015.



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

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319
laura.steffensmeier@iowa.gov
ATTORNEY FOR THE STATE

Susan Walker
susan.walker@mcafeetaft.com
ATTORNEY FOR RESPONDENT

ADDENDUM K

**COMBINED STATEMENT OF CHARGES,
SETTLEMENT AGREEMENT, AND
FINAL ORDER**

**RICHARD UPTON
PHARMACIST LICENSE NO. 19779
SIDNEY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-175
Pharmacist License of)	
RICHARD UPTON)	COMBINED STATEMENT OF
)	CHARGES, SETTLEMENT
License No. 19779,)	AGREEMENT, AND FINAL ORDER
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and Richard (Randy) Upton ("Respondent"), 2487 280th Ave., Sidney, IA 51652, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2013), stating the following:

1. Respondent holds Iowa pharmacist license number 19779, which is currently active and expires on June 30, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

A. STATEMENT OF CHARGES

Count I

UNLAWFUL POSSESSION OF A CONTROLLED SUBSTANCE

Respondent is charged with unlawful possession of a controlled substance in violation of Iowa Code section 124.401(5), pursuant to Iowa Code section 155A.12(5), and 657 IAC 36.1(4)"j".

Count II

UNETHICAL CONDUCT

Respondent is charged with engaging in unethical conduct, pursuant to Iowa Code sections 147.55(3), 155A.12(2), and (3), and 657 IAC 36.1(4)"c".

Count III

INABILITY TO PRACTICE

Respondent is charged with inability to practice with reasonable skill and safety by reason of chemical abuse, pursuant to Iowa Code sections 147.55(9) and 155A.12(1), and 657 IAC 36.1(4)"m".

B. FACTUAL CIRCUMSTANCES

3. Respondent was formerly employed as the Director of Pharmacy at a hospital in Iowa.
4. Respondent admitted to diverting controlled substances, including ketamine, fentanyl, and morphine, from his employer. Respondent admitted to personal use of the diverted controlled substances both at work and at home.

SETTLEMENT AGREEMENT AND FINAL ORDER

5. Execution of this Combined Statement of Charges, Settlement Agreement, and Final Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.

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

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

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 Agreement to the Board and may have *ex parte* communications with the Board while presenting it.

10. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

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

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

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

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

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

IT IS THEREFORE ORDERED:

16. Respondent's license shall be **INDEFINITELY SUSPENDED**. Respondent shall not be permitted to apply for reinstatement of his pharmacist license until all of the following conditions have been satisfied:

- a. A minimum of one year has passed from the date of the Board's approval of this Agreement.
- b. Respondent completes recommended treatment and provides the Board with a current written report from each of Respondent's treatment providers indicating Respondent's status in treatment, recommendations for future treatment, and indicating Respondent is fit to return to work as a pharmacist.
- c. Respondent permits the Board to have complete access to Respondent's medical records, including records of substance abuse treatment, as necessary to fully evaluate Respondent's reinstatement request.

17. At such time as Respondent satisfies all of the requirements set forth in paragraph 16, Respondent may petition the Board for reinstatement of Respondent's license and commencement of a period of probation. Reinstatement of Respondent's license shall be at the discretion of the Board.

18. In the event the Board determines that Respondent's license should be reinstated, Respondent's license to practice pharmacy shall be placed on **PROBATION** for a period of five (5) years. The terms of probation include the following:

- a. Respondent must be employed as a pharmacist for a minimum of forty (40) hours per month for at least thirty (30) months of the probationary term. If Respondent cannot satisfy this requirement, the probationary period will extend beyond five (5) years until such time as Respondent can satisfy this requirement.
- b. Respondent shall not possess or use any controlled substance or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for Respondent by a licensed treating physician or other qualified health care provider. Respondent shall inform all treating physicians and other health care providers of his medical history, including all history of chemical dependency. Respondent shall provide the Board a copy of this notification upon request.
- c. Respondent shall provide witnessed blood, hair, or urine specimens on demand by the Board or its agents. Respondent shall provide such witnessed blood, hair, or urine specimens within the timeframe specified on the day of notice from the Board or the Board's chemical screening program requesting that Respondent provide a specimen. The specimens shall be used for alcohol and drug screening to verify Respondent's compliance with this Agreement. All costs related to the analysis of such specimens shall be paid by Respondent.
- d. To facilitate the preceding paragraph "c", Respondent shall participate in the Board's chemical screening program. Respondent shall complete enrollment in the Board's chemical screening program within thirty (30) days of the date his license is placed on probation. Respondent agrees to comply with all requirements of the chemical screening program and shall be responsible for all costs associated with the program. Respondent consents to disclosure to the

Board, by the chemical screening program, of all medical information, including test results, generated by Respondent's contact with the chemical screening program.

- e. Respondent must comply with all treatment recommendations to address substance abuse issues from treatment providers. Respondent's treatment providers shall submit quarterly reports to the Board documenting Respondent's compliance with treatment for the duration of the treatment. Said quarterly reports are due on March 1, June 1, September 1, and December 1 of each calendar year Respondent is undergoing treatment. Treatment providers shall indicate in the report if treatment is completed and indicate that no further quarterly reports will be submitted as a result.
- f. Respondent permits the Board to have complete access to Respondent's medical records, including records of substance abuse treatment, as necessary to fully evaluate Respondent's compliance with probationary terms.
- g. Respondent shall participate in the Iowa Recovery Network (IPRN) program under the direct support of a pharmacist advocate.
- h. Respondent shall not serve as a pharmacist-in-charge while on probation. Respondent shall not supervise any registered pharmacist-interns or perform any duties of a pharmacy preceptor while on probation.
- i. Respondent shall notify all employers and prospective employers (no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms imposed on Respondent by this Agreement. Within fifteen (15) days of undertaking new employment as a pharmacist, Respondent shall cause his pharmacy employer/s, and any pharmacist-in-charge he works under, to send to the Board a written acknowledgment that the employer and pharmacist-in-charge have read this document and understand the terms.
- j. Respondent shall appear before the Board upon request, for the purpose of reviewing his performance as a pharmacist during Respondent's probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- k. Respondent shall inform the Board, in writing, of any change of home address, telephone number, or place of employment within ten (10) days of such a change.
- l. Respondent shall obey all federal and state laws, rules, and regulations related to the practice of pharmacy.
- m. Respondent understands the Board may impose other terms as a condition of reinstatement Respondent's license.
- n. Respondent shall submit written quarterly reports to the Board, said reports being due on March 1, June 1, September 1, and December 1 during each calendar year

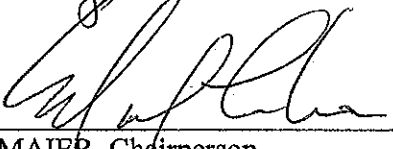
of the probationary period. Each quarterly report shall include Respondent's place of employment, current address, Respondent's most recent efforts to implement the provisions of this Agreement (by date), and any further information requested by the Board.

19. Should Respondent violate the terms of this Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code 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 31 day of DECEMBER, 2014.


RICHARD UPTON, Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the 6th day of January, 2015.


