

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2011-64
MEDICAP PHARMACY)	
License No. 401,)	STATEMENT OF CHARGES
Respondent.)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).
3. Effective December 29, 2011, the Board renewed Respondent's general pharmacy license number 401 for Medicap Pharmacy (hereinafter, "Respondent"), with Michelle Heidebrink as the pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy, subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 401 is current until December 31, 2012.
5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 504 A Avenue, Oskaloosa, Iowa 52577.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(b) with lack of professional competency as demonstrated by Respondent's (a) substantial deviation from the standards of learning and skill ordinarily possessed and applied by other Iowa pharmacies, (b) failure to exercise in a substantial respect that degree of care which is ordinarily exercised by an Iowa pharmacy and (c) willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by Respondent's failure to maintain adequate controls over controlled substances.

COUNT II – EMPLOYMENT OF UNREGISTERED TECHNICIANS

Respondent is charged with employment of unregistered technicians in violation of Iowa Code § 155A.15(2) (2011) and 657 Iowa Administrative Code § 36.1(4)(aa).

COUNT III – FAILURE TO MAINTAIN AND PROVIDE RECORDS

Respondent is charged with failure to maintain and provide to the Board pharmacy records in violation of Iowa Code § 155A.15(2) (2011) and 657 Iowa Administrative Code §§ 8.4(3), 10.34, 10.35, 21.5, 36.1(4)(ac), 36.1(4)(ag).

B. CIRCUMSTANCES

An investigation was commenced on June 14, 2011, which revealed the following:

1. At all times material to this Statement of Charges, Respondent was operating a general pharmacy at 504 A Avenue, Oskaloosa, Iowa 52577, with Michelle Heidebrink as the pharmacist in charge.
2. A routine inspection on June 17, 2011 revealed the following:
 - a. Respondent employed five technicians, two of whom were unlicensed and two of whom had expired licenses.
 - b. No log was being maintained of the dates and hours pharmacists and technicians worked.
 - c. The pharmacy's annual controlled substance inventory had purportedly been removed from the pharmacy following a robbery, but Michelle Heidebrink was unable to produce it for inspection.
 - d. Daily controlled substance refill verification was not being performed.
 - e. Respondent did not maintain a perpetual inventory of schedule II controlled substances.
3. The inspection also revealed disorganized quantities of out-dated drugs, returned medications and general paperwork at Respondent.

Wherefore, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.


LLOYD K. JESSEN
Executive Director

On this 7th day of March 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.



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

cc: Scott M. Galenbeck
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

Medicap Oskaloo-SOC 2-12.doc

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case No. 2011-64
Pharmacy License of)
MEDICAP PHARMACY,) **STIPULATION**
License No. 401) **AND**
Respondent) **CONSENT ORDER**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the “Board”) and Medicap Pharmacy (hereinafter, “Respondent”) have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on March 7, 2012 shall be resolved without a hearing, as the Board and Respondent stipulate to the following:

1. Respondent’s license to operate a general pharmacy in Iowa is evidenced by Pharmacy License Number 401, which is recorded in the permanent records of the Board.
2. Pharmacy License Number 401 is current and active until December 31, 2012.
3. The Board has jurisdiction over the parties and the subject matter herein.
4. A Statement of Charges was filed against Respondent on March 7, 2012.
5. Respondent has chosen not to contest the allegations set for the in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.
6. On the date of the Board's approval of this Stipulation and Consent Order, Respondent’s license shall be placed on probation for two (2) years, upon the following conditions:

(a) Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of an Iowa pharmacy.

(b) Consistent with subparagraph (a) above, Respondent shall assure that all technicians are properly registered with the Board and controlled substance records are fully maintained.