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

Copy to:

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

ADDENDUM L

**NOTICE OF HEARING
AND
STATEMENT OF CHARGES**

**AMANDA KNOUSE
PHARMACY TECHNICIAN REGISTRATION NO. 20304
DES MOINES, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2014-116
Technician Trainee Registration of)	
AMANDA KNOUSE)	NOTICE OF HEARING
Registration No. 20304,)	& STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent was issued Iowa pharmacy technician trainee registration number 20304. Respondent's registration expired on December 31, 2014.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on April 28, 2015, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

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

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

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2013).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148C, and 272C (2013) and 657 Iowa Administrative Code chapter 36.

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

C. CHARGES

Count I

UNETHICAL CONDUCT OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical conduct or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(9) and 155A.6A(3)(a), (5) and 657 Iowa Administrative Code rules 3.28(4), 3.30, and 36.1(4)(c).

Count II

FRAUD IN PROCURING A REGISTRATION

Respondent is charged with fraud in procuring a registration in violation of Iowa Code sections 147.55(1) and 155A.6A(3)(a), (5) and 657 Iowa Administrative Code rules 3.28(1), 3.30, and 36.1(4)(a).

Count III

VIOLATING A STATUTE RELATED TO THE PRACTICE OF PHARMACY

Respondent is charged with violating a statute or law of this state, which relates to the practice of pharmacy or the distribution of controlled substances in violation of Iowa Code sections 147.55(9), 155A.6A(3)(a), (5), and 155A.23 and 657 Iowa Administrative Code rule

36.1(4)(j).

D. FACTUAL CIRCUMSTANCES

1. Respondent was employed as a pharmacy technician trainee at the CVS Pharmacy, located at 3151 SE 14th Street in Des Moines, Iowa.

2. On March 27, 2014, the Board received an Initial Notification of Suspected Controlled Substance Theft or Potentially Significant Loss. The loss was believed to be the result of diversion by a pharmacy technician.

3. On April 18, 2014, CVS submitted a Report of Theft of Loss of Controlled Substances to the Board. The report indicated that loss of controlled substances, with included 2941 hydrocodone/APAP tablets, 98 alprazolam 1 mg tablets, 17 alprazolam 2 mg tablets, 20 Suboxone films, 110 zolpidem 10 mg tablets, and 33 hydrocodone/ibuprofen tablets, was due to diversion by the Respondent.

4. CVS Pharmacy provided a signed statement from the Respondent admitting to diversion.

5. On August 5, 2014, Respondent pled guilty to one count of Prohibited Act—Schedule I, II, or III Controlled Substance, a Class C felony, in violation of Iowa Code section 155A.23. Respondent received a deferred judgment.

6. On her registration application, the Respondent checked “no” to question 8 which asked, “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*)?”

7. Respondent failed to disclose two prior charges. On September 23, 2009, Respondent was charged with assault. That charge was dismissed. On July 26, 2013, Respondent was charged with contempt for violation of a no contact or protective order. That charge was dismissed.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board’s settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this the ^{both} 5th day of January, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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

cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

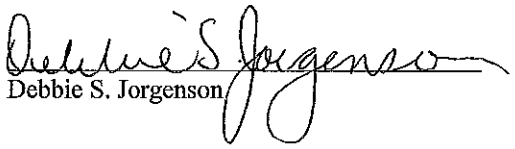
PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755927</u> | <input type="checkbox"/> other _____ |

on the 7th day of January, 2015.

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


Debbie S. Jorgenson

ADDENDUM M
NOTICE OF HEARING
AND
STATEMENT OF CHARGES

STACY JAHLAS
PHARMACY TECHNICIAN REGISTRATION NO. 14928
BELLE PLAINE, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2014-147
Certified Technician Registration of)	
STACY JAHLAS)	NOTICE OF HEARING
Registration No. 14928,)	& STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent was issued Iowa certified pharmacy technician registration number 14928. Respondent's registration is currently active. Her license will expire on January 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on April 28, 2015, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

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

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

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

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2013).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148C, and 272C (2013) and 657 Iowa Administrative Code chapter 36.

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

C. CHARGES

Count I

UNETHICAL CONDUCT OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical conduct or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(9) and 155A.6A(3)(a), (5) and 657 Iowa Administrative Code rules 3.28(4), 3.30, and 36.1(4)(c).

Count II

UNLAWFUL POSSESSION OF PRESCRIPTION DRUGS

Respondent is charged with the unlawful possession of prescription drugs in violation of Iowa Code sections 147.55(9), 155A.6A(3)(a), (5), and 155A.23(1)(a)(1), (h), and 657 Iowa Administrative Code rule 36.1(4)(j).

D. FACTUAL CIRCUMSTANCES

1. Respondent was employed as a certified pharmacy technician at Belle Plaine Pharmacy in Belle Plaine, Iowa.

2. On May 24, 2014, a prescription for Phentermine 30mg was entered into the system by the Respondent for a Toni Douglas. The prescription was reversed out of the system on that same day.

3. On August 25, 2014, Respondent reran the prescription for Phentermine, filled the prescription, paid for the prescription, and took the Phentermine with her upon leaving the pharmacy.

4. The prescriber was contacted and stated that she did not have a patient named Toni Douglas.

5. Respondent admitted to entering a fraudulent prescription and taking the Phentermine.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this the 6th day of January, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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

cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

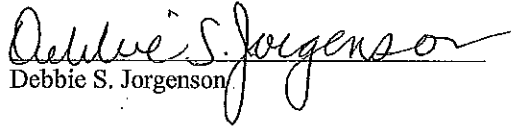
PROOF OF SERVICE

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

- | | |
|--|---|
| <input checked="" type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755897</u> | <input type="checkbox"/> other _____ |

on the 7th day of January, 2015.

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


Debbie S. Jorgenson

ADDENDUM N
NOTICE OF HEARING
AND
STATEMENT OF CHARGES

STEPHEN SCOTT
PHARMACIST LICENSE NO. 18067
TIPTON, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re: _____)	CASE NO. 2014-156
Pharmacist License of)	
STEPHEN SCOTT)	NOTICE OF HEARING AND
License No. 18067)	STATEMENT OF CHARGES
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Stephen Scott ("Respondent"), 423 W. 9th Street, Tipton, Iowa 52772, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent's Iowa pharmacist license number 18067 is currently active and expires on June 30, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 10, 2015, before the Board. The hearing shall be held in the afternoon session beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

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

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. 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 147, 155A, and 272C (2013).

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 under 657 IAC 36.

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

C. CHARGES

Count I

UNLAWFUL POSSESSION OF A CONTROLLED SUBSTANCE

Respondent is charged with unlawful possession of a controlled substance in violation of Iowa Code section 124.401(5), pursuant to Iowa Code section 155A.12(5), and 657 IAC 36.1(4)"j".

Count II

UNETHICAL CONDUCT

Respondent is charged with engaging in unethical conduct, pursuant to Iowa Code sections 147.55(3), 155A.12(2), and (3), and 657 IAC 36.1(4)"c".

Count III

ADDICTION TO DRUGS

Respondent is charged with addiction to the use of drugs, pursuant to Iowa Code sections 147.55(4) and 155A.12(3), and 657 IAC 36.1(4)"d".

D. FACTUAL CIRCUMSTANCES

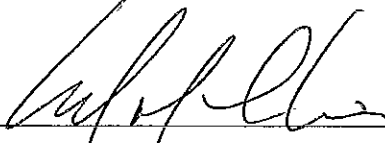
1. Respondent admitted to diverting controlled substances, specifically hydrocodone and oxycodone products, for approximately two years from the pharmacy where he was employed as pharmacist-in-charge.
2. Respondent admits to being addicted to the painkillers he diverted.
3. Respondent has prior discipline from the Board for similar conduct.

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 6th day of January, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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

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


PROOF OF SERVICE

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

- | | |
|--|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755842</u> | <input type="checkbox"/> other _____ |

on the 7th day of January, 2015.

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


Debbie S. Jorgenson

ADDENDUM O

ORDER TO SHOW CAUSE

**PAULA CURRAN
CSA REGISTRATION NO. 5201077
BURLINGTON, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2014-145
Controlled Substance Registration of)
) **ORDER TO SHOW CAUSE**
PAULA CURRAN)
Registration No. 5201077)
Respondent.)

TO: Paula Curran
2301 Agency Road, Apt. 66
Burlington, IA 52601

NOTICE:

Pursuant to the provisions of Iowa Code sections 124.304 and 124.305 (2013) and 657 IAC 10.12, you are hereby ordered to show cause why controlled substance registration number 5201077 should not be suspended.

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

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

I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2013) and 657 IAC 10, the Iowa Board of Pharmacy ("Board") has jurisdiction over those who prescribe controlled substances in Iowa. The Board issued Paula Curran ("Respondent") controlled substance registration number 5201077; subject to the laws of the State of Iowa and the rules of the Board. Controlled substance registration number 5201077 is currently delinquent, having expired on August 31, 2014.

II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent is a registered nurse and an advanced registered nurse practitioner with the Iowa Board of Nursing.

2. On August 20, 2014, the Iowa Board of Nursing approved a Notice of Hearing, Statement of Charges, Settlement Agreement and Final Order (Combined). The Combined Order indefinitely suspended Respondent's licenses/registrations to practice nursing in the state of Iowa.

3. Iowa Code section 124.304(1)"d" and 657 IAC 10.12(1)"e" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has been

disciplined by the registrant's professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances.

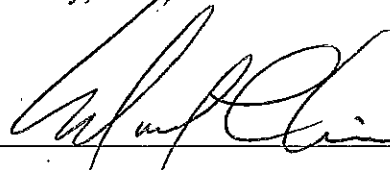
III. ORDER

Respondent is hereby ordered to show cause why controlled substance registration number 5201077 should not be suspended.

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

If Respondent does not request a hearing in this matter within thirty (30) days of service of this Order, controlled substance registration number 5201077 will be SUSPENDED.

IT IS SO ORDERED on this 6th day of January, 2015,



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy

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

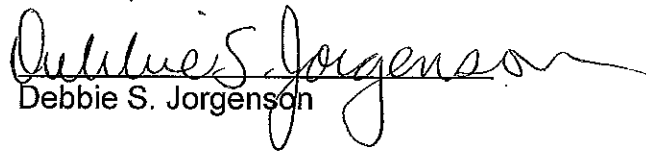
PROOF OF SERVICE

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

- | | |
|---|---|
| <input checked="" type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755903</u> | <input type="checkbox"/> other _____ |

on the 7th day of January, 2015.

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


Debbie S. Jorgenson

ADDENDUM P

ORDER TO SHOW CAUSE

**TIMOTHY SMITH
CSA REGISTRATION NO. 1709957
MARSHALLTOWN, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2014-172
Controlled Substance Registration of)
) **ORDER TO SHOW CAUSE**
TIMOTHY SMITH)
Registration No. 1709957)
Respondent.)

TO: Timothy Smith
311 W Main Street
PO Box 879
Marshalltown, IA 50158

NOTICE:

Pursuant to the provisions of Iowa Code sections 124.304 and 124.305 (2013) and 657 IAC 10.12, you are hereby ordered to show cause why controlled substance registration number 1709957 should not be revoked.

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

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

I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2013) and 657 IAC 10, the Iowa Board of Pharmacy ("Board") has jurisdiction over those who prescribe controlled substances in Iowa. The Board issued Timothy Smith ("Respondent") controlled substance registration number 1709957, subject to the laws of the State of Iowa and the rules of the Board. Controlled substance registration number 1709957 is currently active and expires on February 28, 2016.

II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent was a licensed podiatrist (license number 00464) with the Iowa Board of Podiatry.
2. On October 10, 2014, the Iowa Board of Podiatry approved a Settlement Agreement and Final Order in which Respondent voluntarily surrendered his license to practice podiatry.
3. Iowa Code section 124.304(1)"d" and 657 IAC 10.12(1)"e" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has been

disciplined by the registrant's professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances.

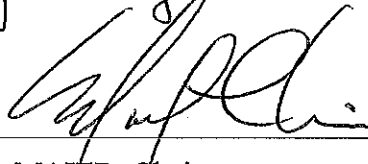
III. ORDER

Respondent is hereby ordered to show cause why controlled substance registration number 1709957 should not be revoked.

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

If Respondent does not request a hearing in this matter within thirty (30) days of service of this Order, controlled substance registration number 1709957 will be REVOKED.

IT IS SO ORDERED on this 6th day of January, 2015.



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy

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

Chad Frese
Kaplan & Frese, LLP
111 E Churst Street
Marshalltown, IA 50158
ATTORNEY FOR RESPONDENT

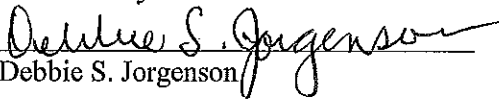
PROOF OF SERVICE

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

- | | |
|---|---|
| <input type="checkbox"/> personal service | <input type="checkbox"/> first class mail |
| <input type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number <u>9171999991703106755910</u> | <input type="checkbox"/> other |

on the 7th day of January, 2015.

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



Debbie S. Jorgenson

ADDENDUM Q

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

**JAMES NIELCEN
PHARMACIST LICENSE NO. 14579
WATERLOO, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:)	
)	Docket No. 2013-140
Request for Reinstatement of)	DIA No. 14PHB049
Pharmacist License)	
JAMES NIELCEN)	
License No. 14579,)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
Respondent.)	DECISION, AND ORDER
)	

STATEMENT OF THE CASE

On November 18, 2014, a hearing was held before the Iowa Board of Pharmacy (Board) on the application for reinstatement filed by Respondent James Nielcen. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratiias; Susan Fréy; Judith Trumpy; Sharon Meyer; and Edward McKenna. Respondent appeared and was self-represented. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of Respondent, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

THE RECORD

The record includes Respondent's June 14, 2014 letter requesting reinstatement; the Notice of Hearing; and State's Exhibits 1 through 12.

FINDINGS OF FACT

Respondent James Nielcen was issued pharmacist license number 14579. Prior to the suspension referenced herein, Nielcen had been licensed as a pharmacist since approximately 1975 and had practiced in Iowa, Illinois, and Minnesota. On November 5, 2013, the Board issued a Statement of Charges alleging that Nielcen had been terminated from employment at Tom's Family Pharmacy for consuming alcohol at work and that Nielcen had admitted to drinking heavily in the days preceding his termination. Additionally, the Statement of Charges alleged that Nielcen admitted to a Board compliance officer that he took small amounts of hydrocodone for personal use from the pharmacy throughout his five-year employment. Nielcen does not dispute any of the factual allegations contained in the Statement of Charges. (Exh. 2; Nielcen testimony).