(c) Respondent shall file sworn quarterly reports with the Board attesting to Respondent's compliance with the terms and conditions of this Stipulation and Consent Order. The reports shall be filed not later than December 5, March 5, June 5 and September 5 of each calendar year and shall include a description of Respondent's most recent efforts to comply with this Stipulation and Consent Order, including paragraph (b) above. Respondent's quarterly reports shall also provide any other information deemed to be necessary, from time to time, by the Board.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of \$1,000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate further

action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

9. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

10. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

11. The State's counsel may present this Stipulation and Consent Order to the Board.

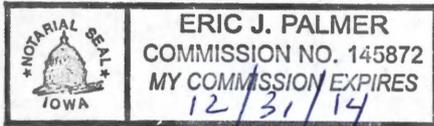
12. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary proceeding.

This Stipulation and Consent Order is voluntarily submitted by Medicap Pharmacy to the Iowa Board of Pharmacy for its consideration on this 20 day of June 2012.



Medicap Pharmacy
Respondent
By Michelle Heidebrink, R.Ph.
Pharmacist In Charge

Subscribed and sworn to before me by Michelle Heidebrink, who has stated to me that she is the pharmacist in charge of Medicap Pharmacy and is authorized to sign this Stipulation and Consent Order on behalf of Medicap Pharmacy on this 20th day of June 2012.



Eric J. Palmer

NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this
27 day of June 2012.

Susan M. Frey

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

cc: Theresa Weeg
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Eric Palmer
palmlaw@mahaska.org

Medicap Oskaloo settle 6-12.doc

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2011-64 & 2012-165
Pharmacy License)	
MEDICAP PHARMACY)	NOTICE OF HEARING
License No. 401,)	& 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 license number 401. Respondent's license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 14, 2014, 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 (2011).

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 (2011) 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

VIOLATION OF A BOARD ORDER

Respondent is charged with violating the terms of a previous Board order in violation of Iowa Code section 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(i).

Count II

FAILURE TO MAINTAIN AND PROVIDE RECORDS

Respondent is charged with failure to maintain and provide records to the Board in violation of Iowa Code section 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 8.4(3), 10.34, 10.35, 21.5, 36.1(4)(ac), and 36.1(4)(ag).

Count III

FAILURE TO MAINTAIN PERPETUAL INVENTORY

Respondent is charged with failure to maintain a perpetual inventory in violation of Iowa Code section 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 10.33 and 36.1(4)(u).

Count IV

FAILURE TO MAINTAIN A COMPLETE AND ACCURATE INVENTORY OF CONTROLLED SUBSTANCES

Respondent is charged with failure to maintain a complete and accurate inventory of controlled substances in violation of Iowa Code section 155A.15(2)(c), (h) and 657 Iowa

Administrative Code rules 10.35 and 36.1(4)(u).

Count V

FAILURE TO MAINTAIN POLICIES AND PROCEDURES

Respondent is charged with failure to maintain policies and procedures for the operation of a pharmacy in violation of Iowa Code section 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 6.2(14) and 36.1(4)(u).

Count VI

FAILURE TO MAINTAIN A CONTINUOUS QUALITY IMPROVEMENT PROGRAM

Respondent is charged with failure to maintain a continuous quality improvement program in violation of Iowa Code section 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 8.26 and 36.1(4)(u).

D. FACTUAL CIRCUMSTANCES

Case No. 2011-64

1. On March 7, 2012, the Board filed a Statement of Charges, alleging the Respondent employed unregistered technicians, and failed to maintain and provide records.
2. On June 20, 2012, the Board and the Respondent entered into a Stipulation and Consent Agreement. In the Stipulation, the Respondent agreed to make a number of remedial measures, including submitting quarterly reports and paying a \$1000 civil penalty.
3. To date, the Respondent has not submitted the required quarterly reports nor paid the civil penalty.