On January 14, 2014, the Board entered a Settlement Agreement and Final Order resolving the then-pending disciplinary proceeding. The order resulted in the indefinite suspension of Nielcen's pharmacist license and set forth terms upon which the suspension could be terminated. Specifically, the order provides that in order to terminate the suspension, Nielcen must: 1) obtain a complete physical and mental health evaluation, including a substance abuse evaluation, from a physician/treatment provider pre-approved by the Board; 2) deliver to the Board a written, fully documented, and current physical and mental health evaluation, including a substance abuse evaluation, which concludes that Nielcen is mentally and physically fit to practice pharmacy, including an assessment of Nielcen's ability to cope with the presence of controlled substances in the pharmacy setting; and 3) permit the Board complete access to his medical records, including records of substance abuse evaluation and treatment. The order goes on to indicate that at such time that Nielcen can satisfy the conditions for termination of the suspension, a five-year period of probation with specified terms shall commence. (Exh. 3).

On August 15, 2013, prior to entering into the settlement agreement with the Board, Nielcen entered intensive outpatient treatment at Horizons in Waterloo, Iowa. He completed treatment there on September 12, 2013. Nielcen's discharge summary indicates that he has a desire for long-term sobriety and has been hitting multiple 12-step meetings weekly with plans to continue. (Exh. 10).

On June 20, 2014, Nielcen requested reinstatement of his pharmacist license. Nielcen expressed in his letter requesting reinstatement his belief that he has fulfilled the terms necessary to lift the suspension.

In August, 2014, Nielcen submitted a substance abuse evaluation from Tim Law, BA, CADC, and Jim Hoeft, MA, LISW, IAADC, who are both affiliated with Horizons. The substance abuse evaluation was conducted on April 16 and July 15, 2014. Law and Hoeft assessed Nielcen's risk across several scales and concluded that his overall risk is low. Of particular note, they assessed Nielcen's relapse risk as low, noting that he has continued to demonstrate change both behaviorally and verbally. He has been attending at least six AA meetings weekly and has contact with his sponsor multiple times weekly, he has continued to attend Horizons' Growth Group, an alumni-led support group, and he has been attending Horizons' community group as an alumni on a regular basis, giving healthy and constructive feedback to peers. They note they have "full confidence in Mr. Nielcen's commitment to sobriety and working a recovery program." (Exh. 9).

Additionally, Law and Hoeft noted that Nielcen has complied with his aftercare plan from Horizons and recommended that he continue to follow the existing aftercare plan, including maintaining current levels of 12-step group attendance, maintaining current levels of contact with his sponsor, and maintaining compliance with all doctor and psychiatric recommendations. They concluded that Nielcen is able to safely return to working in a pharmacy environment in the presence of controlled substances. (Exh. 9).

Nielcen submitted a letter from his primary care provider, Dr. Nicholas Goetsch, dated January 27, 2014, verifying that Nielcen is medically able to return to his duties as a pharmacist. Nielcen's psychiatrist, Dr. Raja Akbar, submitted a letter dated January 29, 2014, stating that Nielcen has been treated for depressive and anxiety symptoms. Akbar stated that Nielcen is maintaining sobriety and is not experiencing anxiety and depressive symptoms that interfere with his daily functioning. From a psychiatric standpoint, Akbar expressed the belief that Nielcen can engage in work as a pharmacist as long as he continues with treatment. (Exh. 12).

Nielcen acknowledges that no addict can offer guarantees about his or her sobriety. He has, however, worked very hard at identifying and implementing steps to increase his chances of success in recovery. The last time that Nielcen attempted to become sober and went to AA meetings, he made mistakes, such as thinking that he did not need a sponsor and participating in a very limited fashion in meetings. Currently, Nielcen is attending between seven and eight AA meetings per week – at least one per day – and has a home group and a sponsor. In the context of his recovery efforts, Nielcen currently feels safe around drugs and alcohol. He does not believe that practicing pharmacy will pose a danger to his recovery. (Nielcen testimony).

Nielcen is interested in getting back into a light retail or limited hours hospital pharmacy practice. During his suspension, he became a nurse's aide in order to pay his bills and fill time. He also started taking nursing classes. (Nielcen testimony).

CONCLUSIONS OF LAW

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

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

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

...

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

The Board's rules place a heavy burden on persons seeking reinstatement of a revoked or surrendered license. In this instance, the Board concludes that Nielcen has met this burden. Nielcen was candid in acknowledging and taking responsibility for the actions that resulted in his suspension. His own testimony and the documents submitted by his physician, his psychiatrist, his counselor, and Horizons' treatment staff demonstrate that he has committed himself fully to the recovery process and continues to actively follow the aftercare recommendations of Horizons and to participate in a significant way in AA and other structured group activities related to recovery.

Nielcen has fully satisfied the terms the Board laid out in the January 2014 settlement agreement. The mental health evaluation Nielcen submitted concluded that he was at a low risk for relapse. Additionally, the treatment professionals who completed the evaluation concluded that Nielcen is able to safely return to working in a pharmacy environment in the presence of controlled substances. Nielcen has demonstrated, by a preponderance of the evidence, that the basis for the suspension no longer exists and that it is in the public interest for his license to be reinstated, subject to the probationary terms outlined in this order.

DECISION AND ORDER

IT IS THEREFORE ORDERED that upon submission of verification of the required continuing education and payment of the applicable fee, Respondent's pharmacist license number 14579 shall be REINSTATED. Respondent's license shall immediately be placed on PROBATION for a term of five years. Periods when Respondent is not employed as a pharmacist shall not count toward satisfaction of the five-year probationary period.

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

- A. Respondent shall inform the Board, in writing, of any change of home address, place of employment, home telephone number, or work telephone number, within ten days of such a change.
- B. Respondent shall report to the Board quarterly, in writing. The report shall include Respondent's place of employment, current address, Respondent's most recent efforts to comply with the terms of probation, and any further information deemed necessary by the Board from time to time. The reports shall be filed no later than March 5, June 5, September 5, and December 5 of each year of Respondent's probation.
- C. Respondent shall notify all employers and prospective employers (no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by this reinstatement order.

- D. Within 15 days of undertaking new employment as a pharmacist, Respondent shall cause his pharmacy employer, and any pharmacist-in-charge he works under, to report to the Board in writing acknowledging that the employer and the pharmacist-in-charge have read this document and understand it.
- E. Respondent shall appear informally before the Board, upon the request of the Board, for the purpose of reviewing his performance as a pharmacist during Respondent's probationary period. Respondent shall be given reasonable notice of the date, time, and place for the appearances.
- F. Respondent shall obey all federal and state laws, rules, and regulations related to the practice of pharmacy.
- G. Respondent shall abstain from alcohol and all other intoxicants.
- H. Respondent shall not possess or use any controlled substance or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for Respondent by a licensed, treating physician or other qualified treating health care provider. Respondent shall inform any treating physician or treating health care provider of his medical history, including any history of chemical dependency.
- I. Respondent shall provide witnessed blood, hair or urine specimens on demand by the Board or its agents. The specimens shall be used for alcohol and drug screening, and to verify Respondent's compliance with this order and any drug therapy ordered by Respondent's physician or treatment provider. All costs related to the analysis of such specimens shall be paid by Respondent.
- J. To facilitate performance of the preceding paragraph, Respondent shall report to and provide a specimen to any healthcare provider specified by the Board – said healthcare provider to be located in reasonable proximity to Respondent – on the same day that the Board provides notice that a specimen is required. Respondent agrees to cooperate with the Board in establishing a specimen testing program through National Toxicology Services. Respondent shall sign all necessary releases to allow National Toxicology Services or any other testing facility to disclose to the Board his medical information, including test results, generated by Respondent's contact with the facility.
- K. Respondent shall promptly provide, upon request of an agent of the Board, copies of or access to all his medical records.
- L. Respondent shall attend and participate in Alcoholics Anonymous (AA), Narcotics Anonymous (NA), or a similarly structured support group on a regular weekly basis and shall maintain documentation of his attendance, which shall be included with his quarterly reports. Respondent shall maintain his relationship with his AA sponsor.

- M. Respondent shall not supervise any registered pharmacist-intern and shall not perform any of the duties of a pharmacy preceptor.
- N. Respondent shall participate in the Iowa Pharmacy Recovery Network (IPRN) program, under the direct support of a pharmacist advocate.
- O. Should Respondent violate or fail to comply with any of the terms and conditions of probation, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacist license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.

Dated this 6th day of January, 2014.



Edward Majer
Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General

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

ADDENDUM R

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

**MATTHEW BIGGERSTAFF
CSA REGISTRATION NO. 1306092
ANKENY, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Controlled Substance Registration of:)	Docket No. 2013-195
MATTHEW BIGGERSTAFF)	DIA No. 14PHB051
Registration Number 1306092,)	
Respondent.)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
)	DECISION AND ORDER

On August 26, 2014, the Iowa Board of Pharmacy (Board) issued an Order to Show Cause regarding the controlled substance registration of Matthew Biggerstaff, D.O. On September 3, 2014, Respondent requested a hearing before the Board regarding the Order to Show Cause.

A hearing was held on November 18, 2014. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratiias; Susan Frey; Judith Trumpy; Edward McKenna; and Sharon Meyer. Assistant attorney general Meghan Gavin represented the state. Respondent Matthew Biggerstaff appeared and was represented by attorney Michael Sellers. The hearing was closed to the public at the election of Respondent, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

Motion in Limine

On November 14, 2014, Respondent filed a Motion in Limine requesting that the Board prohibit an investigator from the Iowa Board of Medicine from testifying at this hearing. Respondent argues in the motion that: 1) the investigator's testimony constitutes hearsay as he has no personal knowledge relating to this Board's concerns; and 2) pursuant to Iowa Code section 272C.6(4)(a), investigative files and materials of a licensing board may be disclosed to other licensing boards, but those materials and files can only be used in disciplinary proceedings before the licensing board that originated and created the file.

The state filed a Resistance to Motion in Limine on November 16, 2014. The state argues that hearsay is admissible in this administrative proceeding and disputes Respondent's characterization of Iowa Code section 272C.6(4)(a) as too narrow.

The Board permitted oral argument on the motion at hearing on November 18 and delegated the decision on the motion to Administrative Law Judge Laura Lockard.

Respondent's Motion in Limine was denied at hearing. As an initial matter, the standard for whether evidence is admissible in a contested case proceeding under Iowa

Code Chapter 17A relates to whether it is the type of evidence on which reasonably prudent persons are accustomed to rely for the conduct of serious affairs. Evidence that meets that standard is admissible even if it would be inadmissible in a jury trial.¹ In this proceeding, whether the evidence is hearsay goes to its weight rather than its admissibility. Exclusion of the investigator's testimony on this basis is not warranted.

Iowa Code section 272C.6(4)(a) provides, in relevant part:

In order to assure a free flow of information for accomplishing the purposes of this section, and notwithstanding section 622.10, all complaint files, investigation files, other investigation reports, and other investigative information in the possession of a licensing board or peer review committee acting under the authority of a licensing board or its employees or agents which relates to licensee discipline are privileged and confidential, and are not subject to discovery, subpoena, or other means of legal compulsion for their release to a person other than the licensee and the boards, their employees and agents involved in licensee discipline, and *are not admissible in evidence in a judicial or administrative proceeding other than the proceeding involving licensee discipline.*

(Emphasis added).

While Respondent argues that the Board of Medicine investigator's testimony regarding matters in the investigative file is privileged and confidential under this section, the text of the statute does not compel such a result. The section outlines a specific exception to the general inadmissibility of investigative materials in judicial and administrative proceedings for proceedings involving licensee discipline. This is precisely such a proceeding, therefore testimony from the investigator and materials from the investigative file are admissible. The fact that the investigative materials were generated by the Board of Medicine and the disciplinary proceeding is before the Board of Pharmacy does not negate the licensee discipline exception.

Lastly, Respondent argues that he has a right to confront witnesses against him in an administrative agency hearing. Respondent asserts that the state must be required by the Board to bring in "any witnesses that they believe have actual credible knowledge of actual facts coming from their own participation and/or direct observations." Neither the law nor the applicable regulations impose such a burden on the state in prosecuting this type of case. Respondent is entitled to subpoena any witnesses he wishes to examine at hearing. Respondent is not, however, entitled to dictate to the state how it must present its case.

THE RECORD

The record includes the Order to Show Cause; Respondent's Request for Hearing; Notice of Hearing; Respondent's Motion in Limine; and Resistance to Motion in Limine.

¹Iowa Code § 17A.14(1) (2013).

The record also includes the state's Exhibits 1 through 18, Respondent's Exhibits A through G, and hearing testimony of James Machamer and Matthew Biggerstaff.

FINDINGS OF FACT

The Board has issued Respondent Matthew Biggerstaff controlled substance registration number 1306092 in accordance with the laws of the state of Iowa and the rules of the Board. The Order to Show Cause issued by the Board on August 26, 2014 alleges that Biggerstaff gave his password information for Allscripts, an electronic prescription program, to his office nurse to use and that he gave his Prescription Monitoring Program (PMP) information to his office nurse to use.

Electronic prescriptions

On November 6, 2013, the Iowa Board of Medicine (BOM) notified the Board that it had completed an investigation of Biggerstaff and referred the matter to the Board's attention. The referral states, in relevant part:

The [BOM] received information which indicates that Dr. Biggerstaff authorized two staff members where he practices medicine to utilize his unique user name and personal password to refill prescriptions in his name on the clinic's e-prescription system. The [BOM] is concerned that Dr. Biggerstaff's conduct may have violated state or federal law. The [BOM] directed that this matter be referred to your attention.

(Exh. 6).

Biggerstaff is a pain specialist. The BOM became aware of the issue through a complaint filed by Biggerstaff's prior employer, Medical Center Anesthesiologists, PC. The complaint was filed in January, 2013. The complaint alleges that Biggerstaff had been directing a nurse for a number of months to use his personal password to refill hydrocodone prescriptions for his patients using the group's electronic prescription system. At the time the complaint was filed, Biggerstaff had already resigned from the group. His resignation immediately followed a meeting in which the physician members of the practice confronted Biggerstaff about this issue and informed him of their intent to take a vote to determine how to proceed. (Exh. 7, 9).

BOM investigator James Machamer was assigned to investigate the complaint. Machamer interviewed Jennifer Robinson, a nurse who had worked with Biggerstaff at Medical Center Anesthesiologists. At the time of the interview, Robinson was still employed there. Robinson was trained by another nurse in the office, Katherine Haugen, who married Biggerstaff in April, 2013 and became Katherine Biggerstaff,² to utilize Biggerstaff's username and password to gain access to the office's electronic prescription system in order to save time. (Exh. 9; Machamer testimony).

² To minimize confusion, Katherine Biggerstaff will be referred to throughout this order as Katherine Haugen, her name during the relevant time period.