Case No. 2012-165

1. On September 27, 2012 a routine inspection was conducted at Medicap Pharmacy.
2. During the inspection, the Respondent could not produce a Perpetual Inventory, an Annual Controlled Substance Inventory, and Schedule II invoices, despite records indicating the pharmacy dispensed Schedule II prescriptions.
3. During the inspection, only a generic Policy and Procedures manual was produced. The manual did not contain sections for technician training and delivery of medication.
4. Daily logs were not kept current.
5. No permanent log was located.
6. The inspection concluded with at least eleven rule violations. Many of these violations mirrored the violations cited in the 2011 inspection, which led to Case Number 2011-


10/17/2013

64.

7. Following the 2011 inspection, the Respondent attested that the deficiencies had been corrected. As of September 2012, these deficiencies remained uncorrected.

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 15th day of October, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



EDWARD MATER, 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 type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| Article Number 917199999170310413657 | <input type="checkbox"/> other _____ |

on the 17 day of October, 2013.

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



Debbie S. Jorgenson
Curtis Gerhold

STATE OF IOWA
BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF THE)	
NOTICE OF HEARING &)	CASE NO. 2011-64 & 2012-165
STATEMENT OF CHARGES)	
AGAINST)	
MEDICAP PHARMACY,)	REVISED
LICENSE NO. 401)	NOTICE OF HEARING
RESPONDENT.)	DATE CHANGE

YOU ARE HEREBY NOTIFIED that on October 15, 2013, the Iowa Board of Pharmacy found probable cause to file a Notice of Hearing & Statement of Charges against you and set the matter for hearing on January 14, 2014. Due to a change in the Board's schedule, the hearing date has been moved to January 13, 2014. 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.

The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of all pleadings filed with the Board 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.

Dated this 22nd day of November, 2013.



Lloyd K. Jessen
Executive Director

Copies to:

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

Medicap Pharmacy
Attn: Michelle Heidebrink
504 A Avenue West
Oskaloosa, IA 52577

Department of Inspections and Appeals

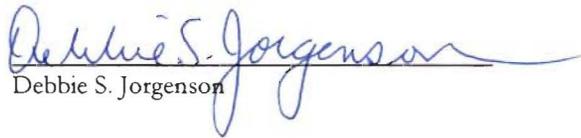
PROOF OF SERVICE

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>9171999991703239553131</u>	<input type="checkbox"/>	other: _____

on the 22nd day of November, 2013.

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


Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case Nos. 2014-49
Pharmacy License)	
MEDICAP PHARMACY)	NOTICE OF HEARING
License No. 401,)	& 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 license number 401. Respondent's license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on July 1, 2014 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 (2011).

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 (2011) 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

FAILING TO MAINTAIN ADEQUATE CONTROL OVER AND ACCOUNTABILITY FOR CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain adequate control over and accountability for controlled substances in violation of Iowa Code sections 155A.15(2)(c); (i), and 657 Iowa Administrative Code rule 36.1(4)(ac).

Count II

FAILURE TO ESTABLISH ADEQUATE SECURITY AND EFFECTIVE CONTROLS AGAINST DIVERSION

Respondent is charged with failure to establish adequate security and effective controls against diversion of controlled substances in violation of Iowa Code sections 155A.15(2)(c); (i) and 657 Iowa Administrative Code sections 10.15 and 36.1(4)(u).

Count III
**FAILURE TO KEEP AND MAINTAIN RECORDS REQUIRED BY THE
CONTROLLED SUBSTANCES ACT**

Respondent is charged with failure to keep and maintain records required by the controlled substances act in violation of Iowa Code sections 124.306 and 155A.15(2) (*h*) and 657 Iowa Administrative Code rules 10.34, 10.35, and 36.1(4)(*u*); (*ac*); (*ag*).

Count IV
FAILURE TO MAINTAIN POLICIES AND PROCEDURES

Respondent is charged with failure to maintain policies and procedures for the operation of a pharmacy in violation of Iowa Code section 155A.15(2)(*c*), (*h*) and 657 Iowa Administrative Code rules 6.2(14) and 36.1(4)(*u*).