The office's electronic prescription system, Allscripts, allowed each doctor, as well as his or her agents, to have a unique username and password. When an agent, such as a nurse, logged in and input a new prescription or a refill, the pharmacy would be alerted that the prescription came from an agent rather than the physician. This would often prompt a call to the office. When Robinson or Haugen logged in with Biggerstaff's username and password, the pharmacy was less likely to make a follow-up call to verify the prescription with the office. (Exh. 9; Machamer testimony).

Haugen confirmed this information to Machamer. She stated that some pharmacies would question the validity of a prescription if a nurse's name appeared at the bottom of the electronic prescription, even though Iowa law allows this practice for Schedule III and IV medications. The majority of the electronic prescriptions that were filled and refilled by Robinson and Haugen using Biggerstaff's credentials were for hydrocodone and Lyrica. (Exh. 9, 10).

Allscripts required a user to change his or her password every 60 to 90 days. Nothing prevented users from switching back and forth between the same two passwords. This is what occurred in Biggerstaff's office. Robinson knew what the password was because it was always one of two known passwords. Biggerstaff would inform her when the password changed. (Machamer testimony; Exh. 9, 10).

Robinson told Machamer that Biggerstaff was aware of her use of his username and password to fill and refill prescriptions for schedule III and IV medications in order to circumvent calls from the pharmacy to verify the validity of the prescriptions. Haugen also told Machamer that she had received permission from Biggerstaff to use his credentials to send electronic prescriptions for controlled substances. (Exh. 9, 10).

On May 6, 2014, the Drug Enforcement Administration sent a letter to Biggerstaff stating, in relevant part:

Recently, the Des Moines Resident Office conducted an investigation of your Drug Enforcement Administration (DEA) Registration, which revealed the following violation of Title 21 of the Code of Federal Regulations (CFR):

- 21 CFR 1311.102(a) – The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person.

This letter is formal notification that your failure to comply with the above regulation constitutes a violation of the Controlled Substances Act, which was outlined by Diversion Investigator George Taylor on April 4, 2014. At this time, you are being afforded the opportunity to voluntarily comply with the requirements of the Controlled Substances Act.

Please advise the Des Moines Resident Office in writing by May 23, 2014, of the action(s) taken or planned to correct the aforementioned violation.

(Exh. 15).

Biggerstaff responded to the DEA's May 6 letter in writing. Biggerstaff reported that as soon as he was made aware of the potential for a violation, he changed all passwords immediately. Additionally, Biggerstaff noted that when he used an electronic prescription system in the future, he would keep secured all passwords, hard tokens, knowledge factors, and biometric information and would not share those with anyone. (Exh. 16).

During the BOM investigation, Biggerstaff admitted to Machamer that he had given Haugen his credentials for her to use. At an appearance before the BOM, Biggerstaff denied involvement in providing his username and password to his nursing staff. (Exh. 9; Machamer testimony).

Biggerstaff wrote a letter dated June 26, 2013 to the Minnesota Medical Board, where he had applied for licensure. In the letter, he states that there was a report made to the BOM that his electronic prescription password was being used by a nurse to call in refills of hydrocodone. Biggerstaff wrote in the letter, "The nurse was using my password without permission but only to cut her workload down. Using her password access necessitates a call to some pharmacies where using mine did not." (Exh. 14).

At this hearing, Biggerstaff testified that he did not authorize the use of his username or password by his nursing staff to transmit electronic prescriptions to pharmacies. Biggerstaff testified he had no knowledge that the nurses at his prior practice were using his password to authorize and refill prescriptions. He did acknowledge, however, that he gave his nursing staff his Allscripts username and password so that they could log in and print out schedule II prescriptions for him to sign. They were unable to print schedule II prescriptions under their own credentials, as a prescriber was required to perform that step. (Biggerstaff testimony).

Biggerstaff is currently practicing in Winterset and Newton and is providing comprehensive pain management to patients on a referral basis. At present, Biggerstaff is not using any electronic prescription system; he is handling all medications and prescriptions and is not delegating any of this work to nursing staff. He has purchased and is in the process of implementing an electronic records system. (Biggerstaff testimony).

Prescription Monitoring Program (PMP)

During the BOM investigation, Haugen reported that she had received permission from Biggerstaff to use his login credentials for the PMP from approximately June 2010 through April 2012. At hearing, Biggerstaff acknowledged that prior to the summer of 2012 his nursing staff had his unique PMP credentials, which they used to log in to the system. (Exh. 9; Biggerstaff testimony).

CONCLUSIONS OF LAW

Under Iowa law, every person who manufactures, distributes, or dispenses any controlled substance within the state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within the state, shall obtain and maintain a biennial registration issued by the Board in accordance with its rules.³ The Board's regulations require every person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, to obtain and maintain such a registration.⁴ The Board may suspend, revoke, or restrict a controlled substance registration upon a finding that the registrant has committed such acts as would render the registration inconsistent with the public interest.⁵ 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.⁶

Prior to denying, suspending, or revoking a registration, or refusing a renewal of registration, the Board shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused.⁷

The state argues that Biggerstaff's failure to comply with the Board's regulations and federal regulations regarding electronic prescriptions of controlled substances, as well as failure to comply with the Board's regulations regarding the PMP, justify suspension

³ Iowa Code § 124.302(1) (2013).

⁴ 657 Iowa Administrative Code (IAC) 10.1.

⁵ Iowa Code § 124.304(1)(d) (2013).

⁶ Iowa Code § 124.303(1)(a)-(g) (2013); 657 IAC 10.12(1)(d), 10.12(4) (2013).

⁷ Iowa Code § 124.305 (2013).

of Biggerstaff's controlled substance registration. The relevant regulatory provisions are cited below:

657 – 8.19 Manner of issuance of a prescription drug or medication order.

8.19(1) Requirements for a prescription. A valid prescription drug order shall be based on a valid patient-prescriber relationship.

...

d. Electronic prescription. In addition to the requirements of paragraph 8.19(1)“a,” an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber’s electronic signature.

(1) An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber’s agent shall be manually signed by the prescriber.

(2) The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.

(3) The prescriber or the prescriber’s agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.

...

8.19(3) Transmitting agent. The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic transmission provided that the first and last names and title of the transmitting agent are included in the order.

657 – 10.21 Prescription requirements

10.21(1) Form of prescription . . . 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. 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. An electronic prescription

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

657 – 21.2 System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer 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.

657 – 37.4 Access to database information.

37.4(1) Prescribers and pharmacists. A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care.

a. Prior to being granted access to PMP information, a practitioner shall submit a request for registration and program access . . . The PMP administrator shall take reasonable steps to verify the identity of a practitioner and to verify a practitioner's credentials prior to providing a practitioner with a secure login and initial password. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to the practitioner's agent.⁸

⁸ Prior to 7/1/12. On July 1, 2012, the Board's regulation was changed to permit a practitioner to authorize no more than three health care professionals, including nurses, to act as the practitioner's agents for the purpose of requesting PMP information regarding that practitioner's patients. The current regulation provides for a practitioner's agent to obtain unique login credentials separate from the practitioner's credentials and requires that each practitioner or agent securely maintain and use his or her own login and password.

21 C.F.R. 1311.102 Practitioner responsibilities.

(a) The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token, knowledge factor, or biometric information may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).