D. FACTUAL CIRCUMSTANCES

1. On January 24, 2014, Board compliance officers conducted a follow-up visit on the Respondent pharmacy following the indefinite suspension of pharmacy owner and former pharmacist-in-charge (PIC) Michelle Heidebrink.
2. Upon that visit, Board compliance officers discovered that a controlled substance inventory was not conducted when Rajan Devan assumed the PIC position. Mr. Devan was instructed to conduct the inventory immediately and report the results to the Board.
3. On March 14, 2014, an ACROS report was requested and received from the Drug Enforcement Administration. The report tracked the controlled substances shipments sent from wholesalers to the pharmacy from January 1, 2013 through March 14, 2014.
4. The pharmacy purchased a large amount of Hydrocodone products during the fifteen-month period.
5. On March 25, 2014 Board compliance officers inspected the pharmacy. A number of deficiencies were noted, including failure of pharmacy staff to wear identification, failure to maintain an orderly and clean environment, failure to maintain a continuous quality improvement program, and failure to conduct and maintain a physical count and record of inventory. Many of these deficiencies were the same or similar to prior deficiencies which were detected by the Board and previously subject to discipline.
6. Following the inspection, the controlled substance inventory performed by PIC Devan was compared with the ARCOS report and the usage report.
7. The comparison revealed more than six thousand Hydrocodone 10/325 tablets were unaccounted for between January 1, 2013 and March 14, 2014. During that time period, the

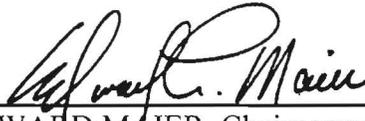
pharmacy ordered 35,000 Hydrocodone 10/325 tablets and legally dispensed 27963. 644 tablets remained in stock at the time of the inventory. 6393 tablets could not be accounted for.

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 28th day of May, 2014, 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

Eric Palmer
114 1st Ave East
Oskaloosa, IA 52577
Attorney for Respondent

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2014-49
Controlled Substance Registration of:)	
MEDICAP PHARMACY)	ORDER TO SHOW CAUSE
Registration Number 1106533)	
Respondent)	

TO: Medicap Pharmacy

NOTICE: Pursuant to the provisions of Iowa Code chapter 124.304–305 (2013) and 657 Iowa Administrative Code rule 10.12(5)–(8), you are hereby ordered to appear before the Iowa Board of Pharmacy to show cause why controlled substance registration number 1106533 issued to Medicap Pharmacy, should not be suspended or revoked. TO REQUEST A HEARING REGARDING THE SUSPENSION OR REVOCATION OF THIS CONTROLLED SUBSTANCE REGISTRATION, YOU MUST FILE A REQUEST FOR A HEARING BEFORE THE BOARD WITHIN THIRTY (30) DAYS OF ISSUANCE OF THIS ORDER.

I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2013) and 657 Iowa Administrative Code rule § 10.12(5)–(8), the Iowa Board of Pharmacy (Board) has jurisdiction over those who manufacture, distribute, and dispense controlled substances in Iowa. The Board issued Medicap Pharmacy (Respondent) controlled substance registration number 1106533 subject to the laws of the State of Iowa and the rules of the Board.

II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent holds pharmacy license number 401 in the State of Iowa.
2. Respondent’s authority for possessing, administering, and dispensing controlled substances pursuant to Iowa Code chapter 124 is dependent on its continued adherence to the laws and rules governing controlled substances.
3. Iowa Code section 124.304(d) and Iowa Administrative Code rule 657–10.12(1)(d) gives the Board authority to suspend or revoke any registration upon finding

that the registrant committed acts that would render its registration under Iowa Code section 124.303 inconsistent with the public interest.

4. Iowa Code section 124.303(1) outlines the factors for the Board to consider when determining the public interest. Amongst those factors is the need to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

5. An audit of the Respondent's Hydrocodone 10/325 tablet inventory from January 1, 2013 to March 14, 2014 revealed a discrepancy of over 6000 tablets. During that period, the Respondent ordered 35,000 Hydrocodone 10/325 tablets and legally dispensed 27,963. 644 tablets remained in stock at the time of the inventory. 6393 tablets could not be accounted for.

III. ORDER

Respondent is hereby ordered to appear before the Board and show cause why controlled substance registration number 1106533 should not be suspended or revoked.

Respondent may request a hearing before the Board in response to this Order by filing that request within thirty (30) days of the date of this Order. Respondent's 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. The Board office telephone number is (515) 281-5944. If Respondent requests a hearing, the hearing will be held at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, on the date of the next regularly scheduled meeting of the Board.

IF RESPONDENT DOES NOT REQUEST A HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S

CONTROLLED SUBSTANCES REGISTRATION WILL BE SUSPENDED.

IT IS SO ORDERED THIS 28th day of May 2014.

A handwritten signature in black ink, appearing to read "Edward Maier", written in a cursive style.

EDWARD MAIER, Chairperson
Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Iowa Attorney General
Drug Enforcement Administration, Des Moines, Iowa

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:)	
)	Docket No. 2014-49
Pharmacist License of)	DIA No. 14PHB034
MICHELLE HEIDEBRINK)	
License No. 17885)	
)	
Pharmacy License of)	
MEDICAP PHARMACY)	
License No. 401)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
Respondents.)	DECISION, AND ORDER
)	

STATEMENT OF THE CASE

On November 5, 2013, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing & Statement of Charges against Respondents Michelle Heidebrink and Medicap Pharmacy. The Statement of Charges against Respondent Medicap Pharmacy alleges four counts: 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 against Respondent Heidebrink alleges three counts: 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.

A hearing was held on July 1, 2014. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratias; Susan Frey; Judith Trumpy; Edward McKenna; and Sharon Meyer. Respondents Medicap Pharmacy and Michelle Heidebrink appeared and were represented by attorney Eric Palmer. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of the licensees, 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 to Continue

On June 30, 2014, Respondents filed a Motion to Continue. In their motion, Respondents asserted that they had been diligently working to prepare for the hearing, but would need additional time to prepare due to the volume of information. As the motion was filed one day prior to the hearing in this matter, the parties were given the

opportunity to argue the motion at hearing. Respondents asserted that one page from the ARCOS report that the Board utilized to analyze the pharmacy's controlled substance inventory had been omitted from the State's exhibits. Respondents asserted that this omission did not allow them to prepare adequately for hearing.

The State opposed Respondents' motion to continue, citing the timing of its filing. Additionally, the State asserted that the one page from the ARCOS report was inadvertently omitted from the exhibits the State provided to Respondents prior to hearing, and that furthermore it was provided to Respondents as soon as Respondents brought the matter to the State's attention.

The Notice of Hearing and Statement of Charges against each of these Respondents was issued on May 28, 2014. At no point prior to June 30, 2014 did Respondents seek a continuance of the matter. No witness or exhibit deadlines were established in the case; the State's action in providing its exhibits to Respondents prior to the date of hearing was a courtesy not required by either the Board's regulations or any order specific to this case.

The Board's regulations require that any application for continuance shall be made at the earliest possible time and no less than seven days before the hearing except in case of unanticipated emergencies.¹ In determining whether to grant a continuance, the presiding officer may consider:

- a. Prior continuances;
- b. The interests of all parties;
- c. The likelihood of informal settlement;
- d. The existence of an emergency;
- e. Any objection;
- f. Any applicable time requirements;
- g. The existence of a conflict in the schedules of counsel, parties, or witnesses;
- h. The timeliness of the request; and
- i. Other relevant factors.²

The Board denied Respondents' motion for continuance. Respondents failed to comply with the deadline for requesting a continuance and did not show any evidence of an unanticipated emergency warranting continuance. Respondents received approximately two months' advance warning of the hearing date and were aware based upon the Statement of Charges that the case revolved largely around a shortage of hydrocodone in the pharmacy's inventory. Respondents had ample time to review their own records related to the shortage prior to hearing. The fact that the State inadvertently omitted one page from an exhibit it was not required to submit to Respondents prior to hearing does not constitute an unanticipated emergency sufficient to require a continuance.