The preponderance of the evidence establishes that Biggerstaff shared his unique credentials, including username and password, for both his practice's electronic prescription system and the PMP system with the nurses in his office. Biggerstaff has denied that he knew that his nursing staff was using his credentials to transmit electronic prescriptions for schedule III controlled substances, including hydrocodone, to pharmacies. Despite Biggerstaff's denials, the Board found the contrary evidence gathered during the Board of Medicine's investigation to be more credible. Both Robinson and Haugen told Machamer during the BOM investigation that Biggerstaff had shared his credentials with them and that they used those credentials, with his knowledge, to fill electronic prescriptions. While the Board did not find Biggerstaff's denials credible, even the conduct that Biggerstaff has admitted to – that is, sharing his credentials in order to allow nursing staff to log in to print out schedule II controlled substance prescriptions – runs afoul of the state and federal regulations cited above.

Respondent argues that state and federal regulations allowing a prescriber's agent to prepare a prescription or communicate the prescription to a pharmacy permits him to share his unique credentials for the electronic prescription system. It is true that, as a general matter, certain prescriptions, such as those for schedule III and IV medications, may be independently prepared and transmitted by a prescriber's agent. It is equally clear, however, that the regulations have special requirements for transmission of electronic prescriptions that supersede the more general dictates regarding agents. Both the state and federal regulations are unequivocal in their prohibition against sharing unique credentials for electronic prescription systems. There is no exception for sharing credentials with a prescriber's agents, including nursing staff.

The DEA independently concluded that Biggerstaff's conduct violated 21 C.F.R. 1311.102, prohibiting a practitioner from sharing the password for electronic prescriptions with any other person. While the DEA assessed no penalty or sanction, its investigation concluded with a finding of a violation.

In addition to the issues relating to electronic prescribing, Biggerstaff has also admitted that he shared his unique credentials to access Iowa's PMP system with his staff prior to July 2012. While not directly related to the prescribing and distribution of controlled substances, this concerns the Board in that it reflects a pattern of Biggerstaff ignoring rules and regulations when such conduct serves his purposes.

The Board concludes that Biggerstaff's acts render his continued unrestricted registration inconsistent with the public interest. In determining whether to suspend, revoke, or restrict Biggerstaff's registration, the Board notes that there is no evidence that Biggerstaff or his staff engaged in any diversion of controlled substances. Biggerstaff's failure to secure his login credentials for Allscripts, however, created the opportunity for diversion.

ORDER

IT IS THEREFORE ORDERED that controlled substance registration number 1306092, issued to Respondent Matthew Biggerstaff, is hereby restricted for the period of one year. During the period of restriction, Respondent is prohibited from prescribing through agents or delegating any prescribing powers to agents. Biggerstaff is also prohibited during the restriction period from authorizing agents to access the PMP system on his behalf.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 Iowa Administrative Code 36.18(2), that Respondent shall pay \$75 for fees associated with conducting the disciplinary hearing. In addition, the executive director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within 30 days of receipt of the bill.

Dated this 6 day of January, 2014



Edward Maier
Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General
Michael Sellers, Attorney for Respondent

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

ADDENDUM S

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

**MEDICAP PHARMACY
CSA REGISTRATION NO. 1106533
OSKALOOSA, IOWA**

BEFORE THE IOWA BOARD OF PHARMACY

RE:)	Docket No. 2014-49
Controlled Substance Registration of)	DIA No. 14PHB040
MEDICAP PHARMACY)	
Registration No. 1106533,)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
Respondent)	DECISION, AND ORDER

STATEMENT OF THE CASE

On May 28, 2014, the Iowa Board of Pharmacy (Board) issued an Order to Show Cause to Respondent Medicap Pharmacy, ordering it to appear before the Board and show cause why controlled substance registration number 11065343 should not be suspended or revoked. On June 30, 2014, Respondent filed a Request for Hearing on the Order to Show Cause.

A hearing was held on November 18, 2014. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratiyas; Susan Frey; Judith Trumpy; Edward McKenna; and Sharon Meyer. Assistant attorney general Meghan Gavin represented the State. Respondent Medicap Pharmacy did not appear. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

THE RECORD

The record includes the Order to Show Cause and Respondent's Request for Hearing. The State introduced Exhibits 1 through 6, which were admitted as evidence.

FINDINGS OF FACT

The Board has issued Respondent Medicap Pharmacy controlled substance registration number 11065343 in accordance with the laws of the state of Iowa and the rules of the Board. The Order to Show Cause issued by the Board on May 28, 2014 alleges that an audit of Respondent's hydrocodone 10/325 tablet inventory from January 1, 2013 through March 14, 2014 revealed a discrepancy of over 6,000 tablets. During that time period, Respondent ordered 35,000 hydrocodone 10/325 tablets and legally dispensed 27,963.

On November 5, 2013, the Board issued a Statement of Charges against Respondent and against Michelle Heidebrink, Respondent's owner. The Statement of Charges alleged four counts against Respondent: 1) failure to maintain adequate control over and accountability for controlled substances; 2) failure to establish adequate security and

effective controls against diversion; 3) failure to keep and maintain records required by the Controlled Substances Act; and 4) failure to maintain policies and procedures for the operation of a pharmacy. The Statement of Charges also alleged three counts against Heidebrink: 1) unethical behavior or practice harmful or detrimental to the public; 2) violating the duties of a pharmacist-in-charge; and 3) failure to maintain adequate control over and accountability for controlled substances.

At the hearing on the Statement of Charges in July, 2014, the Board heard testimony from Board compliance officer Curt Gerhold and reviewed documents admitted into evidence. The Board issued Findings of Fact, Conclusions of Law, Decision, and Order dated September 11, 2014. The Board's findings from that Order are included below and incorporated herein:

Respondent Michelle Heidebrink is the owner of Respondent Medicap Pharmacy in Oskaloosa, Iowa. The pharmacy's license is currently active. During all of 2013, Heidebrink was the pharmacist-in-charge at the pharmacy. (Gerhold testimony).

As a result of two Statements of Charges against Heidebrink and one against Medicap Pharmacy in Oskaloosa, Heidebrink entered into a Settlement Agreement and Final Order with the Board effective on or about January 13, 2014. Under the terms of the agreement, Heidebrink's pharmacist license was suspended indefinitely. The charges against the pharmacy were dismissed pursuant to the Settlement Agreement and Final Order. (Exh. 4; Gerhold testimony).

On January 24, 2014, Iowa Board of Pharmacy compliance officer Curt Gerhold conducted a follow-up visit at Medicap Pharmacy in Oskaloosa, Iowa at the request of the Board. During that visit, Heidebrink informed Gerhold that Raj Devan had just taken over as the new pharmacist-in-charge (PIC) at the pharmacy. Gerhold requested that Heidebrink provide the controlled substance inventory that was completed when Devan assumed the role of PIC. Devan told Gerhold that he had not completed a controlled substance inventory when he started as PIC because he was too busy. Gerhold requested that Devan completed [sic] a controlled substance inventory immediately. Later that day, Devan called Gerhold to inform him that he had completed the controlled substance inventory. (Exh. 5, pp. 19-20; Gerhold testimony).