¹ 657 Iowa Administrative Code (IAC) 35.16(1).

² 657 IAC 35.16(2).

THE RECORD

The record includes the Notice of Hearing and Statement of Charges with regard to both Respondents. The record also includes hearing testimony of Curt Gerhold. The State introduced Exhibits 1 through 14, which were admitted as evidence.

FINDINGS OF FACT

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 complete 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.³ 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.⁴ (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).

CONCLUSIONS OF LAW

Failure to Maintain Adequate Control Over and Accountability for Controlled Substances; Failure to Keep and Maintain Records Required by the Controlled Substances Act

(Counts I and III – Medicap Pharmacy; Count III – Heidebrink)

Under Iowa law, the Board is authorized to impose disciplinary sanctions when a licensee fails to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the Board, including the Controlled Substances Act.⁵ Pursuant to 657 Iowa Administrative Code 10.35, pharmacies are required to complete an annual inventory of all stocks of controlled substances on hand. In addition, an inventory of all controlled substances must be completed whenever there is a change of PIC. That inventory must be taken following the close of business on the last day of the

³ 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).

⁴ 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).

⁵ Iowa Code § 155A.15(2)(c), (h) (2013).

terminating PIC's employment and prior to opening for business the first day of the new PIC's employment.⁶

After Heidebrink ended her tenure as PIC and Devan began acting as PIC for the pharmacy, no controlled substance inventory was completed. This inventory was not completed until Gerhold conducted his follow-up visit on January 24, 2014 and pointed out that it had not been completed. In addition, the pharmacy had not completed an annual controlled substance inventory since prior to January 1, 2013. The preponderance of the evidence establishes a violation of Iowa Code section 155A.15(h) and 657 Iowa Administrative Code 10.35(3) and (5).

Failure to Establish Adequate Security and Effective Controls Against Diversion
(Count II – *Medicap Pharmacy*)

Pursuant to Iowa Code section 155A.15(2), the Board is authorized to impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend the license of a pharmacy, or may place a pharmacy's license on probation, if the Board finds that the licensee has failed to establish effective controls against diversion of prescription drugs.⁷ The Board's regulations set forth both physical security controls and operating procedures necessary to prevent diversion. These include, among other things, periodic review and adjustment of security measures based on changes or discrepancies in the quantity of substances in the possession of the pharmacy.⁸

There is no evidence that the pharmacy detected the discrepancy in hydrocodone 10/325 tablets at any point prior to Gerhold's audit in March, 2014. The discrepancy exceeded 6,000 tablets; that is, the pharmacy received more than 6,000 more tablets than it distributed and the excess tablets were not found in the pharmacy's inventory. The pharmacy did not present any evidence at hearing regarding any security controls or operating procedures necessary to prevent diversion. The pharmacy had not conducted an annual controlled substance inventory for more than one year at the time of Gerhold's first visit in January, 2014. The preponderance of the evidence establishes a violation of 657 Iowa Administrative Code 10.15.

Failure to Maintain Policies and Procedures
(Count IV – *Medicap Pharmacy*)

The Board's regulations provide that the pharmacy and the pharmacist-in-charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.⁹ Pursuant to 657 Iowa Administrative Code 6.2(14), the pharmacy must establish, implement, and periodically review and revise its written policies and procedures to reflect changes in process, organization, and other functions

⁶ 657 IAC 10.35(3), (5).

⁷ Iowa Code § 155A.15(2)(i) (2013).

⁸ 657 IAC 10.15(1).

⁹ 657 IAC 8.3(1).

for all operations of the pharmacy and must ensure that all pharmacy personnel are familiar with those policies and procedures.

The Statement of Charges against Respondent Medicap Pharmacy alleges that the following deficiencies were noted at the time of the Board's March 25, 2014 inspection: failure of pharmacy staff to wear identification; failure to maintain an orderly and clean environment, failure to maintain a continuous quality improvement program, and failure to conduct and maintain a physical count and record of inventory.¹⁰

Gerhold noted in his inspection report from the March 25, 2014 visit deficiencies in the above areas, with the exception of the failure of pharmacy staff to wear identification. It appears that the Statement of Charges may have erroneously confused failure of pharmacy personnel to wear identification with failure of the PIC to display an original license to practice pharmacy, which was a deficiency that Gerhold identified. Notwithstanding this item, Respondent Medicap Pharmacy failed to present any evidence to dispute that the deficiencies that Gerhold identified on March 25, 2014 existed. The preponderance of the evidence demonstrates that Respondent Medicap Pharmacy committed a violation of 657 Iowa Administrative Code 6.2(14).

Unethical Behavior or Practice Harmful or Detrimental to the Public
(Count I – Michelle Heidebrink)

The Board is authorized to impose a disciplinary sanction on a licensee when the licensee knowingly makes misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engages in unethical conduct or practice harmful or detrimental to the public. It is not necessary that there be proof of actual injury for a violation to be found.¹¹

Heidebrink was acting as the pharmacist-in-charge at Medicap Pharmacy during a time period when over 6,000 tablets of hydrocodone 10/325, a controlled substance, went missing. Heidebrink did not provide any explanation, either during the compliance officer's investigation or at hearing, for where those 6,000 tablets went. The loss or diversion of 6,000 hydrocodone tablets by a licensed pharmacy is harmful or detrimental to the public. The preponderance of the evidence demonstrates that Heidebrink committed a violation of 657 Iowa Administrative Code 36.1(4)(c).

Violating the Duties of a Pharmacist-in-Charge
(Count II – Michelle Heidebrink)

Under the Board's regulations, a pharmacist-in-charge is required to, among other things: 1) maintain records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and

¹⁰ See 657 IAC 8.4, 8.5(5), 8.26, and 10.35.

¹¹ Iowa Code § 155A.12(2) (2013); 657 IAC 36.1(4)(c).

federal laws, rules, and regulations; and 2) establish and maintain effective controls against the theft or diversion of prescription drugs and records for such drugs.¹²

As discussed above, with regard to Count I against Heidebrink, she was pharmacist-in-charge at Medicap Pharmacy during a time period when over 6,000 tablets of hydrocodone 10/325, a controlled substance, went missing without explanation. The inventory discrepancy was not discovered until the Board requested that its compliance officer do an audit comparing the controlled substances received by the pharmacy to the controlled substances dispensed by the pharmacy. The fact that Heidebrink had not implemented controls to prevent such a discrepancy constitutes a violation of 657 Iowa Administrative Code 6.2(12) and (13).

Sanction

The Board may consider a number of factors in determining the nature and severity of the disciplinary sanction to be imposed when a violation is established, including the relative seriousness of the violation as it relates to assuring a high standard of professional care; the facts of the violation; any extenuating circumstances; whether remedial action has been taken; and any other factors that reflect upon the competency, ethical standards, and professional conduct of the licensee.¹³

The Board has extremely serious concerns about Heidebrink's ability to safely practice pharmacy. Under her tenure as pharmacist-in-charge, over 6,000 tablets of hydrocodone 10/325 went missing. Heidebrink had no explanation for the discrepancy in inventory, which was not even brought to the Board's attention until after Heidebrink's license had been suspended and the Board requested that its compliance officer conduct a controlled substance audit.

The Board likewise has serious concerns about Respondent Medicap Pharmacy's compliance with the laws and regulations applicable to the practice of pharmacy. During the time that Heidebrink was pharmacist-in-charge at the pharmacy, over 6,000 hydrocodone tablets were diverted. There is no evidence that this discrepancy was discovered or that any action was taken to put in place additional safeguards to protect controlled substances from diversion during that time period. Additionally, the pharmacy has had repeated deficiencies in the area of controlled substance inventories and CQI reporting. While the selection of a new PIC after Heidebrink's indefinite suspension appears to have placed the pharmacy on the right track, it is not clear that the pharmacy will be able to comply with applicable laws and regulations without more extensive monitoring.