In March, 2014, Gerhold contacted the Drug Enforcement Administration (DEA) to request an ARCOS report. When drug wholesalers send shipments to pharmacies that include controlled substances, those wholesalers are required to send a list to the DEA detailing the controlled substances that are shipped to each pharmacy. An ARCOS report compiles that data and shows the type and quantity of controlled substances that a particular pharmacy has received, as reported by the wholesalers who are supplying controlled substances to that pharmacy. The ARCOS report that

Gerhold requested and received covered the time period from January 1, 2013 through March 14, 2014. (Gerhold testimony).

On March 25, 2014, Gerhold conducted a follow-up visit to the pharmacy, which included an inspection. As part of the inspection, Gerhold and another compliance officer compared the controlled substance dispensing data from the pharmacy records with the ARCOS report showing what had been ordered by and shipped to the pharmacy for the time period from January 1, 2013 through January 24, 2014. That analysis reflected that the pharmacy had ordered and received over 6,000 tablets of hydrocodone 10/325 that were unaccounted for; that is, the pharmacy's dispensing records did not reflect that the tablets had been dispensed, but they were not present in the pharmacy's inventory.¹ Heidebrink could not explain the 6,000 tablet discrepancy. Devan stated that he had just taken over as PIC in January, 2014 and had no idea what had happened with regard to the pharmacy's inventory prior to that point. (Exh. 6, 7, 8; Gerhold testimony).

In addition to the discrepancy in the controlled substance inventory, Gerhold noted a number of other deficiencies during the March 25 inspection, including: 1) failure to maintain an orderly and clean environment; 2) failure to document any reportable incidents under the continuous quality improvement (CQI) program; 3) failure to take an annual controlled substance inventory and to take a controlled substance inventory at the time a new PIC began working; and 4) failure of the PIC, Raj Devan, to display a pharmacist license on the premises.² (Gerhold testimony; Exh. 6, 9).

On May 6, 2014, Gerhold conducted a third visit to the pharmacy. Prior to the visit, Gerhold obtained another ARCOS report. Gerhold compared the ARCOS report to the dispensing data during the months following Devan assuming the PIC position. Gerhold did not discover any significant discrepancy in the pharmacy's controlled substance inventory during the time that Devan had been in the PIC position. (Gerhold testimony; Exh. 13).

¹ Because of the pharmacy's poor recordkeeping, Gerhold was unable to ascertain the quantity of controlled substances in the pharmacy's possession as of January 1, 2013. Gerhold therefore assumed that the quantity of each controlled substance in the pharmacy's inventory was zero as of that date. If the pharmacy did have a quantity of any controlled substance in their inventory prior to that date, using zero would actually result in a smaller discrepancy. For example, if the pharmacy had 100 tablets of a particular strength of hydrocodone in its inventory as of January 1, 2013, those 100 tablets would not show up in the shipment records from January 1, 2013 through January 24, 2014 but would be counted as part of the inventory as of January 24, 2014. (Gerhold testimony).

² In 2013, the pharmacy had also had deficiencies identified in several areas, including reporting events in the CQI program, the schedule II perpetual inventory, and annual inventory. (Exh. 9).

Based on its factual findings, the Board concluded that the State had proven all four of the violations alleged against Respondent in the Statement of Charges. Additionally, the Board concluded that the State had proven all three of the violations alleged against Heidebrink. The Board ordered, among other things, that Heidebrink's pharmacist license remain suspended indefinitely; that Heidebrink have no involvement in the ownership, management, direction, or control of any business engaged in the practice of pharmacy during the term of her license suspension; that Heidebrink divest herself of ownership of Respondent within 90 days of the date of the Order; and that Heidebrink not hold the position of pharmacist-in-charge in the future. The Board also placed Respondent's pharmacy license on probation for a period of five years. The Board placed numerous conditions on Respondent's license during the probationary period. (Exh. 5).

CONCLUSIONS OF LAW

Under Iowa law, every person who manufactures, distributes, or dispenses any controlled substance within the state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within the state, shall obtain and maintain a biennial registration issued by the Board in accordance with its rules.³ The Board's regulations require every person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, to obtain and maintain such a registration.⁴ The Board may suspend, revoke, or restrict a controlled substance registration upon a finding that the registrant has committed such acts as would render the registration inconsistent with the public interest.⁵ 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.

³ Iowa Code § 124.302(1) (2013).

⁴ 657 Iowa Administrative Code (IAC) 10.1.

⁵ Iowa Code § 124.304(1)(d) (2013).

g. Any other factors relevant to and consistent with the public health and safety.⁶

Prior to denying, suspending, or revoking a registration, or refusing a renewal of registration, the Board shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused.⁷

The preponderance of the evidence establishes that Respondent, a licensed pharmacy, had an unexplained shortfall of over 6,000 tablets of hydrocodone 10/325 during an approximately 14-month time period. During the majority of that time, Respondent's owner, Heidebrink, was the pharmacist-in-charge. When Heidebrink ceded her role as pharmacist-in-charge, the new PIC, Raj Devan, did not complete a controlled substance inventory, as required. Additionally, a compliance investigation revealed that Respondent was not taking an annual controlled substance inventory. There is no evidence that the pharmacy detected the discrepancy in the hydrocodone 10/325 tablets at any point prior to Gerhold's audit in March, 2014. The Board noted in its September 11, 2014 order that the pharmacy failed to present any evidence at the July, 2014 hearing regarding any security controls or operating procedures designed to prevent diversion at the pharmacy.

As a controlled substances registrant, Respondent is required to abide by all laws that govern the prescribing and dispensing of controlled substances. In its September 11, 2014 order, the Board concluded that Respondent's actions violated 657 Iowa Administrative Code 10.35(3) and (5), relating to a registrant's requirement to take an annual inventory of controlled substances and a registrant's requirement to take an inventory of all controlled substances whenever there is a change of PIC. The Board also concluded that Respondent's actions violated 657 Iowa Administrative Code 10.15, relating to a registrant's duty to establish effective controls against diversion of controlled substances.

The Board remains extremely concerned about an unexplained discrepancy of 6,000 hydrocodone tablets within a 14-month time period. Even more concerning is the fact that the evidence supports the conclusion that the pharmacy did not discover the discrepancy until the Board's compliance officer pointed it out. Respondent's license was placed on probation in September, 2014 and the Board imposed a number of conditions designed to ensure compliance with the laws and regulations relating security of controlled substances. Yet, Respondent failed to appear at the hearing it requested on the Order to Show Cause and failed to provide any evidence that it is complying with the conditions of its probation or that the problems the Board found regarding controlled substance recordkeeping have been remedied.

Under these circumstances, a revocation of Respondent's controlled substance registration is justified. If the Board suspends or revokes a registration, all controlled

⁶ Iowa Code § 124.303(1)(a)-(g) (2013); 657 IAC 10.12(1)(d), 10.12(4) (2013).

⁷ Iowa Code § 124.305 (2013).

substances owned or possessed by the registrant at the time of suspension may be placed under seal.⁸ The Board finds that, based upon Respondent's compliance history, such action is justified.

DECISION AND ORDER

IT IS THEREFORE ORDERED that controlled substance registration number 1106533, issued to Medicap Pharmacy, is hereby revoked. Respondent is ordered to immediately upon receipt of this decision return controlled substance registration number 1106533 to the Board or authorized agent of the Board.

IT IS FURTHER ORDERED that Respondent shall immediately deliver all controlled substances in Respondent's possession to the Board or authorized agent of the Board.

Dated this 6 day of January, 2015



Edward Majer
Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General
Eric Palmer, Attorney for Respondent

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

⁸ Iowa Code § 124.304(3) (2013).