DECISION AND ORDER

IT IS THEREFORE ORDERED that Respondent Michelle Heidebrink's license shall remain suspended indefinitely pursuant to the terms of the January 13, 2014 Settlement

¹² 657 IAC 6.2(12), (13).

¹³ 657 IAC 36.1(3).

Agreement and Final Order. No application for reinstatement shall be made until such time as Heidebrink can show compliance with the reinstatement provisions contained in that Order.

IT IS FURTHER ORDERED that Respondent Michelle Heidebrink shall have no involvement in the ownership, management, direction, or control of any business engaged in the practice of pharmacy during the time that her license is suspended. Heidebrink shall have 90 days from the date of this Order to divest herself of any ownership, management, direction, or control of Respondent Medicap Pharmacy.

IT IS FURTHER ORDERED that Respondent Michelle Heidebrink shall not hold the position of pharmacist-in-charge in the future.

IT IS FURTHER ORDERED that Respondent Michelle Heidebrink shall pay a civil penalty in the amount of \$5,000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa, and mailed to the executive director of the Board within 30 days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

IT IS FURTHER ORDERED that Respondent Medicap Pharmacy's license shall be placed on probation for a period of five years.

IT IS FURTHER ORDERED that, as a condition of probation, within 30 days of the date of this Order, Respondent Medicap Pharmacy shall enter into an agreement with a practice consultant. This agreement shall be at Respondent Medicap Pharmacy's expense. The practice consultant shall be required for the first three years of Respondent Medicap Pharmacy's probationary term.

- a. The practice consultant shall be an Iowa-licensed pharmacist who is approved by the Board to serve as a practice consultant.
- b. The practice consultant shall meet with Respondent Medicap Pharmacy's pharmacist-in-charge on a weekly basis to ensure that Respondent Medicap Pharmacy has fully complied with the terms of this Decision and Order and with the laws governing the practice of pharmacy in Iowa.
- c. Respondent Medicap Pharmacy shall comply with any recommendations made by the practice consultant.
- d. The practice consultant shall file monthly reports with the Board by the fifth day of every month. The reports shall describe Respondent Medicap Pharmacy's compliance with this Decision and Order and include any recommendations the consultant believes necessary to ensure Respondent Medicap Pharmacy is in compliance with this Decision and Order and the laws governing the practice of pharmacy in Iowa. Respondent Medicap Pharmacy is responsible for ensuring the practice consultant's reports are timely filed.

- e. After a period of successful compliance with this requirement, Respondent Medicap Pharmacy may request Board approval for reduction of the requirements for the practice consultant meetings and reports.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Medicap Pharmacy shall maintain a perpetual inventory of all controlled substances with monthly reporting to the Board.

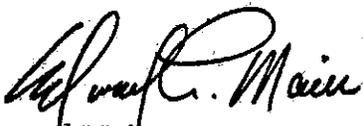
IT IS FURTHER ORDERED that, as a condition of probation, Respondent Medicap Pharmacy shall submit to the Board, on a monthly basis, proof of reconciliation of invoices.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Medicap Pharmacy shall develop and submit its policies and procedures to the Board for approval within 60 days of the date of this Order.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Medicap Pharmacy shall not permit Respondent Michelle Heidebrink to be involved in any aspect of ownership, management, direction, or control of the pharmacy. Respondent Medicap Pharmacy shall have 90 days from the date of this Order to allow for Heidebrink to divest herself of any ownership, management, direction, or control of the pharmacy.

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

Dated this 11th day of *September*, 2014



Edward Maier
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.

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 Gratiias; 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 complete [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, 2014



Edward Maier
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).